A fair balance: health data protection and the promotion of health data use for clinical and research purposes

Kist, I.R.

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"In my view, it is not straightforward to conclude from the GDPR that its objective is to grant data subjects control over their personal data as a right in itself, or that data subjects must have the greatest control possible over those data"

Opinion of Advocate General Campos Sánchez-Bordona of 6 October 2022 in case C-300/21, para 74

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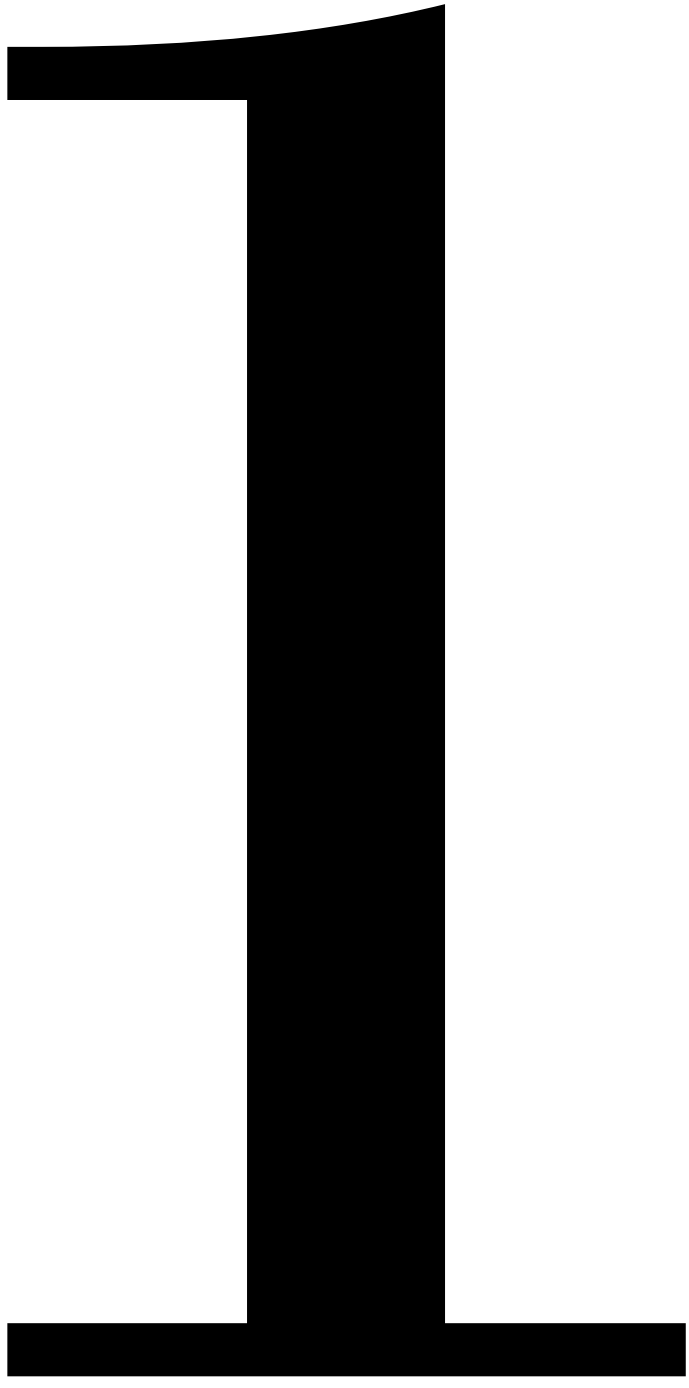
This thesis is dedicated to the memory of my father Johannes Kist (1939 – 2023).

Contents



Introduction

1. Introduction

This thesis is prompted by the problematic exchange of health data, both within the Netherlands and beyond.[1] The exchange of health data is essential for the provision of health care and health research, which serve both the individual and society.[2] If the data exchange for providing health care to a patient does not take place smoothly, then both the care provider and the patient run the risk that care is given without a full medical history of the patient.[3] If the data exchange for both national and international health research is not carried out, then the investigator runs the risk that the data are biased and that reliable results cannot be achieved, or that the research cannot take place at all.[4]

[1] Ploem, M.C. (2022). Laat de huidige wetgeving voldoende ruimte voor gegevensuitwisseling in de zorg? *Tijdschrift voor Gezondheidsrecht*, 46(3), 158 – 188, at 187: *"Zonder adequate en snelle gegevensuitwisseling is verantwoorde zorg anno 2022 niet mogelijk. Om die te realiseren is het wetsvoorstel dat elektronische gegevensuitwisseling verplicht stelt zonder meer een goede ontwikkeling. Maar daarmee zijn we er nog niet. Er zal door de wetgever ook gesleuteld moeten worden aan het toestemmingsvereiste zoals dat thans uit onze nationale wetgeving volgt."*
Peolsson, M. et. al. (2023, March). *Deliverable 5.2. Recommendations for European Countries when planning national legislation on secondary use of health data*. Towards European Health Data Space Consortium Partners, at 13: *"(…) [T]he differing choices of legal basis driven by national preferences for processing personal data (articles 6 and 9 GDPR) as well as differences in semantics and data quality at national level, creates practical challenges to cross-border data sharing (…)."*

[2] Nouwt, J. (2022). De Wegiz: wettelijk verplichte elektronische gegevensuitwisseling in de zorg. *Tijdschrift voor Gezondheidsrecht*, at 238-239: *"Het belang van elektronische gegevensuitwisseling op Europees niveau is gebleken tijdens de COVID-19-pandemie. De Europese Unie wil met de EHDS tevens een bijdrage leveren aan de ontwikkeling van een Europese gezondheidsunie. De bevordering van de gezondheid aan individuele burgers en van de volksgezondheid in Europa zal niet zonder die gegevensuitwisseling kunnen."*

[3] European Commission. (2022c, May 3). *Proposal for a regulation of the European Parliament and of the Council on the European Health Data Space.* The European Health Data Space (EHDS) addresses health-specific challenges to electronic health data access and sharing: *"The general objective is to ensure that natural persons in the EU have increased control in practice over their electronic health data. It also aims to ensure a legal framework consisting of trusted EU and Member State governance mechanisms and a secure processing environment. This would allow researchers, innovators, policy-makers and regulators at EU and Member State level to access relevant electronic health data to promote better diagnosis, treatment and well-being of natural persons, and lead to better and well- informed policies."*

[4] Veen, E.B. van, R.A. Verheij (2022, May). Further use of data and tissue for a learning health system: the rules and procedures in The Netherlands, compared to Denmark, England, Finland, France and Germany, *MLCF/Nivel*, Utrecht, at 10: *"The Dutch discussion about the scope of the consent and the research exception takes place in an extremely fragmented data landscape. Each data source has a separate governance structure and interpretation of the rules and they vary in the way how these translate those into the consent modalities described above. Consequently, there is no common format for reviewing research proposals involving the secondary use of data."*
Peloquin, D., DiMaio, M., Bierer, B., & Barnes, M. (2020). Disruptive and avoidable: GDPR challenges to secondary research uses of data. *European Journal of Human Genetics*, *28*(6), 697-705, at 703: *"[The] GDPR presents several significant difficulties for bio-banking and databanking, including failing to provide a clear basis for processing personal data for secondary research purposes. The few regulatory pathways that GDPR provides lead to complex variations among EU member states, and these variations add significant trans-action costs and barriers to secondary research uses of data and biospecimens."*
Molnár-Gábor, F., Sellner, J., Pagil, S., Slokenberga, S., Tzortzatou-Nanopoulou, O., & Nyström, K. (2022). Harmonization after the GDPR? Divergences in the rules for genetic and health data sharing in four member states and ways to overcome them by EU measures: Insights from Germany, Greece, Latvia and Sweden. *Seminars in Cancer Biology* (84), 271-283, at 275: *"In summary, it can be seen that member states mandate both consent as a legal justification for data processing for scientific research purposes as well as use the privilege of scientific research to create an exception for data processing."*
Abboud, L. et al, (2022). *Report on secondary use of health data through European case studies.* TEHDAS Consortium Partners, at 15-16: *"Data users highlighted that the differences in interpretation of the GDPR across countries and the existence of additional national rules can cause complications in the secondary use of health data across Member State borders. It is important to note that this statement does not refer derogations under the GDPR, but rather additional national level legislation which applies in addition to the GDPR. This existence of overlapping acts at EU and national level has led to differences in interpretation and applications of data sharing across Europe."*

At least four problems can be identified that are at the root of this problematic exchange of health data, i.e.: a) the diverse interpretations of essential elements of consent; b) the use of various legal bases within the European Union for the processing of health data; c) the mere focus on protecting individual rights and interests while obstructing the free flow of data and, hence, the societal interest, and d) the shift away from a risk-based approach towards rule-based regulatory compliance. This section shortly discusses these factors of influence.

Firstly, the lawful basis of consent is interpreted in several ways whereas the role of the individual in health care varies. The individual's consent presupposes a certain degree, or perhaps even full control over his personal data.[5] However, the individual is not always able to fulfil the four elements of consent, i.e. the free, specific, informed and unambiguous indication of his wishes.[6] Furthermore, the individual plays different roles in society, and his role in health care is changing amidst the technological changes. Additionally, the ageing society elicit new questions about the individual consent by the individual who may no longer be able to express his consent.

Secondly, various legal grounds are used for the processing of health data for secondary research purposes. Though the use of the various legal grounds may not cause the problem as such, the lack of acknowledgement of these different legal grounds hampers the free flow of data.[7] For instance, research is obstructed between health institutions in different member states if the institutions do not feel at liberty to accept different consent forms or various legal grounds for the use of patient's data for secondary research purposes.

Thirdly, an imbalance can be observed between data protection rights on one hand, and the free flow of data on the other. A preferential, yet one-sided focus on data

[5] Kosta, E. (2013). Consent in European data protection law. In: *Consent in European Data Protection Law*. Brill Nijhoff, 130-141.

[6] Article 4 (11) GDPR. Mostert, M., Bredenoord, A. L., van Der Sloot, B., & van Delden, J. J. (2018). From privacy to data protection in the EU: Implications for big data health research. *European Journal of Health Law*, *25*(1), at 52: *"(…) [I]ndividuals are often no longer able to make meaningful decisions about the use of their personal data, as a consequence of the rapidly increasing scale and complexity of data-intensive health research (…). What is more, merely relying upon consent and individual rights would not only result in an ineffective protection of individuals and their interests, it could also disproportionately hamper progress in data-intensive health research."*

[7] Kalliola, M., Drakvik E. & Nurmi, M. (Eds.) (2023, September), Advancing data sharing to improve health for all in Europe. Sitra Studies 236, at 12: *"Different national governance systems, lack of standardization of data sets and variations in legal interpretations of EU data protection law are examples of the most common barriers that make transnational studies difficult and increase the costs of research and compliance. Other examples of barriers include differences in data access procedures and lack of harmonized definitions of key terminology."*

protection rights hampers the free flow of data.[8] Though data protection and privacy are fundamental rights, the rights are not absolute. The rights should be reconciled with other fundamental rights and considered within the greater society.[9] In health care, the patient is best served with both data protection and data sharing of his health data, to provide him the best of care. In health research, the patient and the greater society are best served with a set of research data that represents the society as a whole and that includes a representative research population.

Fourthly, data protection and sectoral supervisory mechanisms have adopted a mere rule-based regulatory approach whereas the GDPR allows for a risk-based approach.[10] Additionally, a variety of supervisory mechanisms monitor compliance by health care and research institutions whilst the responsibilities are not closely aligned in the different laws and regulations. For instance, although harmonization guidelines have been adopted, the fines imposed by the data protection authorities in the member states of the European Union still differ substantially, as a result of which legal uncertainty exists among and within the member states.[11]

1.1. Research questions

This thesis investigates the problematic exchange of health data for clinical and research purposes upon which solutions are proposed. The research conducted for this thesis took place between March 2020 and February 2023. I concluded the final revisions in February 2024. The proposed solutions are aimed at clinicians and researchers in practice. Additionally, the solutions are directed to policy makers, the legislator and data protection authorities as well as sectoral supervisory mechanisms.

[8] Solove, D. J. (2022). The Limitations of Privacy Rights. *Notre Dame L. Rev.*, *98*, 975 – 1036, at 993: *"(…) [M]ost privacy laws rely far too heavily on rights. The result is that so many laws create the illusion that they are protecting privacy through rights when they are not. Individuals are often powerless and vulnerable in a world where vast quantities of their personal data are collected and used in ways that affect their lives. It thus seems intuitive to try to give individuals more control over their personal data with privacy rights. Ultimately, however, individuals can never be fully in control. To be effective, control can't just be placed in the hands of individuals; control must come from society."*

[9] Solove, D. J., & Hartzog, W. (2024, forthcoming). Kafka in the Age of AI and the Futility of Privacy as Control, at 9: *"The GDPR, however, still has informational self-determination as its beating heart (…). The GDPR allows a wide range of data processing with consent. GDPR data protection also depends heavily on individual rights, which occupy a substantial amount of internal organizational compliance efforts and external enforcement."*

[10] Karjalainen, T. (2022). All talk, no action? The effect of the GDPR accountability principle on the EU data protection paradigm. *European Data Protection Law Review, 8*(1), 19-30 at 23: *"The notion of a risk-based data protection framework is one of the cornerstones of the data protection reform brought about by the GDPR. The risk-based approach reflects an obligation for controllers to take potential risks to data subjects into account when implementing the GDPR."*

[11] EDPB Guidelines 04/2022 on the calculation of administrative fines under the GDPR Version 2.1. Adopted on 24 May 2023. https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-042022-calculation-administrative-fines-under_en. Accessed 8 February 2024.

The main research question reads as follows:

> *In what way can a balanced approach be found for the exchange of health data that serves the data protection of the individual and patient on one hand, and the furtherance of health care and health research in the interest of society, on the other?*

The main research question is divided into the following five sub-questions:

1. In what way does the focus on the lawful basis of consent influence the provision of care when the individual is unable to express his will?
2. In what way is the data processing for secondary health research solidified in the Dutch GDPR Implementation Act *(Uitvoeringswet Algemene Verordening Gegevensbescherming,* UAVG*)*, Dutch sectoral health law, and the Dutch Code of Conduct for Health Research?
3. In what way does the lawful basis of consent serve as a proper legitimation for re-using health data for scientific research and in what way may other lawful bases legitimize this use?
4. In what way do the developments in the United Kingdom serve as an avenue to be explored in the European Union with regard to the further use of health data for secondary health research and to compliance mechanisms in health?
5. In what way does the existing data protection and health legislative framework protect the individual's autonomy, his health data, and his position as a care receiver where commercial companies deliver health services?

This thesis focuses on both health care (clinical purposes) and health research (research purposes). Sub-questions 1 and 5 focus on health care whilst sub-questions 2, 3 and 4 focus on health research. Each of the following chapters answers one sub-question. Furthermore, each chapter proposes solutions for the problematic exchange of data for care and research. Additionally, sub-question 4 addresses the issue of a rule-based approach by supervisory mechanisms in the United Kingdom upon which solutions for risk-based compliance are presented that could serve as an avenue to be explored in the European Union as well.

1.2. Scope of this thesis

This thesis focuses on the primary use of health data for health care on the one hand and the secondary use of data for research, on the other. Thus, I will not focus on the use of data for prospective clinical trials.[12] To clarify the different uses of health data,

[12] A clinical trial is "*a study performed to investigate the safety or efficacy of a medicine. For human medicines, these studies are carried out in human volunteers.*" Definition by European Medicines Agency, https://www.ema.europa.eu/en/glossary/clinical-trial. Accessed 10 November 2022.

I illustrate this use in (1) health care and (2) research with a fictitious case. Mr. X visits his general practitioner with a complaint about his health. At first, he receives treatment while he continues to live in his own home environment. His health data are used for health care. When his situation does not improve, he receives additional treatment in a hospital. His health data continue to be used for health care.

Health research is then carried out where his health data will be used that have been collected during the provision of health care. Mr. X need not carry out any activities in this respect since his data have already been processed for health care. His health data are processed for secondary research purposes. The existing data have already been recorded.[13] The storage could have taken place in the process of health care, or during a clinical study, for instance. In secondary research, no (additional) intervention takes place.

Furthermore, although this thesis addresses the problematic exchange of health data with various factors involved, it does not entail a discussion of potential clash (-es) between fundamental rights. This could be a topic for future research in a subsequent thesis. Section 7.3 (final considerations for future research) shortly elaborates on topics for future research.

This thesis focuses primarily on the Netherlands as well as the European and Dutch legal framework. Chapter 5, which includes a comparison between the United Kingdom and the European Union, elaborates on the different developments in the United Kingdom and the European Union.

1.3. Legal research methodology

In the first place, the methodology applied for this thesis is doctrinal legal research.[14] The research analyzes the letter of the law, whereas both primary and secondary sources of law are scrutinized. Furthermore, case law is included. Thus, I have carried out dogmatic legal research.[15] Secondly, this thesis also comprises elements of co-production of knowledge.[16] In my capacity of data protection officer at the Netherlands

[13] Hess, R., (2004, October). Retrospective Studies and Chart *Reviews, Respiratory Care* 49 (10), 1171-1174.

[14] Vranken, J.B.M. (2011). Methodology of legal doctrinal research: A comment on Westerman. *Methodologies of legal research: Which kind of method for what kind of discipline* (2011), 111-121.

[15] Vranken, J.B.M. (2012). Exciting Times for Legal Scholarship, *Recht en Methode in onderzoek en onderwijs* (2) 2, at 43: "*Legal-dogmatic research concerns researching current positive law as laid down in written and unwritten European or (inter) national rules, principles, concepts, doctrines, case law and annotations in the literature (…).*"

[16] Mheen, D. van de (2019). De kunst van co-creëren: Kennis die er toe doet! Inaugural lecture at Tilburg University. Also, A. Filipe, A. Renedo & C. Marston (2017). The co-production of what? Knowledge, values, and social relations in health care, *PLOS Biology* 15(5). For two examples of co-production in health research, see the research carried out by Netherlands Institute for Health Services Research (*Nivel, Nederlands Instituut voor Onderzoek van de Gezondheidszorg)*: Nivel_Brochure_Onderzoeksprogramma.pdf. See also the research carried out by Tranzo. Tranzo is the scientific research center for care and well-being at Tilburg University: Tranzo | Tilburg University. Accessed 17 November 2023.

Cancer Institute – Antoni van Leeuwenhoek hospital, I work for and amidst patients, researchers and clinicians. As a result, I use and interpret the legislation and legal theory of data protection in my daily work, and vice versa. The case studies in this thesis reflect daily practice in health care and secondary health research.

My research strategy has consisted of four steps.[17] First, I identified the field of research, i.e. data protection in health care and health research. Secondly, I collected sources. I collected documents on the letter of the law, publications and academic research carried out in previous studies. Thirdly, I analyzed the sources and, finally, I interpreted the sources. Often, the four steps of the research strategy took place parallel to each other, whilst I observed converging and diverging developments as regards both European and national law, and the viewpoints of legal scholars and practitioners in this field. I started this thesis at the dawn of the COVID-19 pandemic when the urgent need for data sharing for health and research became all the more apparent.

1.3.1. Identification of the research field

Before and during the research of this thesis, I attended a variety of conferences, symposia and workshops with a focus on data protection and health law, in particular as regards the further use of health data for secondary research purposes, the European Health Data Space, and data sharing between international consortia in multicenter studies. I participated both as a guest speaker and as an attendee. These conferences and symposia paved the road in identifying and interpreting the key issues at stake as well as the main actors.[18] The exchanges of ideas were the founding fathers for this thesis.

During these conferences and meeting sessions, I gathered insights that served as one of the pillars for evaluating scholarly sources. Additionally, I provide daily advice about the use of personal health data for clinical and research purposes. Since I largely carried out this research during the COVID-19 pandemic, I also provided advice to both clinicians and researchers in the context of the pandemic. The questions all concerned the balance between data protection of personal health data on the one hand, and the necessary data sharing for combatting the pandemic and further health research, on the other. Within this ambit, I reviewed an article that examined the GDPR for COVID-19 research.[19]

[17] The research conducted for this thesis took place between January 2020 and February 2023. The final revisions of this thesis took place in February 2024.
[18] I refer to chapter 11 for a complete list of professional activities and affiliations in the process of writing this thesis.
[19] Becker R, Thorogood A, Ordish J, Beauvais MJS. COVID-19 Research: Navigating the European General Data Protection Regulation. *J Med Internet Res*. 2020 Aug 27;22(8):e19799.

When I began this thesis in the beginning of 2020, very few could have predicted the pandemic's impact on so many fields. Data sharing in emergencies and beyond, data sharing for health research, as well as the rights and interests of the data subjects have been recurring themes. Additionally, parallel to these developments, legislative initiatives were launched at the European level with the Artificial Intelligence Act (AI Act), the Data Governance Act (DGA), the Data Act, and the European Health Data Space (EHDS). Furthermore, since 2020, both the European Data Protection Board (EDPB) and European Data Protection Supervisor (EDPS) have published a large number of guidelines and recommendations that are relevant for this research to some extent: forty-four by the EDPB and six by the EDPS. At an international level, the development of a new cooperation agreement between the United States of America (USA) and the European Union as regards data sharing has drawn our attention. In addition, the developments since Brexit have shed a new light on the cooperation between mainland Europe and the UK regarding data sharing. The road that the United Kingdom (UK) has travelled since Brexit with the UK GDPR and subsequent legislative initiatives has led to a continuous dialogue with the UK.

At the national level, data sharing for clinical purposes has taken a promising step forward. The act on the electronic data exchange in health care (*Wet Elektronische Gegevensuitwisseling in de Zorg,* hereinafter: *Wegiz)* was unanimously accepted by the Dutch Lower House of Parliament (*Tweede Kamer*). Furthermore, policy makers are paving the way for the introduction of the European Health Data Space (EHDS). Section 1.4 (legal framework of data protection and privacy) includes an elaboration on the EHDS.

Parallel to these developments, the Dutch Act on Quality Registrations (*Wet Kwaliteitsregistraties Zorg*) is currently prepared. In the field of research, the draft Dutch Authority over Human tissue Act (*Wet zeggenschap lichaamsmateriaal*, *Wzl*) is currently prepared and a renewed proposal for an amendment is foreseen in the spring of 2024.[20] In view of future developments, if any, as regards a separate lawful basis for scientific research or changes to the interpretation of the lawful basis of consent, the plenary debate was postponed. Lastly, the initiatives by the executive power, i.e., the Dutch Ministry of Public Health, Welfare, and Sport, in cooperation with representatives from the field who joined their efforts in Health-RI and the Royal Netherlands Standardization Institute (*Nederlands Normalisatie Instituut, NEN*), have been fruitful in connecting the dots.

[20] A Letter to Parliament is expected in the spring of 2024.

1.3.2. Collection of the sources

The collection of data took place along the following lines. Firstly, I started with an analysis of relevant international, European and national legislation. Secondly, as regards European legislation, I examined Opinions and Recommendations of the Article 29 Data Protection Working Party, the EDPB and the EDPS. Additionally, I analyzed reports of the European Commission and of the project TEHDAS – Towards European Health Data Space. The TEHDAS project developed joint European principles for the secondary use of health data. The work involves twenty-five countries and the European Commission gives final approval to all joint action's deliverables of TEHDAS.[21] As regards Dutch law, I analyzed the advices of the Dutch Council of State, the letters to Parliament from the Dutch Minister of Health, Welfare and Sport, as well as the Parliamentary Papers (*Kamerstukken*). Furthermore, I analyzed the notifications from the Dutch Data Protection Authority (*Autoriteit Persoonsgegevens*).

Thirdly, I analyzed relevant European case law, both from the Court of Justice of the European Union and the European Court of Human Rights. I also analyzed Opinions of Advocate Generals. As regards Dutch case law, I analyzed the verdicts of the Supreme Court of the Netherlands and verdicts of the lower courts.

Fourthly, in my daily work as data protection officer, I gained valuable insights that paved the road for a critical analysis of scholarly sources. In executing this analysis, I examined literature and online sources. My search started with a study of peer-reviewed articles in journals that focus on a) (European and Dutch) data protection and privacy law; b) (European and Dutch) health law; c) bioethics; d) medical internet research. Furthermore, I searched for legal scholars in particular whom I had met during the conferences and symposia. Hence, my desk research consisted of a literature and internet study. During this process, I thankfully used the expertise of the information specialists at the library of the Netherlands Cancer Institute. They have access to the international network of libraries OCLC WorldShare.[22] This network provides access to both hard copy books and digital versions of articles in journals. Additionally, the Netherlands Cancer Institute closely collaborates with the University Medical Center Groningen in the search for articles.[23] The information specialists at the library also have access to their own network of biomedical libraries in the Netherlands.

[21] Kalliola, M., E. Drakvik & M. Nurmi (Eds.) (2023, September). Advancing data sharing to improve health for all in Europe'. Sitra Studies 236 and TEHDAS Consortium. Also, L. Abboud et al., 'Summary of Milestone 5.1 & 5.2 Annex A | Case studies: different governance and health data systems in Europe', 28 September 2021, TEHDAS, Towards European Health Data Space.

[22] WorldShare: Enable shared efficiencies and innovation | OCLC Accessed 2 November 2023.

[23] Via the following site: https://vraagartikelaan.nl/. Accessed 2 November 2023.

The search took place with the so-called snowballing approach.[24] I studied articles, used the references in these articles and studied new articles. The sources explained in this section 1.3.2 all served as a foundation for the articles, included as chapters, in this thesis.

1.3.3. Analysis of the sources

This thesis analyzes the interpretation and implementation of the law in practice.[25] To this end, fictitious case studies based on realistic scenarios have been included in chapters 2 until 6. These case studies serve to exemplify the interaction between international, European, and national law on the one hand, and the relationship between data protection and health law on the other. Furthermore, the challenges to health data protection and data sharing for clinical and research purposes are scrutinized.

The legislation serves as the foundation of this thesis, followed by the analysis of jurisprudence from the European Court of Justice. As regards the articles in the peer-reviewed journals, I refer to section 1.3.2 in which I explained that I started with the search for peers whom I had met during conferences, symposia and workshops, upon which I analyzed articles that these scholars had used in the preparation of their work, and so on. Furthermore, the Dutch handbook on health law has formed the basis for further research.[26]

Before I submitted the first three articles to the peer-reviewed journals, I held *rebuttals* with peers from the field, i.e. both legal, medical, ethical, social and technical experts. In these *rebuttals*, I started with a short presentation about the contents of the article and, subsequently, the peers rebutted my first explanation. Then, a second round started with my explanation and responses to the questions posed. Finally, the peers asked questions once again. The peers I consulted are employed with, inter alia, the Netherlands Cancer Institute, university medical centers, universities in the Netherlands and abroad, consultants in the legal and technological sector, data protection officers, clinicians, researchers, policy and ethical advisors, pathologists and (senior) managers. An average number of 12 peers attended a rebuttal, thus 36 peers in total. The fourth article is the fruit of a meeting with a British legal expert whom I had consulted during the IAPP conference in Brussels in November 2021. The topic and contents of the fifth article are based on the co-authorship with another PhD candidate, Mrs. Renée Dekker. The composition of this article is explained in section 1.6.

[24] For an explanation of the snowballing approach, see Wohlin, C., (2014). Guidelines for snowballing in systematic literature studies and a replication in software engineering, Proceedings of the 18th international conference on evaluation and assessment in software engineering, 1-10. https://www.wohlin.eu/ease14.pdf. Accessed 31 October 2023.
[25] Langbroek, P. et al., (2017). Methodology of Legal Research: Challenges and Opportunities, *Utrecht Law Review* 13 (3), 1-8.
[26] Leenen, H.J.J. et al. (2020). Handboek gezondheidsrecht.

Finally, though I receive messages on social media about the topic of my thesis on a daily basis, and though I read (online and hard copy) articles in newspapers and magazines, these sources of information did not serve as a source for this thesis as such. These sources mainly served as a side information.

1.3.4. Interpretation of the sources

I have interpreted the sources in a three-step process. Firstly, I interpreted the present European and national legislation, as well as legislative proposals to daily practice in health care and health research. I investigated the preparatory documents and explanatory memoranda of both European and Dutch legislation. Secondly, I interpreted recent and pending case law from both the European Court of Justice, the European Court of Human Rights and Dutch courts. Thirdly, I interpreted publications from scholars in this field. After having carried out this three-step process, I generally observed three approaches in the current debate. One approach primarily addressed the data protection of health data and the individual's rights.[27] A second approach focused on the data exchange for either health care or health research, or both, while the obstacles encountered in this data exchange were addressed.[28] A third approach consisted of a combination of the first or third approach. In this third approach, the GDPR was analyzed, for instance, or the use of a particular type of data for health research, such as biological material from biobanks.[29]

In this thesis, I have aimed at a nuanced and combined interpretation of these approaches. My interpretation sheds light on the attention drawn to data protection on one hand, and the necessary data exchange for health care and research, on the other. Furthermore, I have aimed at proposing solutions that are both legally feasible and useful in practice. The chapters in this thesis include case studies from practitioners

[27] For instance, the Netherlands Patients Federation (*Patiëntenfederatie Nederland*) carried out two studies, one about data sharing in health care, and one about the individual control on health data in case of the further use of data. See 'Delen van data in de gezondheidszorg', February 2021. And, 'Rapport Zeggenschap over gezondheidsgegevens bij secundair gebruik van data'. July 2023. Also, Coppen, R., Groenewegen, P. P., Hazes, J. M. W., de Jong, et al (2016). Hergebruik van medische gegevens voor onderzoek: Wat vindt de Nederlander van het toestemmingsvereiste? *Nederlands Tijdschrift voor Geneeskunde*, *160*(15), 17-23. Hendriks, A. C., Frederiks, B. D., & Verkerk, M. A. (2008). Het recht op autonomie in samenhang met goede zorg bezien. *Tijdschrift voor Gezondheidsrecht*, *32*(1), 2-18.

[28] For instance, Mostert, M., Bredenoord, A. L., Biesaart, M. C., & van Delden, J. J. (2016). Big Data in medical research and EU data protection law: Challenges to the consent or anonymise approach. *European Journal of Human Genetics*, *24*(7). Schermer, B. W., Custers, B., & van der Hof, S. (2014). The crisis of consent: How stronger legal protection may lead to weaker consent in data protection. *Ethics and Information Technology*, *16*(2), 171-182. Solove, D. J., Data Is What Data Does: Regulating Based on Harm and Risk Instead of Sensitive Data (2024, January). 118 *Northwestern University Law Review* 1081 (2024), GWU Legal Studies Research Paper No. 2023-22, GWU Law School Public Law Research Paper No. 2023-22.

[29] For instance, Becker, R., Chokoshvili, D., Comandé, G., et al, (2022). Secondary use of personal health data: When is it 'further processing' under the GDPR, and what are the implications for data controllers? *European Journal of Health Law, 29*, 1-29. Hooghiemstra, T. (2018). *Informationele zelfbeschikking in de zorg*. SDU.
Ploem, M. C., Rigte, T., & Gevers, J. K. M. (2020). Medisch data-onderzoek in het AVG-tijdperk: Een zoektocht naar de juiste regels. *Tijdschrift voor Gezondheidsrecht*, *44*(2), 162-181. D'Abramo, F., Schildmann, J., & Vollmann, J. (2015). Research participants' perceptions and views on consent for biobank research: A review of empirical data and ethical analysis. *BMC Medical Ethics*, *16,* Article 60.

in the field of health care and research. The conclusions that I reached are followed by recommendations and final considerations for future research (chapter 7, sections 7.2 and 7.3).

1.4. Legal framework of data protection and privacy

The rights to private life and data protection were included in the EU Charter of Fundamental Rights, in article 7, regarding the respect for private and family life, and in article 8, regarding the right to the protection of personal data.[30] The Charter came into force by the Treaty on the Functioning of the European Union (TFEU), or the Lisbon Treaty, in December 2009.[31] The Treaty on European Union (TEU) gives the Charter the same legal status as the EU Treaties.[32] The right to the protection of personal data is also enunciated in the TFEU itself.[33] However, the right to data protection in the Charter was not formulated as a right to informational self-determination.[34] Furthermore, both privacy and data protection cannot be considered absolute rights since the rights can be limited under certain conditions.[35] Moreover, the CJEU has explained that the rights to privacy and data protection must be balanced against other fundamental rights, in accordance with the principle of proportionality.[36] Thus, in principle, a hierarchy among fundamental rights does not exist. The Dutch judiciary follows the Court of Justice of the European Union (CJEU) and the European

[30] Charter of Fundamental Rights of the European Union [2012] OJ C326/02. Hereinafter: the Charter. For a detailed overview of the legislation on the protection of personal data, see Court of Justice of the European Union, 'Fact sheet. Protection of personal data', November 2021. https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-10/fiche_thematique_-_donnees_personnelles_-_en.pdf. Accessed 27 November 2022.

[31] Article 16 (1) Consolidated versions of the Treaty on the Functioning of the European Union [2016] OJ C202/1. Hereinafter: TFEU.

[32] Article 6 (1) Consolidated version of the Treaty on European Union of 13 December (OJ C 202, 7 June 2016, 13-46).

[33] Article 16 (1) TFEU.

[34] Hustinx, P. (2015). European Leadership in Privacy and Data Protection. In *Hacia un nuevo régimen europeo de protección de datos /Towards a new European Data Protection Regime*":"*(…) The Convention which prepared the Charter before it was adopted, also considered including a right to informational self-determination in Article 8, but this was rejected. Instead, it decided to include a right to the protection of personal data, to preserve the main elements of Directive 95/46/EC.*"

[35] Preamble and article 52(1) EU Charter of Fundamental Rights. Recital 4 GDPR. Case C-507/17, Google v Commission nationale de l'informatique et des libertés (CNIL) of 24 September 2019, ECLI:EU:C:2019:772, para 60: *"(…) [T]he right to the protection of personal data is not an absolute right, but must be considered in relation to its function in society and be balanced against other fundamental rights, in accordance with the principle of proportionality (…).*"
Case C-136/17, GC and others v Commission nationale de l'informatique et des libertés (CNIL) of 24 September 2019, ECLI:EU:C:2019:773, para 57.

[36] Case C-507/17) of 24 September 2019, Google v Commission nationale de l'informatique et des libertés (CNIL), ECLI:EU:C:2019:772, para 60. Also, Case C-154/21 of 12 January 2023, RW v Österreichische Post AG, ECLI:EU:C:2023:3, para 47.

Court of Human Rights (ECtHR).[37] This means that the prevailing right must be determined on a case-by-case basis.[38]

Article 16 TFEU paved the way for the reform of data protection rules in 2016 with the enactment of the GDPR. The GDPR is based on the fundamental principles of the EU Charter and the Lisbon Treaty.[39] It replaced the 1995 Data Protection Directive, which had emerged from the need for harmonization among the member states, several of which had already adopted national data protection laws.[40] The directive was primarily aimed at the free flow of data in the internal market, while the preamble of the GDPR stresses the importance of both the protection of fundamental human rights and the furthering of the internal market. The Data Protection Directive included the connection to the individual's privacy and other fundamental rights and interests of the individual, but an explicit anchoring of the right to informational self-determination cannot be deduced.[41] The GDPR does not include an absolute, enforceable right to self-determination either.[42] The aim of the GDPR remains equal to that of the Directive, i.e., promoting both the free flow of personal data within the European Union and beyond, and protecting the individual and his personal data.[43]

In short, the right to data protection aims to guarantee that the data will be processed following the principles of data processing,[44] whilst the individual can exercise his rights as a data subject.[45] These rights do not entail an absolute control by the individual over his personal data.[46] Individuals have the right to supervise their data and to intervene when others carry out operations with their data, but this does not mean

[37] Case C-101/01 of 6 November 2003, Bodil Lindqvist, ECLI:EU:C:2003:596, para 76:"*The Netherlands Government points out that both freedom of expression and the right to respect for private life are among the general principles of law for which the Court ensures respect and that the ECHR does not establish any hierarchy between the various fundamental rights. It therefore considers that the national court must endeavour to balance the various fundamental rights at issue by taking account of the circumstances of the individual case.*"

[38] Civil Appeal Court, the Hague, 05/1725 of 20 December 2007. ECLI:NL:GHSGR:2007:BC0619. Dutch Prosecutor General's office of the Supreme Court, 08/01394 of 9 April 2010, para 3.48. ECLI:NL:GHSGR:2007:BC0619. R. Nehmelman & A.J.Th. Woltjer, Annotatie bij EHRM 9 april 2010 – Staat/ Clara Wichmann c.s. NTM/ NJCM-Bull, 35 (2010) 5. 485 – 500, at 496:*"(…) Omdat het hier gaat om een afweging van verschillende grondrechten waartussen gewoonlijk geen rangorde bestaat, moet bij de vraag welk grondrecht het zwaarste moet wegen een begrijpelijk antwoord worden gegeven (…)."*

[39] Recital 1 GDPR.

[40] Directive 95/46/EC of the European Parliament and the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data OJ L 281, 23.11.1995.

[41] Overkleeft-Verburg, G., (1995). *De Wet persoonsregistraties: norm, toepassing en evaluatie*, 1995, 22.

[42] Tweede Kamer der Staten-Generaal. (1998, februari 3). *Wet bescherming persoonsgegevens; Memorie van toelichting,* at 9.

[43] C.J. Hoofnagle, C.J. et al. (2019). The European Union General Data Protection Regulation: What it is and what it means. *Information and Communications Technology Law*, 65-98.

[44] Article 5 GDPR on principles relating to data processing: (1) lawfulness, fairness, and transparency; (2) purpose limitation; (3) data minimization; (4) accuracy; (5) storage limitation; (6) integrity and confidentiality; (7) accountability.

[45] Chapter 3, articles 12 – 23 GDPR.

[46] I follow Advocate General Campos Sánchez-Bordona in his Opinion delivered on 6 October 2022, Case C-300/21, ECLI:EU:C:2022:756 at paras 74 – 76 and 79 – 81.

that the individual can exercise complete control over his data.[47] Then, the right to privacy aims to protect the individual's private sphere.[48]

As regards the (further) processing of health data for research purpose, article 5 (1) b, second sentence of the GDPR provides that

> *"(…) [F]urther processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with article 89 (1), not be considered to be incompatible with the initial purposes (…)."*

Though Union law provides for broader opportunities as regards the processing of health data for research purposes, the Dutch legislator has given a restrictive explanation to the exemption of the prohibition of the further use of health data for research purposes in article 24 UAVG. This provision contains elements of article 7:458 of the Dutch Medical Treatment Contracts Act (*Wet inzake de Geneeskundige Behandelingsovereenkomst*, chapter 7, title 7, section 5 Dutch Civil Code, hereinafter WGBO). However, the provisions in article 7:458 WGBO and article 24 UAVG are not identical. Section 1.5 continues with the introduction of concepts in data protection and health law. The lawful bases for processing health data, among which the (further) processing of health data for research purposes, is mentioned as well.

The Council of Europe Convention 108, i.e., the convention for the protection of individuals with regard to automatic processing of personal data and additional protocols, was adopted in 1981.[49] Furthermore, within the Council of Europe, the right to data protection has seen a development parallel to and distinct from the right to respect for private and family life, home and correspondence. This latter right is enshrined in article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR).[50] The ECHR was adopted in 1950 and entered into force in 1953. The right to data protection is sometimes viewed as being partially based on the right to privacy.[51] For instance, the European Court of Human Rights has also understood the right to privacy as an individual right to control personal

[47] Case C-300/21, ECLI:EU:C:2022:756 at paras 70 – 71.
[48] Hert, P. de & S. Gutwirth (2006). Privacy, data protection and law enforcement. Opacity of the individual and transparency of power, in E. Claes et al., *Privacy and the Criminal Law.* Antwerp/ Oxford: Intersentia.
[49] Council of Europe, Convention for the Protection of Individuals with Regard to the Automatic Processing of Individual Data. Council of Europe, ETS 108, 1981; Additional Protocol to the Convention for the protection of individuals with regard to automatic processing of personal data, regarding supervisory authorities and trans border data flows, CETS 181, 2001; Additional Protocol amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, CETS 223, 2018. With the adoption of the additional protocol in 2018, the previous additional protocol of 2001 became obsolete.
[50] Council of Europe, *European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14*, 4 November 1950, ETS 5. Hereinafter ECHR.
[51] Convention Praesidium, *Explanations Relating to the Charter of Fundamental Rights of the European Union, Brussels*. 11 October 2000, CHARTE 4473/00, CONVENT 49.

information and the right to access one's personal records.[52] At the same time, the right to data protection is also considered a separate right.[53]

The right to data protection is presented as a positive right: the state and private actors (controllers and processors) must adopt measures such as privacy by design and privacy by default, as well as the data subject's access rights, to protect personal data. In addition, the principle of fair processing of data with a specific purpose and implementing data minimization, lawful bases of data processing, and the requirement of an independent supervisor, are all elements of the positive obligation. The European Court of Human Rights has interpreted article 8 ECHR in a broader way with a focus on personal development as well.[54] The right to privacy has also been considered for cases about data protection.[55] Thus, the right to privacy has been seen as including the positive (newer) right of data protection.[56]

In March 2022, a proposal for a Regulation of the European Parliament and the Council on the European Health Data Space (hereinafter: EHDS) was presented.[57] On 7 December 2023, the revised Presidency compromise text was proposed with a view to obtain a mandate for negotiations with the European Parliament on the EHDS-proposal. On 13 December 2023, the European Parliament voted in favor of this proposal with a large majority. This means that the trilogy negotiations may start. The EHDS aims at the following:

> *"The EHDS seeks to provide rules, common standards and practices, infrastructures and a governance framework for both primary use (using personal electronic health data to provide health services to an individual) and secondary use (using electronic health data for broader needs such as health research or public policy) of public health data."*[58]

[52] European Court of Human Rights, *Copland v. United Kingdom* 62617/00 [2007] ECH 253 (3 April 2007).

[53] For instance, European Data Protection Supervisor, Data protection. https://edps.europa.eu/data-protection/data-protection_en. Accessed 15 November 2022. M. Hildebrandt, M. (2020). Privacy and Data Protection, *Law for Computer Scientists and Other Folk* (Oxford, 2020; online edition, Oxford Academic, 23 July 2020), https://doi.org/10.1093/oso/9780198860877.003.0005, accessed 15 November 2022.

[54] European Court of Human Rights, *Gaskin v. United Kingdom*, 10454/83, (1989) ECHR 13 (7 July 1989). And *Odièvre v. France*, 42326/98 (2003) ECHR 86 (13 February 2003). The Court acknowledged that the right to privacy also includes the right to personal development, and the right to personal development also included details of an individual's identity and his vital interest to obtain information in order to reveal the truth about himself and his identity.

[55] Council of Europe, Guide on Article 8 of the European Convention on Human Rights: Right to respect for private and family life, home and correspondence (updated 31 August 2022):"*The protection of personal data is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the Convention (Satakunnan Markkinapörssi Oy and Satamedia Oy v. Finland [GC], § 133).*"

[56] European Data Protection Supervisor, Data protection. https://edps.europa.eu/data-protection/data-protection_en.

[57] European Parliament, Legislative train schedule. Proposal for a regulation on the European Health Data Space. https://www.europarl.europa.eu/legislative-train/. Accessed 8 February 2024. See also Section 1.5.c and chapter 6 of this thesis for a further elaboration on certain components of the EHDS.

[58] Marcus, J. S., Martens, B., Carugati, C., Bucher, A., & Godlovitch, I. (2022). The European Health Data Space. *IPOL| Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament Policy Department studies,* 7.

The EHDS addresses health-specific challenges to electronic health data access and sharing.[59] The EHDS seeks to provide solutions for data sharing as regards the primary and secondary use of data. It aims to give individuals control of and access to their electronic health data. Furthermore, the EHDS aims to enhance the interoperability and harmonization for the use of electronic health data. To this end, the EHDS introduces specific instruments to facilitate the access to data and to support the cooperation between the Member States and other actors involved. Under the EHDS, individuals enjoy their rights of access, data portability and rectification in and between the EU Member States. Additionally, the EHDS aims to build an infrastructure to support the exercise of these rights. Finally, the EHDS introduces a common infrastructure called MyHealth@EU. This infrastructure serves to facilitate the cross-border exchange of electronic health data. For instance, when individuals are travelling abroad, their data can be shared between health care providers in the Union. Section 6.4.2 further elaborates on the EHDS.

1.5. Concepts in data protection and health law relevant for this thesis

I use the terminology referred to in the GDPR as well as in Dutch implementation and health law. Since the EHDS has not been adopted yet, I will generally not use the terminology of this proposal in my thesis. However, where the EHDS has adopted a different definition, I clarify this. For instance, section 1.5.c on data processing explains the different terminology of primary and secondary use of data by the EHDS. When the GDPR or other legislation does not provide for a definition, I will base the definitions used in this thesis on legal and health literature. To avoid confusion about frequently used terminology, I elaborate on these terms in sub-sections (a) until (i). This thesis concerns (a) health data of (b) a data subject that are (c) processed for (d) clinical and research purposes by the (e) data controller with (f) a legitimation, i.e., a lawful basis for processing. I will shortly discuss the lawful bases of (g) explicit consent,[60] (h) public interest,[61] and (i) legitimate interests.[62]

a) Health data

Pursuant to the GDPR, health data, or data concerning health, are "*personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status.*"[63] Health data are special categories of personal data, or sensitive data. The term is interpreted

[59] Explanatory memorandum to the regulation of the European Parliament and of the Council on the European Health Data Space, 3 May 2022, COM(2022) 197 final, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX-:52022PC0197. Accessed 21 March 2023.
[60] Article 9 (2) (a) GDPR together with article 6 (1) (a) GDPR.
[61] Article 9 (2) (i) or (j) GDPR together with article 89 (1) and article 6 (1) (e) GDPR.
[62] Article 6 (1) (f) GDPR.
[63] Article 4 (15) and Recitals 10, 35, 51 GDPR.

broadly. It includes *"(…) all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject (…)*."[64] Put differently, health data are any data "*related to health conditions, reproductive outcomes, causes of death, and quality of life*."[65]

The wide interpretation of the expressions 'special categories of personal data' or 'sensitive data' serves to ensure a high level of protection of the fundamental rights and freedoms of natural persons.[66] This means that both the direct and indirect disclosure of sensitive data constitutes the processing of special categories of personal data.[67] Furthermore, the term "reveal" in recital 35, articles 4 (15) and 9 (1) GDPR not only relates to express disclosure, but it also covers revelations by deductions.[68] Additionally, processed data, either individually considered or aggregated, which allow use profiling based on the sensitive characteristics such as health, fall within the scope of article 9 (1) GDPR and are, in principle, prohibited.[69] Health data are sensitive data and, therefore, require a thorough protection, regardless of the fact whether the personal data *reveal* a certain situation or that the data are inherently sensitive.[70] However, data that only indicate that it may concern a sensitive element do not fall within the scope of the regime for special categories of data.[71]

b) Data subject

The GDPR refers to an identified or identifiable natural person ('data subject') and provides for the following definition: "*an identifiable natural person is one who can be*

[64] Recitals 10, 35, and 51 GDPR. See, inter alia, Case C-184/20, OT v Vyriausioji tarnybines etikos komisija of 1 August 2022, ECLI:EU:C:2022:601, paras 124 – 128.
[65] *McGraw-Hill Concise Dictionary of Modern Medicine* (2002). Accessed 22 August 2022. Schäfke-Zell, W. (2022). Revisiting the definition of health data in the age of digitalized health care. *International Data Privacy Law*, *12*(1), 33-43.
[66] Case C-101/01, Bodil Lindqvist of 6 November 2003, ECLI:EU:C:2003:596, para 50: "*(…) [T]he expression data concerning health (…) must be given a wide interpretation so as to include information concerning all aspects, both physical and mental, of the health of an individual.*" Case C-136/17, GC and others v Commission nationale de l'informatique et des libertés (CNIL) of 24 September 2019, ECLI:EU:C:2019:773, paras 42 – 44. Case C-184/20, OT v. Vyriausioji tarnybinės etikos komisija of 1 August 2022, ECLI:EU:C:2022:601, paras 124 – 128.
[67] Recital 35, article 4 (1), 4 (15), and 9 GDPR. Also, Kamerstukken II (Parliamentary Papers II) 1997–1998, 25892, nr. 3 at 101. And, Autoriteit persoonsgegevens, *Onderzoeksrapport Alcohol- en drugscontroles bij werknemers. De verwerking van persoonsgegevens bij de uitvoering van alcohol- en drugscontroles door Uniper Benelux N.V.* (Dutch Data Protection Authority, 'Research report alcohol and drug tests among employees. The processing of personal data in the execution of alcohol and drug tests by Uniper Benelux N.V.'), 2017, 34 – 36.
In contrast, Solove, D. J., (2024, January). Data Is What Data Does: Regulating Based on Harm and Risk Instead of Sensitive Data. 118 *Northwestern University Law Review* 1081, GWU Legal Studies Research Paper No. 2023-22, GWU Law School Public Law Research Paper No. 2023-22, at 1081:*"Although heightened protection for sensitive data appropriately recognizes that not all situations involving personal data should be protected uniformly, the sensitive data approach is a dead end. The sensitive data categories are arbitrary and lack any coherent theory for identifying them. The borderlines of many categories are so blurry that they are useless."*
[68] Case C-184/20 of 1 August 2022, paras 117 – 128.
[69] Case C-252/21, Meta Platforms Inc. v Bundeskartellamt, Opinion of Advocate General Rantos delivered on 20 September 2022, ECLI:EU:C:2022:704, paras 35 – 39.
[70] District court of Amsterdam, 15 March 2023, ECLI:NL:RBAMS:2023:1407, in particular section 13.11.
[71] Kamerstukken II (Parliamentary Papers II) 2017/18, 34851, nr. 3, para 4.3 at 40.

identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person."[72] I follow this general definition in the GDPR.

In a health context, data subjects are patients, clients, and private individuals as consumers of health information.[73] Thus, when I refer to an individual, patient or client, I refer to a natural person, i.e., a data subject pursuant to article 4 (1) GDPR.

c) Data processing

The processing of data is broadly defined in article 4 (2) GDPR. Additionally, processing sensitive data also includes the possibility that a further categorization takes place that emerges from the type of data processing. This categorization could create a risk to the fundamental rights and freedoms of the individuals.[74]

The processing must be carried out pursuant to the principles enshrined in article 5 GDPR. This section concerns the data processing, whereas the next section (d) continues with the purpose of data processing. Health data are used for (1) health care and (2) research.[75] The first component, *health care*, concerns the processing of data for diagnosis, treatment, medication, and quality improvement in care. The second component, *health research*, consists of two sub-components, namely research with and research without an (additional) intervention or measurement.[76] When research is carried out with an intervention, the investigators watch for outcomes, such as the development of a disease, during the study period and relate these outcomes to other factors, such as suspected risk. This type of research is also referred to as prospective research.[77]

[72] Article 4 (1) GDPR. F.J. Zuiderveen Borgesius, Mensen aanwijzen maar niet bij naam noemen: behavioural targeting, persoonsgegevens en de nieuwe Privacyverordening, *Tijdschrift voor Consumentenrecht* 2016-2, 54-66. Court of Justice of the European Union, Factsheet on protection of personal data, November 2021, https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-10/fiche_thematique_-_donnees_personnelles_-_en.pdf. Accessed 8 November 2022.

[73] For an analysis of the distinction between patient and client, see M. Shevell (2009). What do we call 'them'?: the 'patient' versus 'client' dichotomy, *Developmental Medicine & Child Neurology* (51), 770-772. For an elaboration on the concept of individuals as consumers of health, see Prainsack, B. & A. Buyx, (2012). Solidarity in contemporary bioethics: towards a new approach, *Bioethics* 26 (7), 343-350.

[74] Case C-252/21, Meta Platforms Inc v Bundeskartellamt, Opinion of AG Rantos of 20 September 2022, ECLI:EU:C:2022:704, paras 38, 40, 78 (1).

[75] I use the term health care for both care and cure. For a further elaboration on care and cure, see G.A.M. Widdershoven (1999). Care, cure and interpersonal understanding, *Journal of Advanced Nursing* 29 (5), 1163-1169. See also C. de Valck et al. (2001). Cure-oriented versus care-oriented attitudes in medicine, *Patient Education and Counseling* 45 (2), 119-126.

[76] Rebers, S. et al. (2016). Exceptions to the rule of consent with an intervention, *BMC Medical Ethics* (17), 9. For an explanation of 'intervention', see A Ross, D., G Smith, P., & H Morrow, R. (2015). Types of intervention and their development. In *Field Trials of Health Interventions, 3rd edition*. Oxford University Press. https://www.ncbi.nlm.nih.gov/books/NBK305514/. Accessed 9 November 2022.

[77] For a further explanation of prospective and retrospective research, see Learning Hub | Prospective vs retrospective studies (closer.ac.uk). Accessed 9 November 2022.

The use of data for research without an (additional) intervention is also referred to as the secondary use of health data for research purposes. In this type of research, the data have already been obtained in another clinical or research setting and could be used for secondary research. Furthermore, prospective research may be carried out with these data that have already been gathered. One example is prospective research carried out by the Netherlands Comprehensive Cancer Organization (*Integraal Kankercentrum Nederland*, IKNL).[78] In this thesis, I use the wording of "secondary use of data" when I refer to any use of these data beyond the scope for which they were initially collected or generated.[79]

The European Health Data Space (EHDS) has adopted a different definition of primary and secondary use. It distinguishes between the primary and secondary use of electronic health data. The primary use of electronic health data concerns health care delivery by services and personnel involved in providing health care. The secondary use includes health research, innovation, policy-making, regulatory purposes, and personalized medicine purposes.[80] In a joint opinion to the Proposal for a Regulation on the European Health Data Space, the EDPB and EDPS have expressed their concerns regarding the definitions used in the EHDS on the primary and secondary uses of electronic health data.[81] The wording concerning the secondary use of personal data does not appear in the GDPR, while the second part of the definition of 'secondary use of electronic health data' deviates from the wording of 'further processing of personal data' in article 5 (1) (b) GDPR.[82] This thesis primarily follows the definitions in the GDPR. In the case of a distinct definition, this will be explicitly indicated.

d) Purpose(s)

Pursuant to article 5 (1) (b) GDPR, Personal data must be "*collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes.*" Moreover, the second sentence of article 5 (1) (b) reads that "[the] *further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89 (1), not be considered to be incompatible with the initial purposes ('purpose limitation').*"

[78] https://iknl.nl/en/research. Accessed 13 December 2022. Also, De EHDS en het secundair gebruik van kankergegevens in Nederland (iknl.nl). Accessed 16 January 2023.
[79] Becker, R. et al., Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers? *European Journal of Health Law*, (29), 1-29. I follow R. Becker et al. in this definition of secondary use of data.
[80] Article 2 (d) and (e) of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space (Text with EEA relevance), 3 May 2022, COM (2022) 197 final.
[81] EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space on 12 July 2022 at 4: *"(…) Article 34(1) of the Proposal contain several types of secondary use, which would fall under different categories of grounds for exception foreseen in Article 9(2) GDPR."*
[82] EDPB-EDPS Joint Opinion 03/2022, footnote 81 at para 42.

In short, a data controller must comply with the principles enshrined in article 5 GDPR, among them the principle of purpose limitation.[83] This means that personal data may not be further processed beyond the purpose(s) for which they were initially collected.[84] The term 'further processing' has not been explicitly defined in the GDPR. Recital 50, first sentence, reads as follows:

> "*The processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected (….)*."

Thus, further processing must be compatible with the specific purpose(s) of the initial data collection. The question whether this further processing of personal data is compatible only applies when the purpose(s) of this processing is/are not the same as the initial data collection.[85] Put differently, the further processing may be considered compatible when a specific, logical, and sufficiently close link exists between the purpose for which the data were initially collected and the further processing of those data.[86] This means that the processing must not be disconnected from the original purpose of the data collection or be contrary to that original purpose. Additionally, its content must be compatible with the rationale behind the collection.[87] As regards scientific research, the specific provision in article 5 (1) (b) GDPR gives rise to more general criteria for compatibility. I deduce this from the wording in the second sentence that reads as follows: *"(…) not be considered to be incompatible with the initial purposes (…)."*

As regards the further processing for research purposes, the controller must demonstrate that the processing is permitted as an exemption to the prohibitions listed in article 9 GDPR. The processing must be grounded in a lawful basis.[88] Additionally, the controller must meet the conditions set out in article 9 GDPR. The controller must show compliance with the principles enshrined in article 5 GDPR and must adopt the institutional and technical safeguards described in article 89 (1) GDPR.[89]

[83] Koning, M.E. (2020). The purpose and limitations of purpose limitation. Doctoral dissertation, Radboud University Nijmegen. https://merelkoning.nl/wp-content/uploads/2020/10/M.Koning_The-purpose-and-limitations-of-purpose-limitation_thesis.pdf. Accessed 8 November 2022.
[84] Becker R. et al., Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers? *European Journal of Health Law*, (29), 1-29.
[85] Case C-77/21, Digi Távközlési és Szolgáltató Kft v. Nemzeti Adatvédelmi és Információszabadság Hatóság of 22 October 2022, ECLI:EU:C:2022:805, paras 29 ' 37. R. Becker et al., footnote 84.
[86] Article 29 Data Protection Working Party, Opinion 03/2013 on purpose limitation (WP 203), adopted on 2 April 2013, 12 – 13.
[87] Case C-77/21, Opinion of Advocate General Pikamäe delivered on 31 March 2022, paras 27 – 30. ECLI:EU:C:2022:248.
[88] Article 6 GDPR.
[89] European Data Protection Supervisor, A Preliminary Opinion on data protection and scientific research, 6 January 2020, 17.

Thus, the special regime regarding the further processing for research purposes may not constitute a derogation from the data subject's rights.

Legal uncertainty exists regarding the wording of "further processing" in the GDPR and the wording of "secondary use of health data in the EHDS."[90] The EDPB aims to provide further clarification on the requirement of a legal basis for further processing for scientific research purposes by either the original or a subsequent controller.[91] The EDPB will also take into account recital 50 and article 6 (4) GDPR. The EDPS seems to recognize a more generalized consent to the processing for a broad (-er) range of purposes.[92] This thesis includes the most recent European publications until February 2024 and awaits the EDPB's further clarifications, which were due in 2021.

e) Data controller

Pursuant to article 4 (7) GDPR, the concept of 'controller' means "*the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data*."[93] Though this definition, as well as the particular clauses in Chapter IV GDPR, may seem straightforward at first sight, it is not always easy to disentangle which organizations act as (joint) controllers in large research consortia.[94] This legal uncertainty causes delays and raises questions as regards (joint) responsibility and liability.

Amidst this legal uncertainty, the controller must be able to demonstrate the lawfulness of the data processing.[95] When the lawful basis of consent is used for the processing of personal data, the controller must obtain this consent from the individual for the purposes and means that the controller determines. Furthermore, the controller has the duty to inform the individual.[96] The controller is responsible for the data

[90] Becker R. et al., footnote 84. Dove, E.S. & J. Chen (2020), Should Consent for Data Processing Be Privileged in Health Research? A Comparative Legal Analysis, *International Data Privacy Law* 10 (2), 117-131.
[91] European Data Protection Board, *Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research,* adopted on 2 February 2021. Paras 20 – 21. The clarifications were due in 2021 and have not yet been published.
[92] European Data Protection Supervisor (2015, September). Towards a new digital ethics. Data, dignity and technology. Opinion 4/2015, at 11.
[93] Case C-40/17, Fashion ID GmbH & Co.KG v Verbraucherzentrale NRW eV of 29 July 2019, ECLI:EU:C:2019:629, paras 67 – 70.
[94] Becker, R. et al (2022). Applying GDPR roles and responsibilities to scientific data sharing. *International Data Privacy Law*, 12(3). 207-219. Also, E.B. van Veen et al. (2022). Joint controllers in large research consortia: a funnel model to distinguish controllers in the sense of the GDPR from other partners in the consortium, Open Research Europe.
[95] Articles 5 (2) and 24 (1) GDPR; Case C-61/19, Orange Romania SA v Autoritatea Națională de Supraveghere a Prelucrării Datelor cu Caracter Personal (ANSPDCP) of 11 November 2020, ECLI:EU:C:2020:901, paras 34, 42 and 46. Case C-582/14, Breyer v Bundesrepublik Deutschland 19 October 2016, ECLI:EU:C:2016:779, para 57. Case C-673/17, Bundesverband der Verbraucherzentralen und Verbraucherverbände ' Verbraucherzentrale Bundesverband eV v Planet49 GmbH of 1 October 2019, ECLI:EU:C:2019:801, para 53.
[96] Case C-40/17, at para 106. Also, Case C-154/21, RW v Österreichische Post AG of 12 January 2023, ECLI:EU:C:2023:3, paras 37 – 41.

processing in its entirety; thus, not only those data directly obtained from the data subject, but also any data obtained from another source.[97] In case of the further processing of data, the controller must carry out a compatibility test following article 6 (4) GDPR. Additionally, the controller must inform the individual about the further data processing that it intends to carry out.[98]

In this thesis, the health institution that carries out research or where patients/ clients are treated can fulfil the role of data controller.[99] It can also fulfil the role of data processor.[100] Health institutions can perform the role of joint controllers as well.[101]

f) Legitimation, i.e., a lawful basis for processing

Article 9 (1) GDPR explains the processing of special categories of personal data. Health data fall within the scope of special categories of personal data. Data protection law assumes that the processing of these special categories of personal data violates the fundamental rights and freedoms of individuals and in particular their right to the protection of personal data.[102] Therefore, the processing of these data is prohibited unless an exemption applies.[103] The data controller must meet one of the conditions laid down in article 9 (2) GDPR. Furthermore, the data processing must be carried out with one of the lawful bases under article 6 (1) GDPR.

Explicit consent is one exemption to the prohibition for the use of health data.[104] A second exemption concerns the necessary processing for reasons of public interest in the area of public health[105] or the necessary processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.[106] Article 6 (1) (f) GDPR, without a corollary provision in article 9 (2) GDPR, provides for the necessary processing for the purposes of the legitimate interests pursued by the controller or by a third party. The GDPR allows member states to adopt implementation legislation. This has resulted in various and diverging implementation laws across the Union. [107]

[97] Articles 13 (data collected from the data subject) and 14 (data not been obtained from the data subject) GDPR; article 5 (1) (b) (data collection in general). Also Becker, R. et al., footnote 84 at 8.
[98] Article 13 (3) and 14 (4) GDPR.
[99] Article 24 GDPR.
[100] Article 28 GDPR.
[101] Article 26 GDPR.
[102] Article 1 (2) GDPR.
[103] Article 9 (2) together with article 6 GDPR.
[104] Article 9 (2) (a) together with article 6 (1) (a) GDPR.
[105] Article 9 (2) (i) together with article 6 (1) (e) GDPR.
[106] Article 9 (2) (j) and 89 (1) together with Article 6 (1) (e) GDPR.
[107] European Commission, Assessment of the EU Member States' rules on health data in the light of GDPR, Specific Contract No SC 2019 70 02 in the context of the Single Framework Contract Chafea/2018/Health/03, 2021.

g) Consent

Pursuant to article 4 (11) GDPR, the individual's consent means "*(…) any freely given, specific, informed and unambiguous indication of the data subject's wishes (…)*." Consent presumes that the individual must be given a genuine choice and control over his personal data.[108] The control, however, is not absolute, as will be addressed in further detail below. The individual must be able to withdraw his consent without detriment and at all times. The element of consent in data protection law falls within the *free will theory*.[109] The Collins English Dictionary defines free will as "*the apparent human ability to make choices that are not externally determined.*" The Oxford Advanced Learner's Dictionary defines free will as "*the power to make your own decisions without being controlled by God or fate.*" The Cambridge Dictionary (online) defines free will as "*the ability to decide what to do independently of any outside influences.*"

Articles 7 (respect for private and family life) and 8 (protection of personal data) of the EU Charter of Fundamental Rights explicitly refer to the individual's free will and the controller's obligations.[110] These obligations are included in article 5 GDPR on fairness, necessity, and proportionality, together with data quality.[111] The controller must illustrate the lawfulness of the data processing and must provide the data subject with clear and comprehensive information.[112] The data subject must easily be able to determine the consequences of any consent he gives and he must be well informed before he gives that consent. Furthermore, he must be aware of the controller's identity and the purposes of the data processing.[113] The data subject is then able to make a deliberate choice based on his trust of the data controller. Again, the controller must ensure that it fulfills these obligations.

In the context of health care, the patient gives his consent for diagnosis and treatment within the care provider–care receiver relationship.[114] Thus, the patient gives his consent to the care provider who actually provides medical care to him. The consent requirement in article 7:450 WGBO pertains to consent to enter into a treatment contract on the one hand, and consent for the actual medical treatment on

[108] European Data Protection Board, Guidelines 05/2020 on consent under Regulation 2016/679, version 1.1, adopted on 4 May 2020, para 3 at 5. Hereinafter: Guidelines 05/2020.
[109] Zürcher, T. et al. (2019). The notion of free will and its ethical relevance for decision-making capacity. *BMC Med Ethics* 20 (1), 1-10.
[110] Charter of Fundamental Rights of the European Union, 26 October 2012, 2012/C 326/02. Hereinafter EU Charter.
[111] Recitals 32, 33, 42, and 43, articles 4 (11), 5, and 7 GDPR.
[112] Case C-673/17 of 1 October 2019, Bundesverband der Verbraucherzentralen und Verbraucherverbände - Verbraucherzentrale Bundesverband eV v Planet49 GmbH, ECLI:EU:C:2019:801, para 74. F. D'Abramo et al, Research participants' perceptions and views on consent for biobank research: a review of empirical data and ethical analysis. *BMC medical ethics*, *16*(1), 2015, 1-11.
[113] Recital 42 GDPR.
[114] Chapter 6 of this thesis addresses the situation when the individual gives his consent for the use of his health data beyond the traditional care provider – care receiver relationship.

the other.[115] The patient's informed consent to a particular treatment is vested in his autonomy and self-determination. Appropriate informed consent procedures enhance the mutual trust between the care provider and care receiver and thus provide a basis for shared decision-making.[116] Autonomy encompasses the patient's ability to make choices and it involves the patient's autonomous choice, i.e., his free choice as regards his care. The patient's self-determination is expressed when he is the ultimate arbiter of which treatment may or may not be given, and when.

The term "consent" in research was explicitly included in the Nuremberg code following the atrocities of World War II. The code starts with the first principle that "*the voluntary consent of the human subject is absolutely essential.*"[117] The code consists of ten principles in total that delimit permissible medical experimentation on human subjects. The code states that human experimentation is only justified if the results benefit society. Furthermore, the medical experimentation must be carried out following the principles of morality, ethics and legality. The ten principles were echoed in many subsequent human rights frameworks, among them the Helsinki Declaration of 1964,[118] and in medical standards for research involving human subjects, such as the ICH-CGP guidelines on Good Clinical Practice.[119] The individual may give his consent, for instance, to participate in a clinical study.[120] He may also give his consent regarding the use of his data for secondary research. These two forms of consent should not be confused.[121] The provisions in the Clinical Trials Regulation with regard to informed consent primarily respond to ethical requirements of research projects that involve human beings.[122] These requirements are derived from the Helsinki Declaration. The requirement of informed consent for participation in a clinical study

[115] Art. 7:450 WGBO: "*Voor verrichtingen ter uitvoering van een behandelingsovereenkomst is de toestemming van de patiënt vereist*" ("The consent of the patient is required for any treatment in the performance of a treatment contract"). H.J.J. Leenen et al., *Handboek gezondheidsrecht*, 2020, 137 et seq.

[116] Muscat, D.M. et al. (2021). Health Literacy and Shared Decision-making: Exploring the Relationship to Enable Meaningful Patient Engagement in Healthcare. *Journal of General Internal Medicine* 36, 521-524.

[117] Nuremberg Code, *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law* No. 10, Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949.

[118] Articles 25 – 32 of the 1964 Helsinki Declaration. Ethical principles for medical research involving human subjects, adopted by the 18th World Medical Association (WMA) General Assembly, Helsinki, Finland, June 1964, and with the last amendment adopted by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013.

[119] Article 2.9 of the principles of ICH GCP (International Conference on Harmonisation – Good Clinical Practice), Guideline for Good Clinical Practice, 23 July 2015, https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-clinical-practice-e6r2-4-step-2b_en.pdf. Accessed 20 October 2022.

[120] Recitals 27 – 33, articles 2 (21), 28, and 29(1), Clinical Trials Regulation (CTR). Recital 161 GDPR refers to the application of the Clinical Trials Regulation for consenting to the participation in scientific research activities in clinical trials.

[121] European Commission (2019), Questions and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation, https://health.ec.europa.eu/system/files/2019-04/qa_clinicaltrials_gdpr_en_0.pdf. Accessed 21 November 2022. European Data Protection Board, Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b), adopted on 23 January 2019.

[122] Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC of 16 April 2014, hereinafter CTR.

must be distinguished from the explicit consent as a legitimation for the processing of personal data for scientific research purposes.[123]

This thesis focuses on the consent given by an individual for health care or for secondary health research. In the context of secondary health research, the legitimation for this use can be found in explicit consent.[124] The four elements of consent must be satisfied. The element of 'freely given' comprises two parts: a) free choice and b) control by the individual over his personal data. The element of 'specific' implies that the individual's consent cannot be given for undefined research. Though recital 33 allows for a certain degree of granularity in case of data processing for scientific research purposes at the time of data collection, the data subject must be given the opportunity to give his consent only to certain areas of research, pursuant to the principle of purpose limitation.[125] The requirements of specific consent together with purpose limitation serve as a safeguard against the gradual widening or blurring of purposes.[126] However, in the case of health research, the element 'informed' may not yet be achieved when the research is initiated. In that case, the patient's consent is also reflected in the trust and the reasonable expectations based on his relationship with the controller, i.e., the health research institution.[127]

This thesis addresses the challenges that arise with the elements of the lawful basis of consent, both in the contexts of health care and health research. As stated above, the element 'freely given' comprises two parts: a) the individual's free choice and b) the individual's control over his personal data.[128] In clinical practice, shared decision-making has become a central element of patient-centered care. The patient's values and preferences are incorporated into the decision and reflect his free choice. Health care professionals do not make decisions based only on their knowledge and expertise, but patients must understand the treatment options and participate in decision-making regarding their health.[129] The patient gives his consent to the treatment based on his

[123] European Data Protection Board, Document in response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, adopted on 2 February 2021, para 6, at 4.
[124] Article 9 (2) (a) together with article 6 (1) (a) GDPR; article 22 (2) (a) UAVG. B.W. Schermer et al. (2018). *Handleiding Algemene verordening gegevensbescherming en Uitvoeringswet Algemene verordening gegevensbescherming*.
[125] Article 5 (1) (b) GDPR: a determination of a specific, explicit and legitimate purpose for the intended processing activity must be provided by the controller.
[126] Guidelines 05/2020, para 56 at 14.
[127] Recital 50 GDPR; article 9 (2) (j) and 89 GDPR. N.C.H. Kongsholm & K. Kappel, Is consent based on trust morally inferior to consent based on information?' *Bioethics* 6 (2017), 432-442. S. Kalkman et al., 'Patients' and public views and attitude towards the sharing of health data for research: a narrative review of the empirical evidence, *Journal of Medical Ethics* 48 (2022) (1), 3-13. S. Holm et al., Control, trust and the sharing of health information: the limits of trust, *Journal of Medical Ethics* 47 (2021) (12), e35-e35.
[128] Hooghiemstra, T. et al. (2021). Overwegingen en suggesties voor beleid. Zeggenschap, eigenaarschap en persoonsgegevens. Verslag van de expert bijeenkomst d.d. 29 oktober 2021. https://www.rijksoverheid.nl/documenten/rapporten/2021/10/29/verslag-expertbijeenkomst-zeggenschap-eigenaarschap-en-persoonsgegevens. Accessed 6 January 2023.
[129] Hsu, P.J. et al. (2022). Improving the Process of Shared Decision-Making by Integrating Online Structured Information and Self-Assessment Tools. *Journal of Personalized Medicine* 12 (2), 256. doi: 10.3390/jpm12020256. G. Elwyn et al. (2012). Shared decision-making: a model for clinical practice, *Journal of General Internal Medicine* 27 (10), 1361-1367.

free choice and the information he has gathered during the exchange of information with his health professional. He is able to view his medical records (electronic patient file).[130] Largely, the individual may exercise his data protection rights, subject to such exceptions as required by law.[131] The expression of consent requires an action from the individual. However, an information asymmetry may exist between the care provider and the patient.[132] The individual's complete understanding of, and control over, his personal data is subject to debate. I will turn to the individual's understanding of, and control over, his personal data now.

The second part of the element 'freely given', consent, presupposes the individual's understanding of, and control over, his personal data.[133] 'Freely given' implies that the data subject can actually make a real choice and that he can exercise control over this choice.[134] The term 'control' is frequently used in academic debates on ownership of data. The GDPR does not specifically define 'control'. Recital 7 states that "*(…) [N]atural persons should have control of their own personal data*." Recital 75 then deals with material or non-material damages suffered by natural persons as a result of the control they can no longer exercise over their personal data.

However, the individual's control over his personal data, with the expression of his consent, must be seen within context.[135] Data protection rights must be viewed in relation to other fundamental rights.[136] Both the protection of personal data and the aim of promoting the free movement of data are objectives of the GDPR. The GDPR provides for a general framework that seeks to harmonize the protection of fundamental rights and freedoms of natural persons with respect to processing activities, as well as to ensure the free flow of personal data among member states.[137] Similarly, the individual interest and protection of human rights have a collective dimension in

[130] Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (WP 131), adopted on 15 February 2007. A.G. Keizer, De digitale patiënt centraal – medische informatie in een digitale wereld. In D. Broeders et al (2011). *De staat van informatie*. Amsterdam University Press.

[131] Data subject rights are included in chapter 3, articles 12 – 22 GDPR. Article 23 (1) (e) and (i) provide that union or member state laws may allow for restrictions "*(…) to serve other important objectives of general public interest (…)*" or "*(…) the protection of the data subject or the rights and freedoms of others (…).*" See also articles 455 – 456 WGBO.

[132] Waerdt, P. J. van de, (2020). Information asymmetries: recognizing the limits of the GDPR on the data-driven market. *Computer Law & Security Review* 38, 105436.

[133] Nishimura J. et al. (2013). Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials, *BMC Medical Ethics* 14, at 28.

[134] European Data Protection Board, Guidelines 05/2020 on consent under Regulation 2016/679. Version 1.1. Adopted on 4 May 2020, para 13. Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (WP 131), adopted on 15 February 2007.

[135] Richter, G. et al. (2021). Secondary research use of personal medical data: patient attitudes towards data donation. *BMC medical ethics*, *22*(1), 1-10. Also, Case C-300/21, ECLI:EU:C:2022:756, Opinion of Advocate General Campos Sánchez-Bordona of 6 October 2022, UI v Österreichische Post AG, ECLI ECLI:EU:C:2022:756, para 74:"*In my view, it is not straightforward to conclude from the GDPR that its objective is to grant data subjects control over their personal data as a right in itself, or that data subjects must have the greatest control possible over those data*."

[136] Case C-507/17, Google v Commission nationale de l'informatique et des libertés (CNIL) [2019]. Opinion of Advocate General Szpunar. ECLI:EU:C:2019:15, at para 60.

[137] Recitals 3 – 8 and article 1 GDPR.

society.[138] At all times, the data processing and exchange must take place following the principles with regard to the processing of personal data and with a lawful basis for this processing.[139] Nevertheless, the individual's consent is but one of the legal grounds for lawful processing.

Moreover, according to the European Data Protection Supervisor (EDPS), the assumption cannot be made as if human beings are completely rational and sensitive to economic incentives.[140] The EDPS also considers that consent does not constitute the only legitimate basis for most processing. As mentioned, the lawful basis of consent does not absolve the data controller of accountability.[141] Furthermore, on the topic of data subject's control of his data, the EDPS considers:

> "*Absolute control over personal data is however difficult to guarantee – there will be other concerns such as public interest and the rights and freedoms of others. Control is necessary but not sufficient. However human dignity is always a constant, and under EU law, the analogy of ownership cannot be applied as such to personal information, which has an intrinsic link to individual personalities. There is no provision in EU data protection law for an individual to waive this fundamental right.*"[142]

In the Dutch health context, the patient's consent is requested on multiple occasions during his patient journey, i.e., his diagnostic care pathway.[143] For instance, his explicit consent is asked when health provider A requests additional health information from health provider B.[144] A second occasion concerns his explicit consent for the use of his data for secondary research purposes.[145] A third occasion includes his informed consent when he participates in a clinical trial.[146] The patient's consent may be eroded if he signs several consent forms. Furthermore, consent may lose its value in practice

[138] Fraser, E.E., (2003). The Dimensions of Human Rights: A Confirmatory Factor Analysis of Human Rights Provisions, *International Journal of Sociology* 33 (4), 11-40. And H. Hijmans & C.D. Raab (2018). Ethical Dimensions of the GDPR, in M. Cole & F. Boehm (eds.), *Commentary on the General Data Protection Regulation*, Cheltenham: Edward Elgar, 2018.
[139] Articles 5 and 6 GDPR.
[140] European Data Protection Supervisor, Towards a new digital ethics. Data, dignity and technology. Opinion 4/2015, 11 September 2015, at 11.
[141] EDPS, Opinion 4/2015 at 11.
[142] EDPS, Opinion 4/2015 at 12.
[143] Helsper, C.W. et al. (2017). Time to diagnosis and treatment for cancer patients in the Netherlands: Room for improvement? *European Journal of Cancer* 87, 113-121.
[144] Pursuant to the Dutch Act on Additional Provisions with regard to the data processing in health (*Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg*), article 15a (1), https://wetten.overheid.nl/BWBR0023864/2020-07-01. Accessed 29 November 2022.
[145] Article 9 (2) (a) and article 6 (1) (a) GDPR; article 22 (2) (a) UAVG.
[146] Article 29 Clinical Trials Regulation; article 1 (1) l and 6 (1) Dutch Medical Research (Human Subjects) Act (Wet medisch-wetenschappelijk onderzoek met mensen, hereinafter WMO).

with the requirements to the patient's explicit consent.[147] In addition, there is the risk of 'mechanical proceduralism', which may harm both the consent given by the patient as well as the principle of consent itself, i.e., the expression of the free will.[148] Although reference to the risk of mechanical proceduralism is made regarding the Internet of Things (IoT) and the use of big data in general, the patient may sign consent forms without fully having informed himself as well.

The individual's free choice as regards the use of his data for secondary research is shown by his expression of explicit consent to this re-use of his data. He reaches his decision based on the information that is provided to him. He gives his consent by means of a statement or by a clear, affirmative action. The data controller can collect this through a written or a (recorded) oral statement, including by electronic means.[149] Thus, consent is not validly given in the case of silence, boxes ticked by default, or inactivity.[150] Furthermore, when the data subject gives his consent in the context of a written declaration, that declaration must be presented in an understandable and easily accessible form. It must also be formulated in clear and simple terms. This way, the individual must be able to enjoy genuine freedom of choice. At the same time, the personal right to data protection must be seen in relation to the individual's role in society. Information related to the individual is not only relevant to the individual himself, but also to the greater common good.[151]

h) Public interest

Alternatives to consent as a legitimation for the use of personal health data are a) pursuant to article Article 9 (2) (i) in conjunction with article 6 (1) (e) GDPR: the necessary processing for reasons of public interest in the area of public health and b) pursuant to article Article 9 (2) (j) in conjunction with article 6 (1) (e) GDPR: the necessary processing for archival purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with article 89(1) based on Union or Member State law. The legitimation serves to promote data processing

[147] Schermer, B. et al. (2016). The crisis to consent: how stronger legal protection may lead to weaker consent in data protection, *Ethics and Information Technology*, at 1:"*In our opinion, the overemphasis on autonomous authorization in data protection is the result of a positive and laudable, but ultimately flawed idea about human behavior in the context of privacy and data protection. The current and future legislation is based on the idea that all data subjects are rational actors that will read all privacy statements and carefully weigh and balance the consequences of consent (…).*"

[148] Moerel L. & C. Prins (2016). *Privacy for the homo digitalis. Proposal for a new regulatory framework for data protection in the light of Big Data and the Internet of Things*, at 8:"*(…) Privacy legislation needs to regain its role of determining what is and is not permissible. It is currently characterized by what we will hereafter refer to as mechanical proceduralism, whereby data controllers notify individuals and ask for their consent in a mechanical manner, without offering effective data protection in practice (…).*"

[149] EDPB, Guidelines 05/2020 on consent under Regulation 2016/679, version 1.1, adopted on 4 May 2020, para 77 at 18.

[150] Case C-61/19 of 11 November 2020, Orange România SA v Autoritatea Națională de Supraveghere a Prelucrării Datelor cu Caracter Personal (ANSPDCP), ECLI:EU:C:2020:901, paras 35 – 41.

[151] Rouvroy, A. & Y. Poullet, The Right to Informational Self-Determination and the Value of Self-Development: Reassessing the Importance of Privacy for Democracy, in S. Gutwirth & Y. Poulet et al. (eds.), *Reinventing Data Protection?* (Dordrecht: Springer, 2009), 45-76.

for reasons of public interest in the area of public health,[152] and data processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.[153]

As regards data processing in the public interest pursuant to article 9 (2) (i) GDPR, a necessity and proportionality test must be carried out and the data processing must be based on Union or Member State law. In other words, this processing must be based on Union or Member State law, which shall be proportionate to the aim pursued.[154] Moreover, suitable and specific measures to safeguard the fundamental rights and interests of the data subject are required.[155] These measures include, inter alia, technical and organizational measures such as data minimization and pseudonymization. Dutch law does not include the explicit legitimation as regards the processing of personal data for health research. Other European jurisdictions have not done so either till now.[156] Neither Dutch implementation legislation nor Dutch sectoral laws allow that the health institution carries out secondary health research with the legitimation for the lawful basis enunciated in article 9 (2) (j) GDPR.

Thus, a separate legal ground has not been included in EU legislation for the secondary use of data for research purposes in the public interest. Legal clarity contributes to a proper interpretation of the rules and concepts. A contextual approach leaves room for the judiciary and the executive branch to interpret the rules in a particular situation.[157] Additionally, I consider the definition of the public interest. A strict line cannot easily be drawn between research carried out in the public interest, public-private initiatives, and research that serves particular private interests.[158] To rely on public interest as a lawful basis for processing personal data, the controller must be able to identify a public interest. Furthermore, if data are used for research based on the public interest, then a governance framework is also required to protect public trust. In other words, legal compliance alone is not a guarantee that social legitimacy

[152] Article 9 (2) (i) in conjunction with article 6 (1) (e) GDPR.
[153] Article 9 (2) (j) in conjunction with articles 6 (1) (e) and article 89 (1) GDPR.
[154] Taylor, M.J. & T. Whitton, Public Interest, Health Research and Data Protection Law: Establishing a Legitimate Trade-Off between Individual Control and Research Access to Health Data. *Laws,* 2020; 9(1):6. https://doi.org/10.3390/laws9010006. C. Ploem (2005). Freedom of Research and its Relation to the Right to Privacy, In *Health Law, Human Rights and the Biomedicine Convention,* 161-173. Brill Nijhoff.
[155] Article 9 (2) (j) in conjunction with article 89 (1) GDPR. European Data Protection Supervisor, The EDPS quick-guide to necessity and proportionality, https://edps.europa.eu/sites/edp/files/publication/20-01-28_edps_quickguide_en.pdf. Accessed 30 November 2022.
[156] Becker, R. et al. (2020). COVID-19 Research: Navigating the European General Data Protection Regulation, 22(8):e19799. European Parliament, Fostering coherence in EU health research Strengthening EU research for better health. Panel for the Future of Science and Technology, October 2022, at 45.
[157] Van der Sloot, B. et al (2022). The influence of (technical) developments on the concept of personal data in relation to the GDPR. Tilburg Institute for Law, Technology and Society, at 18. Van der Sloot elaborates on the dangers of over- and under-regulation.
[158] Quinn, P. Research under the GDPR–a level playing field for public and private sector research? *Life Sciences, Society and Policy*, 2021, *17*(4), 1-33.

is similarly obtained.[159] In sum, the lawful basis of the public interest seems an attractive alternative at first sight, yet requires further analysis of the implementation legislation, and of the scope of 'public' in the expression 'public interest'.

i) Legitimate interests

A second alternative to the lawful basis of consent concerns the processing for the purposes of the legitimate interests pursued by the controller or by a third party.[160] This lawful basis has no corollary provision in article 9 GDPR, unlike the lawful bases of consent and the public interest. Furthermore, public authorities cannot rely upon this lawful basis. In applying the lawful basis of legitimate interests, the controller must carry out a balancing test between the legitimate interests of the controller or a third party, and the fundamental rights and freedoms of the data subject.[161] This means that the interests or the fundamental rights and freedoms of the data subject are not overriding, taking into consideration the reasonable expectations of the individual, based on his relationship with the controller.

The processing for research purposes has been recognized as a legitimate interest.[162] However, the existence of that legitimate interest does not automatically mean that article 6 (1) (f) GDPR can be relied on. In terms of research, the balancing test includes weighing the importance of the research interest with the severity of the impact on the rights and freedoms of the individual. Furthermore, in the context of the secondary use of data for health research, a double test must be carried out.[163] First, the data must be used for compatible purposes.[164] Secondly, an appropriate lawful basis for the processing must apply. The lawful bases of consent, public interest, and legitimate interests are legitimations for this secondary use. Additionally, the controller must implement appropriate safeguards. In particular, one must ensure that the data processing will not pose a risk of infringement to the privacy of data subjects.

[159] Taylor, M.J. & T. Whitton (2020). Public Interest, Health Research and Data Protection Law: Establishing a Legitimate Trade-Off between Individual Control and Research Access to Health Data, *Laws,* 9(1):6. https://doi.org/10.3390/laws9010006, 2. P. Carter et al. (2015). The social licence for research: Why care.data ran into trouble, *Journal of Medical Ethics* 41, 404-409.
[160] Article 6 (1) (e) GDPR.
[161] Recital 47 GDPR; CJEU 4 May 2017, C-13/16, ECLI:EU:C:2017:336, nr. 28.
[162] Article 29 Data Protection Working Party, Opinion 06/2014 on the notion of legitimate interests of the data controller under Article 7 of Directive 95/46/EC, adopted on 9 April 2014, at 25.
[163] Opinion 06/2014, at 28.
[164] Article 5 (1) (b) GDPR. Article 29 Data Protection Working Party, Opinion 03/2013 on purpose limitation, adopted on 2 April 2013, at 28. M. Koning, *The purpose and limitations of purpose limitation*. Doctoral thesis, Radboud University Nijmegen, 23 September 2020. See also section 1.5 d) purpose(s).

1.6. Design, structure and statement of authorship

This thesis is based on five articles that have been published in legal peer-reviewed journals. The articles are presented as chapters in this thesis. All chapters elaborate on the quest to legitimize the use of health data together with the balance between data protection and the promotion for the use of data for health care and scientific research. The thesis has a thematic approach. Chapters 2 to 6 focus on the main topic from two angles.

Chapter 2 addresses the main topic from the angle of health care. Chapters 3, 4 and 5 address the main topic from the angle of health research. Chapter 6, just as chapter 2, also addresses the main topic from the angle of health care. This chapter 6 focuses on the role that the individual plays amidst technological innovations. He is no longer only a patient but also a consumer of health care deliverables. Chapter 5 includes a comparison between the United Kingdom and the European Union on health research and rule-based versus risk-based compliance.

Two articles have been published in a Dutch legal journal, *Privacy & Informatie*, and reviewed by the editorial board. A sworn and certified legal translator has translated these articles into English. Additionally, a native English speaker (PhD), with a specialization in the review of dissertations, has completely reviewed this thesis. One article has been published in *European Data Protection Law Review* and reviewed by the editorial board. Two articles have been double blind peer-reviewed. One article has been published in the *European Journal of Health Law* and one has been published in *European Data Protection Law Review*. I am the sole author of four articles, i.e. the articles included in chapters 2, 3, 4 and 5.

I have written the article included in chapter 6 with another Ph.D. researcher, Mrs. Renée Dekker. Before and during the writing process of this article, we also held four writing sessions in person during which we elaborated on the framework and sketched the contents of the article. The division of our work, then, has been as follows. Irith Kist wrote the abstract. Section 6.1 (introduction), together with the sub-sections 6.1.1 and 6.1.2, were written by both authors during the writing sessions in person. Irith Kist wrote section 6.1.3. Renée Dekker wrote sections 6.2, 6.2.3 and 6.2.4. Irith Kist wrote sections 6.2.1 and 6.2.2. Renée Dekker wrote section 6.2.4, as well as sections 6.3, 6.3.1 and 6.3.2. Irith Kist wrote sections 6.4 and 6.4.1, whilst Renée Dekker wrote section 6.4.2. Finally, Irith Kist wrote section 6.5: conclusions and recommendations after an elaboration together during the fourth writing session in person.

The articles have been included in this book as chapters. Each chapter answers one sub-question. The sub-questions are added in italics before the original articles and the sub-conclusions are added at the end of each chapter. Typographical and syntactical errors in the original articles have been corrected. In addition, when new legal developments have taken place since the publication of an article, an explanation with a footnote has been added to the text. The numbering of the chapters generally follows the chronology of the articles. However, I inverted the following chapters. The article in chapter 3 was published prior to the one in chapter 2. Furthermore, the article in chapter 5 was published prior to the one in chapter 4. For the sake of structure, I chose to invert these chapters.

Chapter 2 is based on the first article, published in *Privacy & Informatie*, on "the sustainability of consent by elderly persons developing dementia."[165] This chapter addresses the topic of the thesis in the context of health care and answers the first sub-question:

> *In what way does the focus on the lawful basis of consent influence the provision of care when the individual is unable to express his will?*

The elements of the individual's autonomy, i.e., his ability to make a choice about his treatment and to reach an autonomous, free choice, are discussed.[166] I argue that the predominant focus on individual autonomy and self-determination cannot offer a solution to long-term care relations.[167] Data sharing is one of the crucial elements in providing care. Furthermore, I challenge the elements of consent, i.e., an individual's freely given, specific, informed, and unambiguous consent, in a situation where the care recipient becomes increasingly dependent on the care provided to him.[168] The various stages in the sustainability of consent are explored alongside the different stages of dementia.

Chapter 3 is based on the second article, published in *European Journal of Health Law*, on the "Assessment of the Dutch rules on health data in the light of the GDPR."[169] This chapter addresses the topic of the thesis from the angle of secondary health research and answers the second sub-question:

[165] Kist, I. (2021). De houdbaarheid van toestemming door de dementerende oudere. *Privacy & Informatie* (4), 165-171.
[166] Norman, G. van. (2011). Informed Consent: Respecting Patient Autonomy, in G. van Norman (ed.), *Clinical Ethics in Anesthesiology: A Case-Based Textbook*, Cambridge University Press, 36.
[167] Weele S. van der et al. (2021). What is the problem of dependency? Dependency work reconsidered, *Nursing Philosophy* (22), 1-10.
[168] Article 4 (11) GDPR: "(…) 'consent' of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes (…)."
[169] Kist, I.R. (2022). Assessment of the Dutch rules on health data in the light of the GDPR. *European Journal of Health Law*, *30*(3), 322-344.

In what way is the data processing for secondary health research solidified in the UAVG, as well as in sectoral health law and the Code of Conduct for Health Research?

The chapter highlights the relationship between the GDPR and the Dutch implementation legislation as well as sectoral health laws. Again, a number of challenges to the lawful basis of consent for the use of health data are addressed. I consider that further clarification on certain legal norms in the GDPR is required. For instance, a further opinion on article 89 GDPR is currently being prepared by the EDPB. In particular, an opinion from the EDPB is awaited on appropriate safeguards for scientific research under article 89(1), following a study carried out in 2019.[170] Furthermore, clarification from the EDPB is awaited on the requirement of a legal basis for further processing for scientific research purposes by the original or a subsequent controller, also taking into account recital 50 and article 6(4) GDPR.[171] The Guidelines were due in 2021 and have not yet been published.

Chapter 4 is based on the third article, published in *Privacy & Informatie*, on "the Dutch Code of Conduct for Health Research and the implementation of the lawful basis of consent."[172] This chapter addresses the research topic in the context of health research and answers the third sub-question:

In what way does the lawful basis of consent serve as a proper legitimation for re-using health data for scientific research and in what way may other lawful bases legitimize this use?

I elaborate on challenges to data processing and exchange as regards the secondary use of health data for research. First, I note the challenges in defining the concepts of secondary use, research purposes, and the scope of consent for the secondary use of health data.[173] Although the European Data Protection Board and European Data Protection Supervisor have also observed these challenges, a satisfactory answer has not

[170] Kindt, E. et al (2019). Study on the appropriate safeguards under Article 89(1) GDPR for the processing of personal data for scientific research. Final Report, EDPS/2019/02-08. European Data Protection Board, Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (Art. 70.1.b)). Adopted on 23 January 2019. European Data Protection Supervisor, Preliminary Opinion 8/2020 on the European Health Data Space, 17 November 2020, https://edps.europa.eu/sites/edp/files/publication/20-11-17_preliminary_opinion_european_health_data_space_en.pdf, Accessed 26 April 2022.

[171] EDPB, Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, adopted on 2 February 2021, at 6.

[172] I.R. Kist, I.R. (2021). De Gedragscode Gezondheidsonderzoek en de inbedding van de grondslag toestemming, *Privacy & Informatie* (6), 252-260.

[173] Becker, R. et al., (2022). Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers? *European Journal of Health Law*, 29, 1-29. https://doi.org/10.1163/15718093-bja10094.

yet been provided.[174] Similar to the previous chapter, this chapter focuses on consent as the lawful basis for secondary health research in the Netherlands. Subsequently, the exemptions are discussed. The Code of Conduct was completely revised and updated, after which the final version was published in December 2021.

Chapter 5 is based on the fourth article, published in *European Data Protection Law Review*, on the "Proposal for a new data regime in the UK: an avenue to be explored by the EU."[175] This chapter addresses the research topic in the context of health research and answers the fourth sub-question:

> *In what way do the developments in the United Kingdom serve as an avenue to be explored in the European Union with regard to the further use of health data for secondary health research and to compliance mechanisms in health?*

The article sheds light on the proposal for a new data regime in the UK. Similar challenges to the use of health data for research are discussed, followed by proposed solutions to the data regime in the UK. Furthermore, the monitoring by the Information Commissioner's Office, the British Data Protection Authority, is considered. The article continues with avenues to explore in the EU.

Chapter 6 is based on the fifth article, published in *European Data Protection Law Review*, on "Closing the gaps in patients' data protection rights: a glance into the future with a Dutch case study."[176] This chapter addresses the research topic in the context of health care and answers the fifth sub-question:

> *In what way does the existing data protection and health legislative framework protect the individual's autonomy, his health data, and his position as a care receiver where commercial companies deliver health services?*

This chapter 6 discusses the legislative framework of data protection and health law in today's world, where the individual has become an active player in governing his health. The traditional, clinical health setting is complemented with actors from a non-clinical background, such as commercial companies that provide health care

[174] EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, adopted on 2 February 2021, para 26. European Data Protection Supervisor, A Preliminary Opinion on data protection and scientific research, 6 January 2020 at 19:"*(…) Specific consent normally required under the GDPR may therefore become less appropriate in the case of collected and inferred data and especially in the case of special categories of data on which much scientific research relies (…).*"

[175] Kist, I.R. (2022). Proposal for a new data regime in the UK: an avenue to be explored by the EU, *European Data Protection Law Review* 8 (2), 295-301. DOI https://doi.org/10.21552/edpl/2022/2/18.

[176] Dekker, R. & I.R. Kist (2022). Closing the gaps in patients' data protection rights: a glance into the future with a Dutch case study, *European Data Protection Law Review* 3 (8), 331-345.

deliverables. New mechanisms for data protection and safeguarding a data subject's rights are required, and the article elaborates on the European Health Data Space as a starting point.

Chapter 7 answers the main research question based on the answers to the five sub-questions. Furthermore, it comprises recommendations and final considerations for future research. I address the recommendations to the Dutch and European legislator as well as to supervisory authorities in data protection and health law.

The sustainability of consent by elderly persons developing dementia

2. The sustainability of consent by elderly persons developing dementia[177]

This chapter answers sub-question 1 that reads as follows:

In what way does the focus on the lawful basis of consent influence the provision of care when the individual is unable to express his will?

Abstract

Patient-centered self-management and shared decision-making are popular concepts in health care. A diverse array of rules and legislation center around the patient's position and his[178] rights as a patient. Self-determination and autonomy are key concepts. Patients can give their consent for their health data to be used, have the right to make decisions about their treatment and, in principle, control the care provided to them. The boundary between the self-management that an elderly person, developing dementia, can exercise over the processing of his personal data and the care he receives differs for each individual case. Whether his (formal or informal) representative co-decides differs in each situation as well. Although Dutch health legislation offers a framework for this issue, the implementation of that framework may prove intractable in practice.

In this chapter, I discuss the principle of consent: consent for the processing of health data and for the provision of care to elderly persons developing dementia. I conclude that focusing only on the consent given by the patient to legitimize the use of his health data and the provision of care to the patient, may restrict the exchange of health data among various health institutions. It may also create the risk of depriving the patient of optimum health care, for example because he has refused to give consent for the sharing of his file or for receiving domestic or other care.

[177] Kist, I.R. (2021). De houdbaarheid van toestemming door de dementerende oudere, *Privacy & Informatie* (4), 165-170. Key reference words: autonomy, consent, dignity, self-determination.
[178] References to he, him and his may be read as references to she and her.

2.1. Introduction

In principle, processing health data is prohibited. An exemption to this prohibition consists in the explicit consent of the person involved. Consent as a legitimization for sharing data or providing care is set out in several sections of health care legislation. In this introduction, I discuss consent as included in the Dutch Medical Treatment Contracts Act (*Wet inzake de Geneeskundige Behandelingsovereenkomst*, chapter 7, title 7, section 5 Dutch Civil Code, hereinafter WGBO), the General Data Protection Act (hereinafter GDPR), the *Uitvoeringswet Algemene Verordening Gegevensbescherming* (Dutch GDPR Implementation Act, hereinafter UAVG), and the Dutch Care and Compulsion (Psychogeriatric and Intellectually Disabled Patients) Act (*Wet zorg en dwang psychogeriatrische en verstandelijk gehandicapte cliënten*, hereinafter Wzd).

The consent requirement in article 7:450 WGBO pertains to consent to enter into a treatment contract on the one hand, and consent for the actual medical treatment on the other.[179] To this end, articles 7:454 and 7:455 WGBO include the record-keeping requirement for care professionals. Patients are entitled to inspect their files. [180] In addition, articles 7:457 and 7:458 WGBO state how personal data may be supplied to other recipients than the care professional, for example, for further scientific research. The point of departure is the patient's consent (article 7:457 WGBO), with an exemption in some situations (article 7:458 WGBO). In principle, it is assumed in the WGBO that a patient is able to understand and take stock of his choices.[181]

If explicit consent has been obtained, health data[182] can be processed despite the prohibition in article 9 (1) GDPR.[183] Article 9 GDPR provides several exemptions to the prohibition on processing special personal data, in this case health data, to protect vital interests,[184] for the provision of health care,[185] for reasons of public interest in the area of public health,[186] and with a view to scientific research.[187] Article 22 UAVG lists the general exemptions from the regulation regarding the processing of special categories of personal data, including health data. Consent constitutes one of the exemptions to the prohibition on processing. In article 30 UAVG together with article

[179] Art. 7:450 WGBO: "*Voor verrichtingen ter uitvoering van een behandelingsovereenkomst is de toestemming van de patiënt vereist*" ("The consent of the patient is required for any treatment in the performance of a treatment contract"). Also H.J.J. Leenen et al (2020). *Handboek gezondheidsrecht*, 137 et seq.
[180] Art. 7:456 WGBO.
[181] J. Legemaate, *Staat van de gezondheidszorg 2006: patiëntenrechten in wetgeving en rechtspraak*. Report commissioned by the Dutch Healthcare Inspectorate, May 2006, 12.
[182] See section 1.5 sub a for an explanation about health data as a special category of data in the GDPR.
[183] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, art. 6 (1) (a) in conjunction with art. 9 (2) (a).
[184] Art. 9 (2) (c) GDPR.
[185] Art. 9 (2) (h) GDPR.
[186] Art. 9 (2) (i) GDPR.
[187] Art. 9(2) (j) GDPR.

9 (2) (h) GDPR, the prohibition on processing health data is lifted for care professionals.[188] Article 24 UAVG sets out exemptions to the prohibition on processing data for the benefit of scientific or historical research or statistical purposes, in view of article 9 (2) (j) GDPR.

The Wzd provides that, in principle, clients decide on the care provided to them.[189] I discuss consent by an elderly person developing dementia, for data processing and medical treatment. The principle of consent is based on a person's autonomy, dignity, and self-determination as enshrined in international and European treaties. Self-determination is a right of all human beings and is closely related to freedom, in particular the freedom to organize one's life.[190] Autonomy is defined as a person's ability to further his own life and to give it authenticity. In addition, autonomy comprises a moral right: each person's right to give shape and meaning to his own life and to reach his own decisions.[191] Autonomy has several dimensions, focusing on the individual and on the individual's relationships with his loved ones and his immediate circle.[192] A person's dignity is not just a fundamental right but also the foundation of all fundamental rights.[193] Human dignity is inalienable.

In this chapter, I discuss how the right to self-determination, autonomy, and dignity of persons developing dementia may be retained in the provision of care and the processing of personal data. I support the view[194] that the current approach to the individual, the explicit consent of and the self-management exercised by clients, do not do justice in all stages of life and at all decision moments, to the everyday lives of people with dementia, their loved ones, and their care professionals. In this context, I discuss the triangle of care that connects the care professional, the client, and the formal or informal representative. I will call the person developing dementia "client" pursuant to article 1(1)(c) Wzd and "patient" pursuant to article 7:446 (1) WGBO. Although the designation *client* is not identical to that of *patient* or *resident*, this distinction is beyond the scope of this chapter.

I start with the legal framework of the principle of consent, and the way in which the position of the client is enshrined in the Wzd (section 2.2). Subsequently, I will explain

[188] Art. 30 (3) (a) in conjunction with art. 30(4) UAVG.
[189] Art. 3 (1) Wzd.
[190] H.J.J. Leenen et al., *Handboek gezondheidsrecht* (Den Haag: Boom Juridisch, 2020), 55-63.
[191] J.J.M. van Delden, Over de autonomie van de oudere patiënt, in C. Hendriks et. al., *Grondrechten in de gezondheidszorg. Liber Amicorum voor prof. Mr. J.K.M. Gevers* (Houten: Bohn Stafleu van Loghum, 2010), 104-111.
[192] In a broader sense, also the general interest or '*Gemeinwohl*'. See Bundesverfassungsgericht 15-12-1983, ECLI:DE:BVerfG:1983:rs19831215.1bvr020983.
[193] Preamble to the Universal Declaration of Human Rights 1948, GA Res, 217 A (III) (hereinafter UDHR); art. 1 Charter of Fundamental Rights of the European Union 2012/C 326/02.
[194] Anne-Mei The, *Dementie en wat er uiteindelijk echt toe doet. Naar een socialere benadering van dementie*, Dutch National Health care Institute, 2016 lecture.

that in European and national legislation, a system has been established based on the client's autonomy and self-determination as expressed by the client's consent (section 2.3). I describe a case to illustrate the legal fiction that a person developing dementia gives his consent independently (section 2.4). I test the real-life situation described in the case against the standards, and conclude that the embeddedness of autonomy and self-determination in the explicit consent of the client may have undesirable effects on nursing home care. I end this chapter with a conclusion (section 2.5).

2.2. Legal framework

Articles 10 and 11 of the Dutch Constitution (*Grondwet*, hereinafter Gw) include the right to respect for one's privacy and physical integrity.[195] The GDPR provides a prohibition on the processing of health data, which may be lifted with the client's explicit consent.[196] In principle, consent is also the legal basis provided in the WGBO for any treatment carried out in the performance of a treatment contract.[197] The Wzd centers on the client's self-management, expressed in the *ultimum remedium* principle of 'no, unless'. This means that involuntary care may be used only as a last resort, when other suitable solutions are no longer available.[198] In other words, any alternatives based on voluntariness must be exhausted before involuntary care may be provided without the client's consent. Clients must consent to the care provided to the greatest possible extent, even if involuntary care is given. The clients decide on this care and on the exercise of rights and obligations as based on the law. A representative can only act in his behalf once a client can no longer be deemed capable of making a reasonable evaluation of his interests as regards a decision about him.[199] If court authorization is sought, the client will be heard by the court beforehand, assisted by a legal counsel. The client plays a central role in this process.

The comprehensive section-by-section explanation of the Dutch Constitution (*Integrale Artikelgewijze toelichting*)[200] shows that the client's representative has specific powers only and exclusively if and insofar as the client is incapable of making a specific decision. It is doubtful whether the client can reach adequate decisions and if he grasps the consequences of his choices. Again, involuntary care may only be given once no options for voluntary care are available.[201] Admittance to or continuation of

[195] M. Overkleeft-Verburg, Artikel 10, in A.K. Koekkoek et al., *De Grondwet – een systematisch en artikelsgewijs commentaar* (Deventer: W.E.J. Tjeenk Willink 2000), 177. See also B.J. Koops, Digitale grondrechten en de Staatscommissie: op zoek naar de kern, *Tijdschrift voor Constitutioneel recht*, March 2011.
[196] Art. 6 (1) (a) in conjunction with art. 9 (2) (a) GDPR.
[197] Art. 7:450 (1) WGBO. An exception to this is art. 7:450 (3) in conjunction with art. 7:465 WGBO.
[198] Art. 10 Wzd.
[199] Art. 3 (2) Wzd.
[200] See https://www.dwangindezorg.nl/documenten/publicaties/implementatie/wetgeving/1/wzd-artikelgewijze-toelichting. This informal section-by-section explanation of the Dutch Constitution was mainly intended as field support for the implementation of the Wzd.
[201] Art. 10 Wzd.

a stay in a registered accommodation takes place pursuant to an in-patient treatment decision of the Dutch Care Needs Assessment Center (*Centrum Indicatiestelling Zorg*, hereinafter CIZ). In this situation, the client neither exhibits the requisite willingness for this admission or continuation, nor resists it.[202] The CIZ must decide whether serious harm resulting from the client's behavior, because of his condition or impairment or a mental disorder related thereto, or a combination of these factors, can only be averted by his admission.[203] If the client resists this, court authorization is required for involuntary admission.[204]

2.3. Dignity, self-determination, autonomy, and respect for one's privacy

Consent as a legal basis for processing personal data stems from the respect for human dignity, self-determination, autonomy, and privacy. Human dignity and the right to self-determination are formulated in the Universal Declaration of Human Rights (hereinafter UDHR).[205] The right to self-determination is also included in article 17 of the International Covenant on Civil and Political Rights (hereinafter ICCPR).[206] The UN Convention on the Rights of Persons with Disabilities (UN, 2006) was ratified by the Netherlands in 2014 and centers on autonomy and self-determination, as expressed in a client's self-management and supported decision-making, inter alia.[207]

In article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (hereinafter ECHR), the right to one's private and family life is honored.[208] Article 8 of the Charter of Fundamental Rights of the European Union (hereinafter CFREU) includes privacy, and article 9 provides the right to protection of one's personal data.[209] The European Court of Human Rights (ECtHR) connects the right to self-determination to the right to personal autonomy and privacy,[210] recognizing that the right to privacy also comprises the right to personal development, including the individual's vital interest in receiving information about himself, thus obtaining personal freedom regarding himself and his identity.[211] In addition, the

[202] Art. 21 Wzd.
[203] Art. 21(2) Wzd.
[204] Art. 24 Wzd.
[205] Preamble and art. 12 UDHR.
[206] 16 December 1966, New York.
[207] Kingdom Act approving the Convention on the Rights of Persons with Disabilities adopted on 13 December 2006 in New York (Treaty Series 2007, 169 and Treaty Series 2014, 113). Parliamentary Papers II 2014-2015, 33992-(R2034) no 5.
[208] 1950, ETS 5.
[209] 2012/C 326/02 ELI: http://data.europa.eu/eli/treaty/char_2012/oj. O. Lynskey, Deconstructing data protection: the 'added-value' of a right to data protection in the EU legal order, *International and Comparative Law Quarterly* 63 (2014) (3), 569-597.
[210] ECtHR 29 April 2002, *Pretty v. United Kingdom*, no 2346/02; ECtHR 11 July 2002, *Christine Goodwin v. United Kingdom*, no 28957/95, ECtHR 16 October 2008, *Renolde v. France*, no 5608/06, para 83, ECtHR 20 March 2007, *Tysiąc v. Poland*, no 5410/03, para 15. Council of Europe 'Guide on Article 8 of the European Convention on Human Rights', 31 August 2019.
[211] ECtHR, 7 July 1989, *Gaskin v. United Kingdom*, no 10454/83, ECtHR 13. See also ECtHR, 13 February 2003, *Odièvre v. France*, no 42326/98, ECtHR 86.

ECtHR recognizes autonomy pursuant to article 8 ECHR.[212] In 1997, the ECtHR explicitly acknowledged for the first time that medical personal data also fall under the scope of application of article 8 ECHR.[213] Autonomy has several dimensions, centering on the individual and on the relationships of the individual to his loved ones and his immediate circle, respectively.[214] The ECtHR has repeatedly held that necessary treatment (compulsory or otherwise) does not constitute a violation of article 3 ECHR. Accordingly, providing necessary care may justify involuntary admission to a nursing home pursuant to article 5 (1) ECHR.[215]

In Dutch law, article 10 of the Constitution pertains to privacy and article 11 to physical integrity.[216] These two classic constitutional rights safeguard the freedom and equality of the individual and restrict public powers. Those rights may be limited by or pursuant to the law, as in article 7:450 in conjunction with 7:465 WGBO and in article 3 (2) Wzd. If a client cannot be deemed capable of a reasonable evaluation of his interests in relation to a decision about him, a representative may act on the client's behalf. In this situation, the representative has been tasked with the client's representation by the law or a physician, who has the requisite expertise and is not involved in the client's care, has decided that the client cannot be deemed capable. If a person is legally capable, he has the right to reach his own decisions about his own life.[217]

Self-determination does not merely comprise a right in the relationship between the state and the citizen.[218] The right also affects horizontal relationships, such as those between health care professionals and patients.[219] In case law, the connection between the provision of information by a practitioner and the patient's consent as an expression of his self-determination has also been recognized.[220] In sum, the principles of

[212] ECtHR 20 March 2007, *Tysiąc v. Poland*, no 5410/03, NJCM Bulletin 2007, p. 497 (annotated by A.C. Hendriks). NL Supr. Ct. judgment in re. Baby Kelly, Netherlands Supreme Court 18 March 2005, NL 2006, 606. ECLI:NL:HR:2005:AR5213.
[213] ECtHR, 25 February 1997, *Z. v. Finland,* ECLI:NL:XX:1997:AD4448, *NJ* 1999, 516, with commentary from Knigge, *NJB* 1997, pp. 1722-1724. *NJCM-Bulletin* 1997, 712 et seq. annotated by A.C. Hendriks.
[214] In a broader sense, also the general interest or '*Gemeinwohl*'. Bundesverfassungsgericht 15-12-1983, ECLI:DE:BVerfG:1983:rs19831215.1bvr020983.
[215] ECtHR 24 September 1992, *Herczegfalvy v. Austria*, no 10533/83, NJ1993, 523; ECtHR 10 February 2004, *Gennadi Naoumenko v. Ukraine*, no 42023/98 and ECtHR 11 July 2006, *Jalloh v. Germany*, no 54810/00; ECtHR 26 February 2002, *H.M. v. Switzerland*, no 39187/98, BJ 2002, 20.
[216] Parliamentary Papers II 1978/79, 15463 nos. 1 and 4. See also B.C. van Beers, Commentaar op artikel 11 van de Grondwet, in E.M.H. Hirsch Ballin & G. Leenknegt (eds.), *Artikelsgewijs commentaar op de Grondwet*, webeditie 2020. https://www.nederlandrechtstaat.nl. Accessed 1 March 2021.
[217] J.J.M. van Delden, Over de autonomie van de oudere patiënt, in A.C. Hendriks (ed.), *Grondrechten in de gezondheidszorg. Liber Amicorum voor prof. Mr. J.K.M. Gevers* (Houten, Bohn Stafleu van Loghum, 2010), 104-111.
[218] NL Supr. Ct. 9 January 1987, *Bespiede bijstandsmoeder*. ECLI:NL:HR:1987:AG5500, NJ 1987/928, annotated by E.A. Alkema, and AB 1987/231, annotated by F.H. van der Burg.
[219] NL Supr. Ct. 23 November 2001, NJ 2002, 386 and 387, annotated by J.B.M. Vranken. ECLI:NL:PHR:2001:AD3963. See also A.J. Akkermans, *De 'omkeringsregel' bij het bewijs van causaal verband* (Den Haag: Boom Juridische Uitgevers, 2002) and R.P. Wijne, *De omkeringsregel in medische zaken opnieuw toegepast*. Annotated by the District Court of Amsterdam, 13 November 2013, ECLI:NL:RBAMS:2013:7837. ECtHR 13 August 1981, *Young, James & Webster v. United Kingdom*, Series A, No. 44, Ch. 49.
[220] NL Supr. Ct. 12 March 2013, LJN BY4876/ BY4858, ECLI:NL:HR:2013:BY4876.

self-determination and autonomy comprise the client's freedom from infringement on his life and integrity by others, and the freedom to choose and to develop himself. In practice, these principles may cause tension with persons developing dementia as is shown in the case set out in section 2.4. It concerns a fictitious case based on a realistic scenario.

2.4. Case study: Mr. X

Mr. X (69) goes to his general practitioner (GP) with memory complaints. The GP carries out checks with X and refers him to the geriatrics department of the regional hospital. X takes more tests and an overview is made of his living conditions. He receives the diagnosis of dementia and he is referred to mental health care for the elderly. X is asked to sign a consent form for the exchange of his personal data, including the test results, between the hospital and the mental health care organization. He is also asked to give his consent that his data be sent from the regional hospital to the academic hospital. He voluntarily participates in a study on memory complaints at the academic hospital. Over the years, X's mental and physical condition deteriorates. However, X is convinced that he does not need any help. He refuses to consent to a modular or comprehensive package of home care, in spite of the decision regarding necessary care from the CIZ, in which it has been established that he needs this care. Subsequently, he refuses his consent for voluntary admission to nursing home care. Eleven years after his initial visit to the GP, X is placed in a nursing home following a court authorization. The first assessment there takes place after six months. X is asked whether he consents to an extension of his stay. He looks at the CIZ and nursing home staff questioningly. The CIZ concludes that X neither consents to nor resists the extension of his stay. X's stay is continued.

With his consent, X expresses his self-determination and autonomy. He is deemed legally capable of making decisions up to the moment he cannot be deemed capable of reasonably evaluating his own interests in the matter. In this context, the view on his legal capacity is dynamic, based on his capacity to make a decision.[221] The criteria of Appelbaum and Grisso can serve as a guideline upon which to base an assessment of legal capacity. An assessment of a person's legal capacity can be made using a step-by-step plan.[222] In the case at hand, the question of legal capacity is relevant in every expression of consent. I will elaborate on the various decision moments. The first moment is when the mental geriatric health care facility requests the test results from the regional hospital. The second moment is when the academic hospital sends the

[221] C.H. Vinkers et. al., *Is mijn patiënt wilsbekwaam? Volg de leidraad*, *Nederlands Tijdschrift voor Geneeskunde* 2014;158: A7229, 1-8. See also *Stappenplan wilsbekwaamheid. Van wet naar praktijk*. https://www.goedvertegenwoordigd.nl/wp-content/uploads/sites/14/2013/12/Stappenplan-wilsonbekwaamheid.pdf. Accessed 23 April 2021.

[222] See H. Vinkers et al. footnote 221 and T. Grisso & P.S. Appelbaum, Comparison of standards for assessing patients' capacities to make treatment decisions, *American Journal of Psychiatry* 152 (1995), 1003-1037.

results of a medical research to the regional hospital. At this time, the diagnosis of dementia has just been made. X may have been able to express his will based on the information provided to him. However, it remains unknown whether he was able to give his explicit consent and whether he had a full or partial grasp of the consequences of the expression of his will. Upon giving his consent, X can receive care based on the complete file. If he refuses to give his consent, the file will remain incomplete.

Nonetheless, medical treatment can be continued, pursuant to article 7:450 (2) WGBO, "*if this is clearly necessary to avoid serious harm to the patient*." Pursuant to article 7:465 (2)-(6), a representative can give consent on X's behalf, while involving X to the greatest possible extent in carrying out his representative task. If X had not given his consent, it would have been better to involve X's (formal or informal) representative already in the decision-making process. This would have allowed the legitimization of consent to continue – in the triangle of care that connects the patient, the care professional, and the representative. Because Mr. X was not capable or only partly incapable of expressing his will in the initial stage of dementia, his consent or co-consent served a purpose. The representative could have supported X in the decision-making process, whereas X's consent lies at the heart as well.

The third moment concerns the necessity of – perhaps comprehensive – home care for X, for which X does not give consent. Article 7:465 (5) WGBO contains an indirect reference to the wishes of the legally incapable patient to be honored to the greatest possible extent, since the representative is held to involve the patient as much as possible in the exercise of his duties. Article 8.1.2 (4) of the Dutch Long-Term Care Act (*Wet langdurige zorg*, hereinafter Wlz) starts with the perspective that the care professional follows the client's views unless this is inconsistent with the care to be provided in good clinical practice, and provided that the care professional has consulted another care professional about this.[223] The Wzd follows the WGBO in establishing legal incapacity. In practice, the situation may be more intractable. Even if, as evidenced from his illness process, a client can no longer grasp the consequences of expressing his will when he refuses the home care offered. Although the case at hand may be considered one of legal incapacity, the care professionals accepted X's refusal. In practice, the (formal or informal) representative is not always involved in the decision-making.

I would argue that self-determination and autonomy, as expressed in X's self-management and his choice to refuse his consent to receive care, clash with the objective to provide appropriate care. Moreover, the representative could also have played a part in serving X's interests. X's dignity would have been better served in the triangle of

[223] Art. 8.1.2(2) Wlz.

care connecting the care professional, the representative and the client. He would have received care, both in line with his wishes as a client and in line with the necessity for care as observed by the care professional and the representative. His self-determination and autonomy are expressed in his refusal to give consent, and this backfires: he fails to receive the care he deserves.[224] If more attention were paid to the situation of X in relation to his immediate circle and the context in which he lives, X can be offered the suitable care he deserves, with respect for his dignity throughout.

The fourth moment concerns the stay in a nursing home and the extension of that stay. Following the court authorization, X is placed in a nursing home. After a period of six months, the CIZ reviews the situation to decide whether to extend his stay.[225] X is the first to answer the questions. His opinion is asked, and based on his response it is concluded that X does not resist the extension of his stay. This could be observed as another clash between the respect for his self-determination and autonomy, as expressed in the conversation in which his consent is requested, and the necessity of suitable support and the involvement of the representative, by which X's interests are served to the greatest extent possible. However, in the situation at hand, X's legal incapacity has been established. Unfortunately, his condition, dementia, is progressive, as a result of which his legal incapacity is not temporary or incomplete. Considering the triangle of care, this third situation warrants giving a stronger voice to the care professional and the representative, in the interest of the client.

2.5. Conclusion

This chapter answered sub-question 1 that reads as follows:

> *In what way does the focus on the lawful basis of consent influence the provision of care when the individual is unable to express his will?*

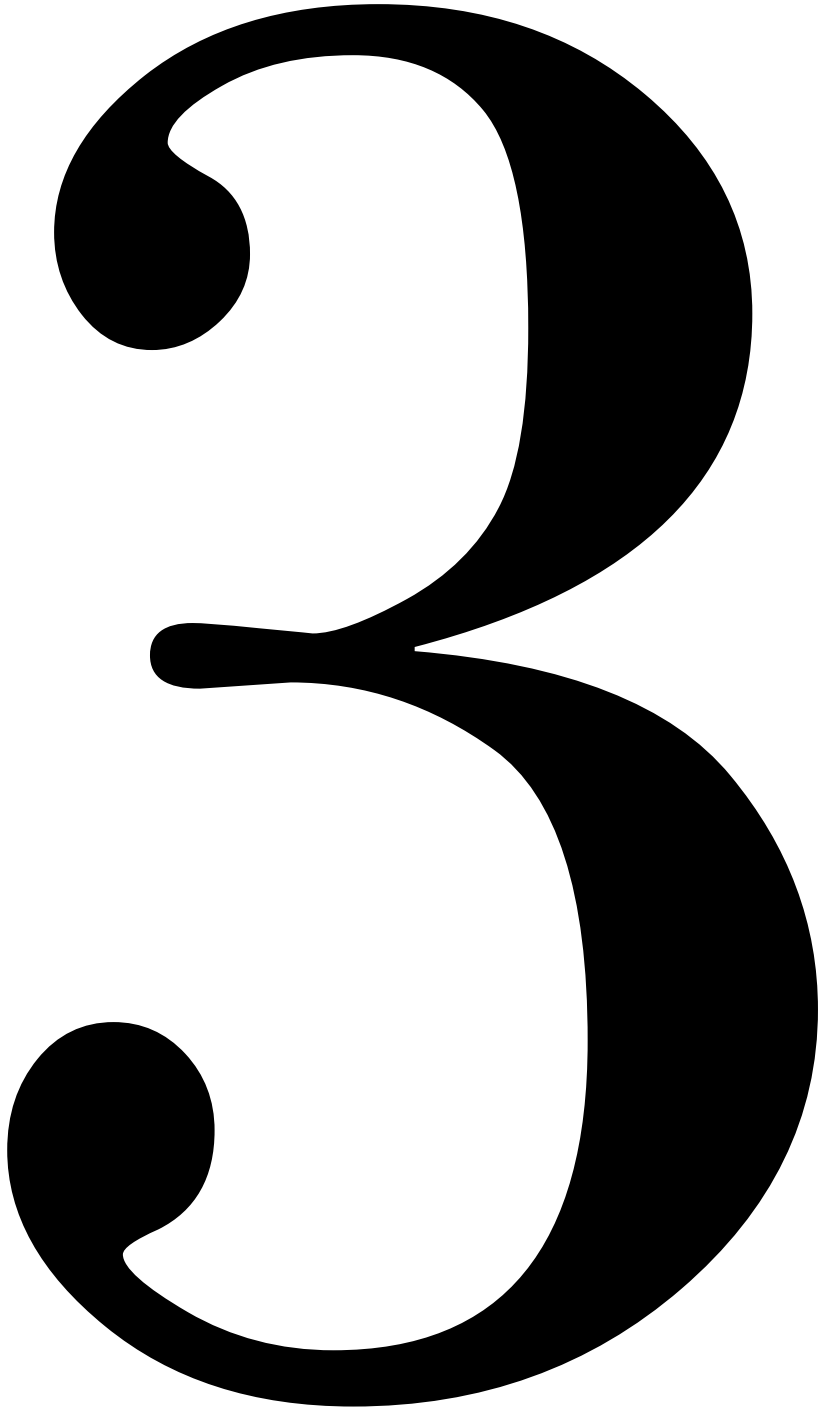
I conclude that, by giving or withholding his consent to the use of his personal data and for medical treatment, a person exercises his right to self-determination as an autonomous individual. He is considered an independent, rational person, who is free to make choices. However, exercising this consent requires specific capacities of the individual, such as the capacity to understand the information received and to make a well-considered choice, and the capacity to view his autonomy also in the context of his relationships with his loved ones and his immediate circle.

[224] A.C. Hendriks, B.J.M. Frederiks & M.A. Verkerk, Het recht op autonomie in samenhang met goede zorg bezien. *Tijdschrift voor Gezondheidsrecht* 32, 1 (2008), 2-18.
[225] Art. 21 Wzd.

The freedom of choice and his self-management, expressed in his consent, may diminish the dignity of a person developing dementia, and the value of expressing his preferences. Hence, the focus on the lawful basis of consent may influence the provision of care to the individual who is unable to express his will, since the consent is not based on a well-considered choice. His human dignity may better be served with the recognition of his partial or comprehensive legal capacity or incapacity, and the attention this warrants for the client together with those around him. It is beyond dispute that the care professional involves the client in the decision-making. The representative must serve the client's interests to the best of his ability.

Unfortunately, it is a fact that the value of expressing his preferences by a person developing dementia decreases as the process of his illness progresses. Accordingly, I conclude that the strength lies in the triangle of care in which the person developing dementia is involved as much as possible, with suitable care given by the care professional, and in which the representative serves or helps to serve the client's interests in the best possible way. In this triangle of care, the client's dignity is respected, as served by the representative, and with appropriate care provided by the care professional.

And Mr. X? After his legal incapacity had been established, his consent for the use of his personal data and his consent to receiving care were repeatedly asked. His dignity as a human being was not served. The representative was not always involved. More careful implementation of the triangle of care connecting the client, the care professional, and the representative may have offered a solution to these issues.



Assessment of the Dutch rules on health data in the light of the GDPR

3. Assessment of the Dutch rules on health data in the light of the GDPR[226]

This chapter answers sub-question 2 that reads as follows:

In what way is the data processing for secondary health research solidified in the UAVG, Dutch sectoral health law and the Dutch Code of Conduct for Health Research?

Abstract

In 2021, the European Commission published its Assessment of the EU member states' rules on health data in the light of General Data Protection Regulation. The Commission concluded that the GDPR has been interpreted in many ways in the EU as regards health research, and national implementation legislation has resulted in a fragmented legal landscape. Several lawful bases are used to legitimize the secondary use of health data. I address the Dutch legislation on the re-use, or secondary use, of health data for scientific research where explicit consent is the general rule. However, both the GDPR, the UAVG and sectoral health legislation leave room for alternatives. I conclude that a further review of these alternatives is required to enhance scientific health research with the secondary use of health data, and I sketch a few avenues for further exploration.

[226] I.R. Kist, Assessment of the Dutch rules on health data in the light of the GDPR, *European Journal of Health Law* 30.3 (2022), https://doi.org/10.1163/15718093-bja10096. Key words: explicit consent, health data, lawful bases, scientific research, secondary use.

3.1. Introduction

More than three years have passed since the advent of the General Data Protection Regulation (GDPR).[227] Unfortunately, one of the primary objectives of the GDPR, i.e., to provide a set of harmonized data protection laws across all member states,[228] has not yielded full effects as regards the secondary use of health data for scientific health research. A truly coherent European approach has not yet been achieved, since member states have adopted various implementation laws, while the interpretation of the GDPR framework substantially differs as well.[229] As a result, a fragmented legal landscape has arisen. The GDPR provides for six lawful bases for the processing of personal data, as well as a number of exemptions for the processing of health data for scientific research purposes. The different approaches by member states obstruct transnational, multi-center research, for instance because research consortia must use several lawful bases or different consent mechanisms. This has a material impact on scientific research and public health.[230]

This chapter elaborates on the following themes. I begin with the scope (section 3.1.1) after which I explain the aim of this chapter (section 3.1.2). I continue with the EU data protection framework, in particular the lawful basis of the data subject's explicit consent, and alternatives to consent for health research (section 3.2). Next, I outline the legal framework in the Netherlands, with a focus once again on the lawful basis of consent and alternatives to consent for health research (section 3.3). Three examples illustrate the quest for the (most) appropriate lawful basis and the hurdles to overcome regarding the lawful basis of consent in health research (section 3.4). Subsequently, I sketch a few avenues for further exploration (section 3.5). This chapter ends with a conclusion (section 3.6).

3.1.1. Scope

Pursuant to the GDPR, personal health data encompass all data regarding the health status of an individual.[231] Health data are used for diagnosis and care, and for purposes

[227] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). Hereinafter GDPR. European Commission, Assessment of the EU Member States' rules on health data in the light of General Data Protection Regulation, 2021, https://ec.europa.eu/health/sites/default/files/ehealth/docs/ms_rules_health-data_en.pdf. Assessed 10 January 2022. European Data Protection Supervisor, Preliminary Opinion 8/2020 on the European Health Data Space, https://edps.europa.eu/sites/default/files/publication/20-11-17_preliminary_opinion_european_health_data_space_en.pdf. Assessed 4 February 2022.

[228] Recitals 3, 5, 7, 8, and 9 GDPR.

[229] For an overview of the different approaches as regards health data systems and governance in Europe, see L. Abboud et al., Summary of Milestone 5.1 & 5.2 Annex A | Case studies: different governance and health data systems in Europe, 28 September 2021, TEHDAS, Towards European Health Data Space, https://tehdas.eu/app/uploads/2021/09/tehdas-annex-a-case-studies-different-governance-and-health-data-systems-in-europe-2021-09-28.pdf. Assessed 29 April 2022.

[230] Consortium Partners Towards European Health Data Space, Deliverable 5.1, Report on secondary use of health data through European case studies. Barriers on cross-border sharing of health data for secondary use and options to overcome these, 28 February 2022.

[231] Article 4 (15) GDPR: definition of *data concerning health*.

other than the original purpose, for instance the secondary use for health research. When health data are used for secondary health research, no (additional) intervention is asked from the (former) patient. In other words, the health data already exist and have been obtained for diagnosis and care. This secondary use must be distinguished from the use of health data for clinical trials, inter alia, when an (additional) intervention from the patient is required. This chapter focuses on the secondary use of health data for research purposes. This use may encompass big data research and research using the techniques of artificial intelligence.[232]

The chapter primarily focuses on the Dutch implementation legislation. Thus, while discussing other lawful bases for secondary use, I focus on the Dutch situation. Implementation legislation in other EU member states will also be slightly touched upon to illustrate other legislative options. Furthermore, I will confine myself to the secondary use of health data for scientific research, both by public and private organizations. Thus, for now, the (further) use of health data for public health or international health emergencies, for instance, will not be discussed.[233]

On a semantic level, I generally refer to the identified or identifiable natural person as the data subject.[234] When elaborating on sectoral health legislation, I also refer to the individual as the patient.

3.1.2. Aim

The aim of this chapter is to shed light on the Dutch implementation of the GDPR as regards data processing for secondary health research. I illustrate some hurdles that impede secondary health research. First, this chapter elaborates on the lawful basis of consent reflected in the GDPR and Dutch legislation, in particular the UAVG,[235] sectoral health legislation, and the Code of Conduct for Health Research. Secondly, this chapter focuses on alternatives in the GDPR and Dutch legislation to the lawful basis of consent for secondary health research.

[232] M. Mostert et al., From Privacy to Data Protection in the EU: Implications for Big Data Health Research, *European Journal of Health Law* 25 (2018), 43-55. M.B Forcier et al., Integrating artificial intelligence into health care through data access: can the GDPR act as a beacon for policymakers? *Journal of Law and the Biosciences* (2019), 317-335. L. Moerel & C. Prins, Privacy voor de homo digitalis: proeve van een nieuw toetsingskader voor Gegevensbescherming in het licht van *big data* en *Internet of Things*, *Handelingen Nederlandse Juristen Vereniging* 146 (2016) (1).

[233] Inter alia, the statement by the Science Academies of the Group of Seven (G7) nations, Data for international health emergencies: governance, operations and skills, 31 March 2021, https://royalsociety.org/-/media/about-us/international/g-science-statements/G7-data-for-international-health-emergencies-31-03-2021.pdf. Accessed 12 January 2022. World Health Organization, Regional office for Europe, The protection of personal data in health information systems – principles and processes for public health, Copenhagen: 2020. R. Becker et al., COVID-19 Research: Navigating the European General Data Protection Regulation, *Journal of Medical Internet Research* 22 (2020) (8), 1-9. B.M. Knoppers et al., Modelling consent in the time of COVID-19, *Journal of Law and the Biosciences* (2020), 7(1), 1-6.

[234] Article 4 (1) GDPR. M. Finck & F. Pallas, They who must not be identified – distinguishing personal from non-personal data under the GDPR, *International Data Privacy Law* 10 (2020) (1), 11-36.

[235] Uitvoeringswet AVG, https://wetten.overheid.nl/BWBR0040940/2021-07-01. Accessed 30 April 2022.

3.2. EU legal framework

The right to the protection of personal data is a fundamental but not an absolute right.[236] It must always be considered in relation to its function in society and balanced against other fundamental rights, in accordance with the principle of proportionality.[237] The GDPR provides for rules that aim to give data subjects control over their own personal data.[238] To this end, the GDPR stipulates that personal data may be processed based on consent by the data subject or on another legitimate basis.[239]

As health data are, by their nature, particularly sensitive, the GDPR contains strict rules for the processing of such data.[240] At the same time, the GDPR recognizes the importance of scientific research and the use of health data for this purpose.[241] Under the conditions set out in the regulation, member states may implement a regime for the use of health data for scientific research.[242] Moreover, the regulation acknowledges that the explicit consent by data subjects may not always be the most appropriate lawful basis for processing their health data for such scientific research.[243] The lawful basis of public interest[244] and legitimate interests,[245] all in combination with article 89 GDPR, are other lawful bases for processing health data. Furthermore, the GDPR incorporates a number of principles that foster scientific research, as noted above.[246] For instance, article 5 (1) (b), second sentence of the GDPR leaves room for *"further processing (…) for research purposes (…) in accordance with article 89 (1), which is not considered incompatible with the initial purposes*." I consider the lawful basis of consent in health research without an (additional) intervention in section 3.2.1. I continue to elaborate on alternatives to the lawful basis of consent in section 3.2.2. Both the GDPR, as well as Opinions, Guidelines and Recommendations by the European Data

[236] V.E.T. Dörenberg et al., Grondrechten in de gezondheidszorg. Liber Amicorum voor prof. mr. J.K.M. Gevers. *Tijdschrift voor Gezondheidsrecht*, 7, 625-628. M.C. Ploem, Towards an Appropriate Privacy Regime for Medical Data Research, *European Journal of Health Law* 13 (2006), 41-64.

[237] Recital 4 GDPR. See European Data Protection Supervisor, EDPS Guidelines on assessing the proportionality of measures that limit the fundamental rights to privacy and to the protection of personal data, 19 December 2019. G. Pavlakos, Between Reason and Strategy: Some Reflections on the Normativity of Proportionality, in G. Huscroft, B.W. Miller & G. Webber (eds.), *Proportionality and the Rule of Law: Rights, Justification, Reasoning* (New York: Cambridge University Press, 2014), 90-122.

[238] Recital 7 GDPR.

[239] Recital 40; article 6 (1) GDPR.

[240] Recital 51; article 6 (1) together with article 9 (1) and 9 (2) GDPR. In this respect, I follow the interpretation that article 9 (2) is complementary to article 6 GDPR. E.S. Dove, The EU General Data Protection Regulation: Implications for international scientific research in the digital era, *Journal of Law, Medicine and Ethics* 46 (2018) (4), 1013-1030.

[241] Recital 159 GDPR with a clarification that the research objectives pursued by the Regulation should take into account the Union's objective under Article 179 (1) TFEU of achieving a European Research Area.

[242] Recitals 52, 156 and 159; articles 9 (2) (j) and 89 GDPR.

[243] Recitals 33 and 156; article 89 GDPR; article 6 (1) (a) together with article 9 (2) (i) or (j) GDPR. See E.S. Dove (2018), footnote 240, who argues that other equally valid and lawful bases exist which may be more appropriate. I follow this line of argument.

[244] Article 6 (1) (e) together with article 9 (2) (i) or (j) GDPR.

[245] Article 6 (1) (f) together with article 9 (2) (j) GDPR.

[246] G. Comandè & G. Schneider, Differential Data Protection Regimes in Data-driven Research: Why the GDPR is More Research-friendly Than You Think, *German Law Journal*, 2022 (4), 1-55.

Protection Board (EDPB) and the European Data Protection Supervisor (EDPS), will be included in the analysis.

3.2.1. GDPR consent

Consent, as defined in article 4(11) GDPR, means

> *(…) [A]ny freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.*[247]

Article 9 (1) GDPR prohibits the processing of special categories of personal data, including health data. Subsequently, article 9 (2) GDPR lists exemptions to this prohibition, one of which is the data subject's explicit consent. The concept of this explicit consent emphasizes the data subject's autonomy and informational self-determination with regard to the (re-)use of his data while he is also entitled to share in scientific advancement and its benefits.[248] In addition, the GDPR neither defines the scope of consent to certain areas of scientific research, nor defines the scope of scientific research itself.[249]

The EDPB Guidelines on consent under Regulation 2016/679 state that

> *(…) [G]enerally, consent can only be an appropriate lawful basis if a data subject is offered control and is offered a genuine choice with regard to accepting or declining the terms offered or declining them without detriment (…).*[250]

This leaves the door ajar for a somewhat broader interpretation of the concept of consent. Recital 33, for instance, recognizes that it is often not possible to fully identify the purpose of the processing for scientific research purposes at the time of data collection and, therefore, allows data subjects to consent to certain areas of scientific research when in keeping with recognized ethical standards for scientific research.[251]

[247] See also the Opinion of Advocate General Szpunar of 21 March 2019 in Case C-673/17, Planet 49 GmbH v Bundesverband der Verbraucherzentralen und Verbraucherverbände - Verbraucherzentrale Bundesverband e.V. (Request for a preliminary ruling from the Bundesgerichtshof (Federal Court of Justice, Germany)), in particular paras 68 – 70, CURIA - Documents (europa.eu). Accessed 12 January 2022.

[248] F. Thouvenin, Informational Self-Determination: A Convincing Rationale for Data Protection Law? *J. Intell. Prop. Info. Tech. & Elec. Com. L.*, 12 (2021), 246. T. Hooghiemstra, Informational Self-Determination, Digital Health and New Features of Data Protection, *European Data Protection Law Review* 5 (2019), 160-174. A. Rouvroy & Y. Poullet, The Right to Informational Self-Determination and the Value of Self-Development: Reassessing the Importance of Privacy for Democracy, in S. Gutwirth & Y. Poulet et al. (eds.), *Reinventing Data Protection?* (Dordrecht: Springer, 2009), 45 -76.

[249] Recitals 33, 50, 51, 52, 156, and 159 GDPR; article 9(2) (j) and 89 GDPR.

[250] European Data Protection Board (EDPB), Guidelines 05/2020 on consent under Regulation 2016/679, version 1.1, adopted on 4 May 2020, para 3, 5.

[251] E. Gefenas et al., Controversies between regulations of research ethics and protection of personal data: informed consent at a cross-road, *Medicine, Health Care and Philosophy* 25.1 (2022), 23-30.

Nevertheless, the EDPB adds: *"[A]pplying the flexible approach of recital 33 will be subject to a stricter interpretation and requires a high degree of scrutiny*."[252] In the case of health research, the element "informed" may not be completely achieved at the time the research starts. In this respect, the patient's consent is reflected in the trust and the reasonable expectations based on his relationship with the controller, i.e., the health research institution.[253]

Thus, the Guidelines set extra conditions to ensure that the notion of scientific research is not stretched too far. The Guidelines require that a research project be established pursuant to relevant sector-related methodological and ethical standards. For instance, the concept of broad consent is included in the World Medical Association's Declaration of Taipei,[254] the Organization for Economic Cooperation and Development's Guidelines on Human Biobanks and Genetic Research Databases,[255] and the Council of Europe's Recommendation of the Committee of Ministers to member states on research into biological materials of human origin.[256]

Recital 33 GDPR allows for some flexibility to the degree of specificity of consent within the framework of scientific research.[257] In a research project, it may occur that research purpose(s) cannot be specified at the time of data collection, but only in a general way. However, the EDPB reiterates that the phrase 'broad consent' has been included neither in the recitals nor in the GDPR itself. Thus, although consent for scientific research can be provided at a more general level, the scope of consent may not be stretched too far either.

The lawful basis of consent poses other dilemmas in scientific health research as well. Explicit consent requires an action from the data subject. Health research often consists of longitudinal research over a prolonged period. When the health data were collected from the data subject, the researchers may not have been aware of findings

[252] Guidelines 05/2020 on consent under Regulation 2016/679, para 157, at 31.
[253] Recital 50 GDPR; article 9 (2) (j) and 89 GDPR. Kongsholm, N.C.H. & K. Kappel, Is consent based on trust morally inferior to consent based on information*? Bioethics* 6 (2017), 432-442. S. Kalkman et al., Patients' and public views and attitude towards the sharing of health data for research: a narrative review of the empirical evidence, *Journal of Medical Ethics* 48 (2022) (1), 3-13. S. Holm et al., Control, trust and the sharing of health information: the limits of trust, *Journal of Medical Ethics* 47 (2021) (12), e35.
[254] Article 12, WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks, adopted by the 53 WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67 WMA General Assembly, Taipei, Taiwan, October 2016.
[255] Article 4.6 OECD Guidelines on Human Biobanks and Genetic Research Databases, 2009.
[256] Article 11 Council of Europe Recommendation CM/Rec (2016)6 of the Committee of Ministers to member States on research on biological materials of human origin (Adopted by the Committee of Ministers on 11 May 2016 at the 1256th meeting of the Ministers' Deputies).
[257] EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research. Adopted on 2 February 2021, para 25, 7. The forthcoming Guidelines by the GDPR on the processing of personal data for scientific research purposes will elaborate on this matter. R. Becker et al., Secondary use of Personal Health Data: when is it "Further Processing" under the GDPR, and what are the Implications for Data Controllers? *European Journal of Health Law*, 29, 1-29. https://doi.org/10.1163/15718093-bja10094.

that became known at a later stage and which may give rise to new research. From an ethical perspective, asking repetitive consent may pose an additional burden on the data subject. Moreover, the data set will hardly ever be complete, as a result of which a bias in the research data may exist. Additionally, the use of data for another research purpose is considered incompatible with the original data processing and consent asked from the patient at an earlier stage. Furthermore, EU member states provide different interpretations of the concept of consent.[258] Lastly, the concept of explicit consent as one of the exemption to the processing of special categories of personal data has not been defined separately in the GDPR. In view of this, I will explore to what extent other lawful bases, notably the lawful bases of public interest and legitimate interests, may be alternatives for explicit consent in health research.[259]

3.2.2. Alternatives to consent for secondary health research in the GDPR

The GDPR encourages scientific research, including health research. Nevertheless, the processing must be fair, lawful, and transparent, and the data subject's rights must be observed.[260] Some exemptions apply to the information requirement, the right to erasure and the right to object. In recital 54, the GDPR refers to the processing of special categories of personal data for reasons of public interest in the areas of public health, without consent from the data subject.

The first alternative to consent is enunciated in article 6 (1) (e) together with article 9 (2) (i) GDPR. However, the exemption must be based on national or EU law, where the legislation must include the protection of rights and freedoms of the data subject. One example to this end is the implementation into national law of the WHO regulations on infectious, transmittable diseases, such as the COVID-19 virus.[261] Another example is public based registries, such as tumor or cardiovascular registries or registries relating to chronic illnesses. Recital 157 of the GDPR refers to these registries, but the acknowledgment of the public interest as the lawful basis with (additional) national legislation remains subject to discussion. These registries are an important source of data for scientific research. I examine the Dutch situation in section 3.3 below.

[258] Article 4 (11) GDPR.
[259] Articles 6 (1) (e) and 6 (1) (f) GDPR.
[260] The organization that processes the personal data must meet with the requirements of fairness, lawfulness and transparency. In my view, the GDPR provides for a general framework that has to be shaped by the respective data controllers or processors. See also P. J. van de Waerdt, Information asymmetries: recognizing the limits of the GDPR on the data-driven market, *Computer Law & Security Review* 38 (2020) (105436), 1-18.
[261] For Dutch legislation in this respect, see Public health act *(*Wet publieke gezondheid*)*, https://wetten.overheid.nl/BWBR0024705/2022-03-01, concept Act Quality registrations healthcare (Wet kwaliteitsregistraties zorg*)*, https://www.internetconsultatie.nl/wetkwaliteitsregistratieszorg. Also G. Richter et al., Secondary research use of personal medical data: attitudes from patient and population surveys in The Netherlands and Germany, *European Journal of Human Genetics* 29 (2021), 495-502. https://doi.org/10.1038/s41431-020-00735-3. Accessed 22 March 2022.

The second alternative to consent concerns article 6 (1) (e) together with article 9 (2) (j) and article 89 (1) GDPR, which provides for the research exemption.[262] In this regard, the controller must implement the necessary safeguards and conditions that have been included in article 5 GDPR to protect the rights and freedoms of the data subject. Article 89 (2) GDPR and recital 156 GDPR allow member states to adopt a longer list of derogations. Similar to the principle of the processing of health data in the public interest, this exemption must also be based on national law. Additionally, article 9 (2) (j) together with article 89 (1) and (2) GDPR require a proportionality test, i.e., balancing the processing of personal data in the interest of health research and the minimum use of personal data with the required safeguards and conditions accounted for. Once again, the data controller must adopt the necessary safeguards, i.e., data minimization, technical and organizational measures, privacy by design and default, and guidelines regarding pseudonymization and further processing.[263] Furthermore, the ethical standards must be recognized parallel to the lawful parameters.

Although the GDPR does not provide a definition of scientific research, recital 159 refers to the objective of achieving a European research area, as laid down in article 179 of the Treaty on the Functioning of the European Union (TFEU).[264] Therefore, personal data may be processed for research purposes, including technological developments. Furthermore, the GDPR recognizes the importance of the compilation of data in registries for research purposes and the difficulty that might arise from the fact that a subsequent purpose of data processing for research does not yet exist at the beginning of the data collection.[265]

The third alternative to the lawful basis of consent is the legitimate interests in article 6 (1) (f) GDPR, together with article 9 (2) (j) and article 89 (1) GDPR.[266] This lawful basis stipulates that three conditions must be met: the processing must be necessary

[262] M. Beauvais, The public interest and the GDPR, brief on the online platform of the Global Alliance for Genomics and Health (GA4GH). Accessed 29 January 2022. D. Townend, Conclusion: harmonization in genomic and health data sharing for research: an impossible dream? *Human Genetics* 137 (2018) (8), 657-664.

[263] C.F. Mondschein & C. Monda, The EU's General Data Protection Regulation (GDPR) in a Research Context, in P. Kubben, M. Dumontier, & A. Dekker (eds.), *Fundamentals of Clinical Data Science* (Champ: Springer, 2019), 67.

[264] Consolidated version of the Treaty on the Functioning of the European Union, 26 October 2012, OJ L. 326/47-326/390; 26 October 2012.

[265] Recitals 33, 157 and 159 GDPR.

[266] Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)), Adopted on 23 January 2019, https://edpb.europa.eu/sites/default/files/files/file1/edpb_opinionctrq_a_final_en.pdf, accessed 21 July 2022. See in particular paras 25 – 32 and 34. European Data Protection Supervisor (EDPS), A Preliminary Opinion on data protection and scientific research, 6 January 2022, https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf, accessed 21 July 2021. In particular para 7.4, 26.

(the necessity-test), it must serve a well-defined purpose (the purpose-test), and it serves a right that goes beyond individual rights and freedoms (the balancing test).[267]

3.3. Legal framework in the Netherlands: consent and other lawful bases

The Dutch legal framework includes a wide array of legislation in addition to the GDPR and the UAVG.[268] First, the Dutch Constitution, in particular article 10 (right to privacy) and article 11 (right to integrity), protects the individual's privacy, which is inherent in his informational and physical self-determination.[269] Next, the Medical Treatment Contracts Act governs the processing of personal data concerning health (*Wet Geneeskundige Behandelingsovereenkomst*, hereinafter: WGBO).[270] The Authority over Human tissue Act (*Wet Zeggenschap Lichaamsmateriaal*, hereinafter: Wzl*)* is a draft act on the collection and usage of human tissue and other human tissues. This act has been under construction by the Dutch Parliament since 2004 but has yet to be implemented.[271] Then, in January 2022, a new Code of Conduct for Health Research (*Gedragscode Gezondheidsonderzoek*) was published.[272] It replaces the previous Code of Conduct for Health Research (2004) and the Code of Conduct for Responsible Use of Human Tissue (2011).[273] The codes are self-regulatory codes of conduct.

The next two sections 3.3.1 and 3.3.2 elaborate on the provisions regarding the secondary use of health data for research in Dutch law.[274] The focus is on the WGBO, the UAVG and the Code of Conduct for Health Research. Reference is also made to the draft Wzl, although the Dutch Parliament has not yet adopted this act.[275] Similar to

[267] I. Kamara & P. de Hert, Understanding the balancing act behind the legitimate interest of the controller ground: a pragmatic approach, Brussels Privacy Hub Working Paper, vol. 4, nr. 12, August 2018. For an overview of relevant case law on the legitimate interest, see G. Zanfir-Fortuna & T. Troester-Falk (The Future of Privacy Forum and Nymity), Processing Personal Data on the Basis of Legitimate Interests under the GDPR: Practical Cases, Processing personal data on the basis of legitimate interests under the GDPR: Practical Cases (fpf.org), accessed 21 July 2022. E.B. van Veen, Observational health research in Europe: understanding the General Data Protection Regulation and underlying debate, *European Journal of Cancer* 104 (2018), 70- 80. Opinion 06/2014 on the notion of legitimate interests of the data controller under Article 7 of Directive 95/46/EC, WP 217, https://ec.europa.eu/justice/article-29/press-material/public-consultation/notion-legitimate-interests/files/20141126_overview_relating_to_consultation_on_opinion_legitimate_interest_.pdf. Accessed 21 July 2022. M. Donnelly & M. McDonagh Health Research, Consent and the GDPR Exemption, *European Journal of Health Law* 26 (2019) (2), 97-119, para 3.1.

[268] https://wetten.overheid.nl/BWBR0040940/2021-07-01.

[269] https://wetten.overheid.nl/BWBR0001840/2018-12-21.

[270] For an analysis of the relationship between European (data protection) law and Dutch health law, see A.C. Hendriks, Europeesrechtelijke dimensies van het gezondheidsrecht: de vooruitziende blik van Leenen (Henk Leenenlezing, 2020), *Tijdschrift voor Gezondheidsrecht* 45 (2021)(2), 131-140.

[271] www.eerstekamer.nl/behandeling/20211015/verslag_inzake_regels_voor/document3/f=/vln5g2qe69zw.pdf. M.C. Ploem, Wetsvoorstel 'zeggenschap lichaamsmateriaal': nog veel om over na te denken… *Tijdschrift Zorg & Recht in Praktijk* (2017) (2), 21-26. A new proposal is foreseen in the spring of 2024.

[272] https://www.coreon.org/gedragscode-gezondheidsonderzoek/.

[273] https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/codes-of-conduct.

[274] M.C. Ploem, T. Rigter & J.K.M. Gevers, Medisch data-onderzoek in het AVG-tijdperk: een zoektocht naar de juiste regels, *Tijdschrift voor Gezondheidsrecht* 44 (2020) (2), 162-181.

[275] A new proposal is foreseen in the spring of 2024: https://www.tweedekamer.nl/kamerstukken/wetsvoorstellen/detail?qry=wetsvoorstel%3A35844&cfg=wetsvoorsteldetails. Accessed 21 January 2024.

the elaborations on the EU legal framework, I begin with the lawful basis of consent in Dutch law, followed by alternatives to consent in secondary health research.

3.3.1. Consent in Dutch law

The WGBO provides for the general rule of consent for the (further) use of health data for research purposes (article 7:457), followed by the exception (article 7:458).[276] The exception is subject to the following conditions pursuant to article 7:458 section 1: a) asking consent is reasonably not possible and, in the execution of the research, there are safeguards such that the data subject's privacy is not disproportionately harmed; or b) considering the nature and objective of the research, consent cannot be asked in reasonableness and the physician has ensured that the data be issued in such a way that retracing the data to individual, natural persons is reasonably prevented. Furthermore, article 7:453 section 2 dictates that the data only be issued pursuant to these exceptions, provided that the research is carried out in the public interest, the research cannot be carried out without these data and in so far as the patient involved has not explicitly objected to the submission of these data. Article 7:453 section 3 then provides that a notification be included in the medical record regarding the submission of data.

The draft Wzl includes similar provisions in article 14 (consent) together with article 17 (exception to the general rule of consent).[277] However, article 6 on the use of sensitive human tissue is subject to consent only.[278] Article 1 (definitions) of the draft provides for a definition of consent that has the same components as the GDPR consent in article 4 (11) GDPR. The UAVG imposes four cumulative obligations on the controller when the exception to the general rule of consent is invoked.[279] These four conditions are as follows. Firstly, the processing must be necessary with a view to, inter alia, scientific research pursuant to article 89 (1) GDPR. Secondly, the investigation must be for purposes in the public interest. Thirdly, asking explicit consent proves to be impossible or requires a disproportionate effort on the part of the controller. Fourthly, in its execution, there are safeguards ensuring that the data subject's privacy is not disproportionately harmed.

The Code of Conduct for Health Research also provides for the general rule of explicit consent for the secondary use of health data for research, pursuant to article 6 (1) (a) together with article 9 (2) (a) GDPR and article 14 of the draft Wzl.[280] In brief,

[276] WGBO: https://wetten.overheid.nl/BWBR0005290/2019-11-15/#Boek7_Titeldeel7_Afdeling5.
[277] https://zoek.officielebekendmakingen.nl/kst-35844-2.html.
[278] Article 6 draft Wzl: https://zoek.officielebekendmakingen.nl/dossier/kst-35844-2.html. See also para 5.13 Explanatory Memorandum: https://zoek.officielebekendmakingen.nl/kst-35844-3.html, 27.
[279] Article 24 UAVG.
[280] Chapter 5 of the Code of Conduct for Health Research.

explicit consent is the general rule for the secondary use of health data. However, the WGBO, the UAVG, the draft Wzl, and the Code of Conduct for Health Research all provide for an exception to this general rule. The next section focuses on alternatives to explicit consent in Dutch law.

3.3.2. Alternatives to consent for secondary health research in Dutch law

The exception to explicit consent in the Dutch legislation (see section 3.3.1 supra) leaves room for data processing in the public interest by a research institution.[281] The four cumulative conditions must be met and the institution must guarantee that the relevant technical and organizational measures have been implemented. Furthermore, the data subject must individually be informed about the main facts of the research, its purpose, and the further use of his data. Additionally, the data subject has the right to object and must be able to exercise this right easily. This system is also referred to as 'opt-out-plus'.[282]

In other words, if explicit consent as referred to in article 6 (1) (a) together with 9 (2) (a) GDPR is not feasible, then recourse can be taken to the exception in article 7:458 WGBO, article 24 together with article 28 UAVG, article 17 draft Wzl and Section 5 Code of Conduct for Health Research.[283] In these instances, the further processing must be in the public interest. The lawful basis of the legitimate interests is not used in the Netherlands, as opposed to its application in other member states.[284] The focus on the lawful basis of consent with room for few alternatives obstructs scientific health research. Other lawful bases merit further exploration to enhance the secondary use of health data for further research. The next section continues with three examples where the search – and struggle – for the (most) appropriate lawful basis come to light and which call for a solution.[285]

[281] Article 24 and 28 UAVG; article 7:458 WGBO. Also, *Assessment of the EU Member States' rules on health data in the light of GDPR*, 2021, 67.

[282] S. Rebers et al., Zeggenschap over nader gebruik van lichaamsmateriaal: patiënt is het best gediend met 'geen bezwaar'-procedure, *Nederlands Tijdschrift voor Geneeskunde* 156 (2012), 14485. S. Rebers et al., A Randomised Controlled Trial of Consent Procedures for the Use of Residual Tissues for Medical Research: Preferences of and Implications for Patients, Research and Clinical Practice, *PLoS ONE* 11 (2016) (3), e0152509. E. Vermeulen et al., Connective tissue: Cancer patients' attitudes towards medical research using excised (tumour) tissue, *BioSocieties* 6 (2011) (4), 466-486. E. Vermeulen et al., A trial of consent procedures for future research with clinically derived biological samples, *British Journal of Cancer* (2009) (101), 1505-1512.

[283] https://www.coreon.org/wp-content/uploads/2022/01/Gedragscode-Gezondheidsonderzoek-2022.pdf. Accessed 23 March 2022.

[284] *Assessment of the EU Member States' rules on health data in the light of GDPR*, 2021.

[285] I follow the conclusions reached in this report: J. Gerritsen & P. Verhoef, *Datasolidariteit voor gezondheid – Verbeterpunten met oog voor ieders belang* (Den Haag, Rathenau Instituut, 2020).

3.4. In search of the (most) appropriate lawful basis for secondary health research: three examples

The first example concerns the data processing by population-based registries and further research carried out using these data.[286] I consider that the further use of data collected by these registries could fall either within the lawful basis of the public interest, [287] the legitimate interests,[288] or within the exception of 7:458 WGBO. Furthermore, new legislation is currently designed for population-based registries in the Netherlands.[289] However, this new legislation finds its lawful basis in articles 6 (1) (c) together with article 9 (2) (i) GDPR, i.e., the processing is necessary for reasons of public interest in the area of public health, such as ensuring high standards of quality and safety of health care.[290] The further processing for scientific research has not been included. National health registries, for example the Netherlands Cancer Registry (*Nederlandse Kanker Registratie, NKR*), provide statistics on various diseases in the Netherlands, such as cancer. The Netherlands Cancer Registry is an important source of data for the Netherlands Comprehensive Cancer Organization (*Integraal Kankercentrum Nederland, IKNL*), which carries out scientific research using these data.[291]

Additionally, the legislative proposal does not (yet) include all registries, whereas the recent pandemic has given rise to the necessity of new registries, with similar questions about the lawful processing of health data. I mention the initiative by Health-RI for a national COVID-19 citizen control registry.[292] On the one hand, this initiative focuses on the expression by citizens via a web-based register to consent and/or object to the use of their health care data and samples for COVID-19 studies. On the other hand, the web service enables researchers and caregivers to verify whether the participants in their research have consented or objected to the use of their data. I would argue that further clarification of the lawful basis proves useful for the public

[286] Advies Commisie Governance van Kwaliteitsregistraties (Advice by the Committee on Governance of Quality Registrations), Kamerstukken (Parliamentary papers) II, 2018 – 2019, 31476, nr. 28 (Annex), https://zoek.officielebekendmakingen.nl/kst-31476-28.html. Accessed 26 April 2022.
[287] Article 6 (1) (e) and 9(2)(j) together with article 89(1) GDPR; article 24 and 30 UAVG. ECIS, European Cancer Information System, https://ecis.jrc.ec.europa.eu/info/cancer_registries.html. Accessed 24 March 2022. As regards the lawful basis, the Register of the Data Protection officer refers to scientific or statistical research purposes in para 2, https://ec.europa.eu/dpo-register/detail/DPR-EC-00417.
[288] Article 6 (1) (f) together with article 89(1) GDPR. J.A.L. Krabben, Onderzoek Landelijke Zorgregistraties, Rapport 3 (Research on National Care registries, report 3), College Bescherming Persoonsgegevens (predecessor of the Dutch Data Protection Authority), The Hague, March 2005, 28. G.J. Zwenne et al., Eerste fase evaluatie Wet bescherming persoonsgegevens. Literatuuronderzoek en knelpuntenanalyse (First evaluation phase Dutch data protection act. Literature research and constraint analysis), Dutch Ministry of Justice, 2007.
[289] Dutch Quality registrations in Care act (Wet Kwaliteitsregistraties Zorg: https://www.internetconsultatie.nl/wetkwaliteitsregistratieszorg. Accessed 24 March 2022. This act finds its origin, inter alia, in the final report by H. Keuzenkamp, Een programma voor regie op kwaliteitsregistraties en verbetering van data governance (A program aimed at the control of quality registrations and improvement of data governance), 2020.
[290] Also recitals 52, 53 and 54 GDPR.
[291] https://iknl.nl/en. Accessed 4 April 2022.
[292] https://www.health-ri.nl/national-covid-19-citizen-control-registry. Accessed 24 March 2022.

communication to inform citizens about the use of health data for research purposes. Currently, both the opportunity to consent or to object are mentioned in the National COVID-19 citizen control registry as part of the Data Support Program. In other EU member states, such as Sweden, Denmark, and Finland, health data are processed for all patients according to their National Policy on Data Registries and Epidemiologic Research.[293] An exception is made for those patients who explicitly deny access, i.e., opt out of this further use. A shared feature of legislation in these Nordic countries is that informed patient consent is not required for the collection of large-scale data in national registries such as the National Cancer Registries.

The second example concerns those situations in which the (former) patient is unable to provide his explicit consent. In the Dutch Code of Conduct for Health Research, reference is made, inter alia, to (former) patients who have died or (former) patients whose current address is not known in the national key register of persons (*Basisregistratie Personen*), as a result of which the risk of a data breach arises. Additionally, asking (repetitive) consent could pose an unethical burden on the data subject, for instance, when he finds himself in a vulnerable position or when he would like to continue with his life and leave the period of his illness behind.[294] In these instances, the risk of incomplete data sets and, therefore, a bias in the data, may occur.

The third example concerns the complexity regarding the concept of consent itself. The GDPR includes extra requirements for consent.[295] As a result, it is difficult to determine further conditions for explicit consent. Moreover, the data subject himself may be confused about the different types of consent that he gives in various situations. For instance, the informed consent by a patient in a clinical trial differs somewhat from the explicit consent in the GDPR.[296] Additionally, EU member states have approached the concept differently. In the Netherlands, the former Dutch Data Protection Act (*Wet bescherming persoonsgegevens,* hereinafter: Wbp) provided for the data subject to express his explicit consent in spoken or written words, or in acts performed by him.[297] The EDPB refers to "*an unambiguous indication of wishes*" by

[293] For instance, the Swedish act on health data registers. Kristina Laugesen et al., Nordic Health Registry-Based Research: A Review of Health Care Systems and Key Registries, *Clinical Epidemiology* 13 (2021), 533-554.
[294] Dutch Code of Conduct for Health Research, 68 – 71.
[295] Recitals 32 (conditions for consent), 42 (burden of proof and requirements for consent) and 43 (freely given consent); Article 4(11) and 7 GDPR. D. Hallinan, Broad consent under the GDPR: an optimistic perspective on a bright future, *Life Sciences, Society and Policy* (2020) (16), 1. O. O'Neill, Some limits of informed consent, *Journal of Medical Ethics* 2003 (29), 4-7. T. Ploug & S. Holm, Meta consent – A flexible solution to the problem of secondary use of health data, *Bioethics* 30 (2016) (9), 721-732.
[296] Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC of 16 April 2014, hereinafter CTR. See in particular article 2 (2) (21) as regards the definition of informed consent.
[297] Parliamentary Papers II, 1997–1998, 25 892, nr. 3, in particular pp. 21 and 67: *"(…) [D]e betrokkene dient in woord, schrift of gedrag uitdrukking te hebben gegeven aan zijn wil toestemming te verlenen aan de hem betreffende gegevensverwerking."* (The data subject must have given an express statement of his consent in words spoken, written or acts performed by him as regards the data processing concerning him).

means of a statement or by a clear affirmative action.[298] I would argue that consent could lose its value in practice given the different interpretations of consent.[299] The lawful basis of consent serves the data subject's interests, but the concept deserves clarification as a lawful basis for health research.[300]

In Europe, other methods for data processing of health data for research are found that equally serve the individual's and society's interest.[301] The GDPR provides for alternatives to explicit consent, i.e., the lawful bases of the public interest or the legitimate interests in combination with article 9 (2) (i) or (j) GDPR. However, the comparison in Europe referred to above shows a varied approach in this respect. For instance, Germany allows for the further use of health data in case of "an overriding legitimate interest," and other member states allow for data processing in the public interest. In my view, the advantage of the lawful basis of the public interest is also a disadvantage. It is subject to debate when the processing takes place "in the public interest." As regards the lawful basis of the legitimate interests, both the advantage and disadvantage are vested in defining the principle as well.

In short, all lawful bases encompass both advantages and disadvantages. However, the largest hurdles to overcome are the varied approaches across Europe in terms of the application of various lawful bases. This results in a delay of international multi-center research. Secondly, the lawful basis of explicit consent may not be feasible in certain studies, such as longitudinal research where multiple sub-studies are carried out which were not known from the outset. Thirdly, the lawful basis of explicit consent may impose a disproportionate burden on the individual, whereas the data controller is actually accountable and responsible for the data processing, regardless of the individual's rights as a data subject, and regardless of whichever lawful basis is invoked. The next section offers some avenues for further exploration.

[298] European Data Protection Board, Guidelines 05/2020 on consent under Regulation 2016/679 Version 1.1, adopted on 4 May 2020, para 3.4, p. 18. See also Article 29 Data Protection Working Party Opinion 15/2011 on the definition of consent (WP 187).

[299] B. Schermer et al., The crisis of consent: how stronger lawful protection may lead to weaker consent in data protection, *Ethics and Information Technology* (2016), 1: *"In our opinion, the overemphasis on autonomous authorization in data protection is the result of a positive and laudable, but ultimately flawed idea about human behavior in the context of privacy and data protection. The current and future legislation is based on the idea that all data subjects are rational actors that will read all privacy statements and carefully weigh and balance the consequences of consent (…)".*

[300] E.S. Dove & Jiahong Chen, Should consent for data processing be privileged in health research? A comparative lawful analysis, *International Data Privacy Law* 10 (2020) (2), 117: *"(…) [W]e argue that there is merit in distinguishing research ethics consent from data processing consent, to avoid what we call 'consent misconception', and come to advocate a middle-ground approach in data protection law, i.e. one that does not mandate consent as the lawful basis for processing personal data in health research projects – but does encourage it. This approach, we argue, achieves the best balance for protecting data subject/research participant rights and interests and promoting socially valuable health research".*

[301] As has also been recommended by the Council of Europe, Recommendation CM/Rec (2019)2 of the Committee of Ministers to member states on the protection of health-related data (Adopted by the Committee of Ministers on 27 March 2019 at the 1342nd meeting of the Ministers' Deputies).

3.5. Avenues for further exploration

The current legal framework, both in Europe and the Netherlands, neither solves pending, practical questions nor provides for a comprehensive structure as regards the secondary use of data for health research. I now sketch two avenues for further exploration. The first avenue addresses the general framework of the GDPR and the harmonization pursued with this framework regulation. Though the GDPR aimed at further harmonizing the free flow of data on the one hand and data protection on the other, a coherent approach across Europe cannot be observed. The GDPR provides for a general framework as the regulation itself states, and it includes the necessary provisions for enhancing health research within the EU borders and beyond. I do not deem a revised GDPR necessary as such, but I welcome further clarification of certain concepts by the EDPB and/or EDPS. For instance, a further opinion on article 89 GDPR is being prepared by the EDPB. In particular, an opinion from the EDPB is awaited on appropriate safeguards for scientific research under article 89(1), following a previous study carried out in 2019.[302]

Additionally, I welcome the adoption of specific EU legislation that would promote the transfer of data across borders, thereby supporting both delivery of care as well as research and innovation. In this respect, the European Commission and the European Data Protection Supervisor (EDPS) advocate the creation of a European Health Data Space.[303] I also refer to the regulations of the European Parliament and of the Council on European data governance (Data Governance Act),[304] as well as the Data Act.[305] The Data Governance entered into force on 23 June 2022 and is applicable since September 2023. This follows the end of the transitional period of 15 months.[306] The Data Act entered into force on 11 January 2024 and will become applicable in September 2025.[307]

As regards Dutch law, a further harmonization can be realized on the interpretation of the relevant provisions of the WGBO, in particular article 7:457 together with

[302] Study on the appropriate safeguards under Article 89 (1) GDPR for the processing of personal data for scientific research, Final Report, EDPS/2019/02-08, https://edpb.europa.eu/system/files/2022-1/lawfulstudy_on_the_appropriate_safeguards_89.1.pdf, accessed 7 February 2022. Opinion 3/2019. European Data Protection Supervisor, Preliminary Opinion 8/2020 on the European Health Data Space, 17 November 2020, https://edps.europa.eu/sites/edp/files/publication/20-11-17_preliminary_opinion_european_health_data_space_en.pdf, accessed 26 April 2022.

[303] Legislative train schedule: promoting our European way of life after 2022-01, https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-european-health-data-space. Accessed 5 April 2022. Digital Health Europe, Recommendations on the European Health Data Spac, 2021, https://digitalhealtheurope.eu/wp-content/uploads/DHE_recommendations_on_EHDS_July_2021.pdf. Accessed 5 April 2022.

[304] COM/2020/767 final of 25 November 2020, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX-%3A52020PC0767. Accessed 5 April 2022.

[305] COM (2022) 68 final, Proposal for a regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act) of 23 February 2022, https://digital-strategy.ec.europa.eu/en/library/data-act-proposal-regulation-harmonised-rules-fair-access-and-use-data. Accessed 26 April 2022.

[306] https://digital-strategy.ec.europa.eu/en/policies/data-governance-act. Accessed 21 January 2024.

[307] https://digital-strategy.ec.europa.eu/en/policies/data-act. Accessed 21 January 2024.

article 7:458, and article 24 UAVG. At present, the patient gives his consent to use his health data for further research, or he is individually informed about this further use and may object to it.[308] In this respect, I welcome a more flexible approach to the scope of consent in the first place. For instance, a patient gives his broad (-er) consent to the use of his health data for further research at his initial appointment at the health institution. He is properly and individually informed and has the right to withdraw his consent.[309] Secondly, when asking consent is not feasible, as explained in section 3.3.2 above, then recourse can be taken to the exception in article 7:458.

Another long-term solution includes the introduction of sectoral health legislation for the purpose of scientific research.[310] Several explorations have already been carried out, which vary from an extension of the Dutch Medical Research Involving Human Subjects Act (*Wet medisch-wetenschappelijk onderzoek met mensen*) to integral sectoral health legislation.[311] Apart from the question of whether integral sectoral health legislation is feasible considering the large scope, it will definitely be a lengthy process, while a speedy solution is necessary at the same time. Moreover, the scope for change also depends on the trust expressed by the population in legislative initiatives and the institutions that process the health data.[312]

The second avenue addresses the optimum regulatory approach to further harmonization. I would argue that codes of conduct could be helpful in a further harmoni-

[308] See, for instance, the information leaflet for patients of Antoni van Leeuwenhoek hospital: https://www.avl.nl/media/3645/gebruik-van-uw-gegevens-en-materiaal-voor-wetenschappelijk-onderzo.pdf. And Radboud University Medical Center: https://www.radboudumc.nl/patientenzorg/uw-afspraak/patient-in-een-umc/gebruik-van-uw-medische-gegevens-en-lichaamsmateriaal. The Amsterdam University Medical Center provides the patients with information about the use of their health data for further research: https://www.amsterdamumc.nl/nl/rechten-plichten/locatie-amc/dossier-inzien.htm, at para 'beroepsgeheim & privacy', final sentence. The Groningen University Medical Center also informs the patients about the use of their health data for further research: https://www.umcg.nl/medisch-wetenschappelijk-onderzoek, at para 'Gebruik van lichaamsmateriaal en/of medische gegevens voor toekomstig wetenschappelijk onderzoek'. Accessed 22 July 2022.

[309] A study was carried out in 2019 on the choice for a system based on consent or on opt-out: R. Stüssgen et al., Zorggegevens voor onderzoek: bezwaar of toestemming? De wet en de praktijk, Nivel 2019. See also R. Coppen et al., Hergebruik van medische gegevens voor onderzoek: Wat vindt de Nederlander van het toestemmingsvereiste? *Nederlands Tijdschrift voor Geneeskunde* 2016 (160), A 9868. And the Netherlands Patients Federation also carried out a study: Delen van data in de gezondheidszorg, February 2021. https://www.datavoorgezondheid.nl/binaries/datavoorgezondheid/documenten/publicaties/2021/03/31/rapport-delen-van-data-voor-de-gezondheidszorg---onderzoek-patientenfederatie-nederland/210325+Definitieve+rapportage+Delen+van+Data.pdf. Accessed 22 July 2022.

[310] J.G. Maessen et al., Adviesrapport Knelpunten oplossen bij opstarten van wetenschappelijk onderzoek door medisch specialisten, Federatie Medisch Specialisten, March 2019. Afsprakenstelsel Health-RI, Ambitie, Uitgangsprincipes, Obstakels, Oplossingsrichtingen, Governance, October 2021. Niet-WMO-plichtig onderzoek en ethische toetsing. Verkenning in opdracht van het Ministerie van VWS, 14 February 2020.

[311] Position adopted by the Dutch Federation of University Medical Centers (NFU, Nederlandse Federatie van Universiteiten) Federation of Medical Specialists (FMS, Federatie Medische Specialisten), Committee on Regulations of Health Research (COREON (Commissie Regelgeving in Onderzoek), and Health-RI, Inbreng op wetsvoorstel Wet zeggenschap lichaamsmateriaal, October 2021.

[312] S. Kalkman et al., Patients' and public views and attitude towards the sharing of health data for research: a narrative review of the empirical evidence, *Journal of Medical Ethics* 48 (2022) (1), 3-13. M. Boyd et al., Secondary use of health data in Europe, Open Data Institute, 2021, 1-39.

zation.[313] International and European initiatives have been launched with a Code of Conduct in health research developed by BBMRI-ERIC, the Code of Conduct for Health care Professionals and Scientific Organizations developed by the Alliance for Biomedical Research in Europe, and the Framework for Responsible Sharing of Genomic and Health-Related Data developed by the Global Alliance for Genomics and Health.[314] The EDPB issued Guidelines on Codes of Conduct and Monitoring Bodies in 2019.[315] However, the EDPB introduced the obligation of a monitoring body pursuant to article 41(1) and (4) GDPR, whereas article 41(1) GDPR refers to the possibility ("…*may be carried out by a body*…") rather than an obligation.[316] Because of this additional requirement and the fact that not all member states would want to rely on self-regulatory codes of conduct, it is unlikely that this instrument will be implemented in Europe in the short run. In the Netherlands, the new Code of Conduct for Health Research provides for an extensive framework to equally protect the individual and enhance health science. At present, an implementation and communication plan has been drafted for further dissemination.

In sum, the European and Dutch legal frameworks echo the need for further guidelines and an insight into the general framework that the GDPR provides. Over the years, Dutch sectoral legislation has resulted in a legislative patchwork, with 'old' and 'new' legal answers to the secondary use of data in health research. I recommend a further harmonization of the interpretation of the WGBO, while sectoral health legislation continues to be further elaborated. At a European level, the initiative for a European Health Data Space and specific legislation on data exchange can enhance both innovation and research across Europe and beyond. I recommend that the EDPB and EDPS continue to provide answers to legal, practical dilemmas using guidelines and opinions.

3.6. Conclusion

This chapter answered sub-question 2 that reads as follows:

> *In what way is the data processing for secondary health research solidified in the UAVG, Dutch sectoral health law and the Dutch Code of Conduct for Health Research?*

[313] Kamerstukken (Parliamentary Papers) II, 1989-1990, 21 561, nr. 3, 16-17. The initiative for a Code of Conduct for Health Research was applauded in the Explanatory Memorandum. Also pp. 40-41, in which article 1653m (old) of the Dutch Medical Treatment Contracts Act is exemplified.

[314] B.M. Knoppers et al., A human rights approach for an international code of conduct for genomic and clinical data sharing, *Human Genetics* (2014) (133), 895-903.

[315] EDPB, Guidelines 1/2019 on Codes of Conduct and Monitoring Bodies under Regulation 2016/679, adopted on 4 June 2019.

[316] See Guidelines 1/2019, footnote 315, section 27, at 12: *"(…) [A] draft code that involves processing activities of private, non-public authorities or bodies, must also identify a monitoring body and contain mechanisms, which enable that body to carry out its functions as per Article 41 of the GDPR (…)."*

Explicit consent is the primary lawful basis of data processing for secondary health research, as enunciated in article 6 (1) (e) together with article 9 (2) (a) GDPR, article 22 (2) (a) UAVG, article 7:457 WGBO and Section 5 of the Dutch Code of Conduct for Health Research. However, the focus solely on explicit consent obstructs scientific health research.

I have elaborated on the following dilemmas caused by the legal basis of consent. Firstly, research institutions across Europe apply different consent mechanisms and may not accept the mechanism adopted by a research institutions in another member state. Secondly, according to the EDPB, the definition of consent does not leave much room for a broad (-er) interpretation in view of consideration 33 GDPR. Thirdly, consent requires an action from the individual, i.e. the data subject whereas in longitudinal research, he may be difficult to find and, even more importantly, he may not want to give repetitive consent. As a result, secondary health research takes place with incomplete datasets or does not take place at all.

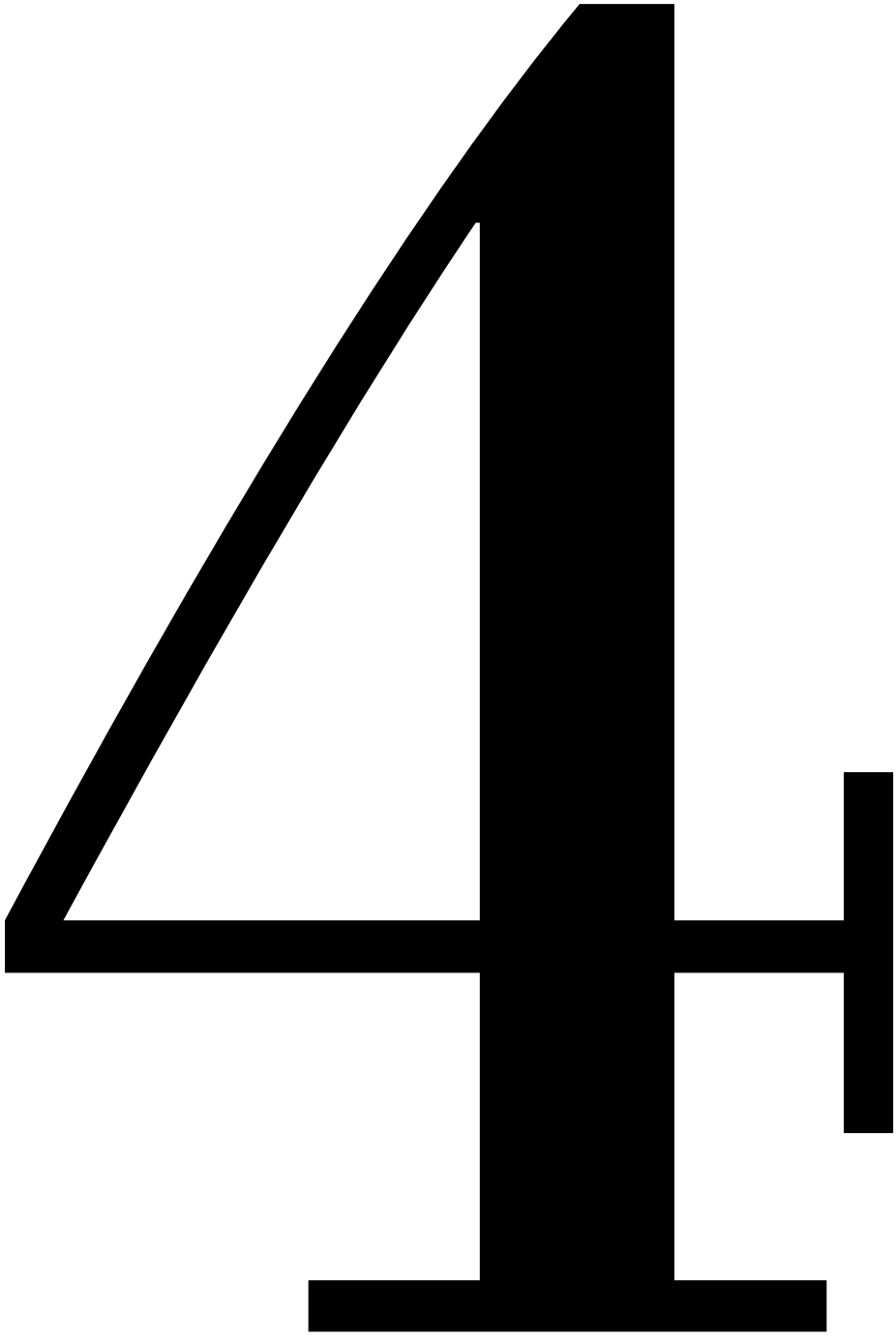
I have provided the following solutions in this chapter that serve to enhance data sharing for secondary health research. Firstly, the use of other lawful bases in the GDPR and Dutch sectoral health legislation could solve the dilemmas surrounding consent. In the Netherlands, the 'opt-out plus' system as incorporated in the Dutch Code of Conduct and Dutch sectoral health legislation (section 7:458 WGBO) is used, provided that the conditions in sub-sections 2 and 3 of article 7:458 are met. Secondly, some member states in Europe apply the lawful bases of the public interest and legitimate interests, as laid down in article 6 (1) (e) or (f) together with article 9 (2) (j) and article 89 (1) GDPR.

Thirdly, I consider that revised sectoral health legislation can solve the difficulties with the application of explicit consent in secondary health research. In Europe, new legislation such as the European Health Data Space can be a solution for the varied approaches in terms of the application of different lawful bases applied at present for secondary health research.

Fourthly, before sectoral health legislation and European legislation will enter into force, a clarification of concepts in the GDPR may bridge the gap between current and future legislation. For instance, a clarification of the concept of scientific research and appropriate safeguards for scientific research is awaited from the EDPB.

Fifthly, as regards the Code of Conduct for Health Research, I conclude that this framework provides for relevant, practical solutions. However, if a monitoring body

need be implemented, then I consider that existing monitoring bodies for health research within the health institutions could fulfil this task themselves.



The Dutch Code of Conduct for Health Research and the implementation of the lawful basis of consent

4. The Dutch Code of Conduct for Health Research and the implementation of the lawful basis of consent[317]

This chapter answers sub-question 3 that reads as follows:

In what way does the lawful basis of consent serve as a proper legitimation for re-using health data for scientific research and in what way may other lawful bases legitimize this use?

Abstract

This chapter focuses on the Dutch Code of Conduct for Health Research (*Gedragscode Gezondheidsonderzoek*) and the implementation of the lawful basis of consent in that Code. Based on a case study, I specifically discuss the processing of patient data and a patient's control over the secondary use of health data for scientific research. In this type of research, existing patient data resulting from diagnostics and treatment are made accessible for science. I discuss how the provision of consent in articles 7:457 and 7:458 WGBO, and in article 14 Wzl relates to consent as a legal ground for processing data in article 6 (1) (a) in conjunction with article 9 (2) (a) GDPR, and in article 24 UAVG. The WGBO sets out the rights and obligations of the patient, whereas in the draft Wzl, the conditions are listed under which it is possible to use human tissue, for example for scientific research or the development of medications. Examples of human tissue are connective and muscle tissue, blood, and saliva.

I conclude that with the consent given by the patient, and the exceptions to consent where the secondary use of health data for scientific research is concerned, several consent modalities are used in the context of using personal data and human tissue. I would argue that consent does not constitute the only legitimization for re-using health data for scientific research. The GDPR also entails the legal ground of the public interest in processing personal data pursuant to article 6 (1) (e) in conjunction with article 9 (2) (i) and (j) and in conjunction with article 89 (1) GDPR. However, Dutch legislation and regulations are based on the consent given by the patient, or on the latter's option to object to his personal data and human tissue being re-used for scientific research. I welcome a further exploration of a different legal ground for processing data that have already been included in the GDPR, and a further imple-

[317] I.R. Kist, 'De Gedragscode Gezondheidsonderzoek en de inbedding van de grondslag toestemming', *Privacy & Informatie* 2021 (6), 252-259. A sworn and certified translator translated this chapter into the English language in the spring of 2022. Key words: code of conduct, health research, the lawful basis of consent, secondary use of health data for scientific research.

mentation of this in Dutch legislation. Lastly, I propose the option of developing sectoral legislation regarding data sharing for scientific research purposes.

This chapter starts with an introduction (section 4.1) followed by the introduction of a case study (section 4.1.1), an explanation of the legal European and national framework (section 4.1.2), and the lawfulness of processing (section 4.1.3). Section 4.2 continues with the lawful basis of explicit consent as a point of departure in the Dutch Code of Conduct for Health Research whilst section 4.3 focuses on consent modalities in the context of re-using health data for scientific research in this Code. Section 4.4 elaborates on the relationship between consent in the WGBO, the draft Wzl, the GDPR and the UAVG. Section 4.5 discusses four other exceptions to the lawful basis of consent in the Code of Conduct. This chapter ends with a conclusion (section 4.6).

4.1. Introduction

As commissioned by the Dutch Committee on Regulation of Health Research (*Commissie Regelgeving Onderzoek*, hereinafter COREON), a new Dutch Code of Conduct for Health Research was adopted in January 2022. This Code has replaced the 2004 Dutch Code of Conduct for Medical Research (*Code Goed Gebruik*). An earlier attempt to achieve this, undertaken by COREON in 2013, was not successful because the Dutch Data Protection Authority (hereinafter: DPA) did not recognize this Code at that time. With the entry into force of, inter alia, the GDPR and the innovations in scientific research, the actualization of a Code of Conduct has become important. The 2011 Dutch Code of Conduct for the responsible use of human tissue for scientific research (*Gedragscode Verantwoord omgaan met lichaamsmateriaal ten behoeve van wetenschappelijk onderzoek*), also referred to as the Dutch Code of Conduct for Medical Research, has been included into the new Dutch Code of Conduct for Health Research.[318]

This new Dutch Code of Conduct was developed pursuant to articles 40 and 41 GDPR. The consultation round was finalized on 9 September 2021 and the Code of Conduct was adopted in January 2022. The DPA has not formally accepted this Code.[319] Codes of Conduct seek to protect personal data through self-regulation.[320] In this Dutch Code of Conduct for Health Research, the various legal grounds for

[318] Dutch Code of Conduct for Health Research, January 2022, https://www.coreon.org/gedragscode-gezondheidsonderzoek/. Accessed 13 November 2023. See also L. Ramerman, E.-B. van Veen & T. Schermer, *Inventarisatie herziening gedragscode gezondheidsonderzoek*, Nivel / FEDERA-COREON 2019.

[319] *Plan van Aanpak herziening Gedragscode gezondheidsonderzoek*, version 5.1, COREON and MLC Foundation. An English translation of the Code was published in July 2023: https://www.coreon.org/wp-content/uploads/2023/06/Code-of-Conduct-for-Health-Research-2022.pdf. Accessed 13 November 2023.

[320] EDPB, Guidelines 1/2019 on Codes of Conduct and Monitoring Bodies under Regulation 2016/679, Version 2.0, 4 June 2019.

processing data are set out, as well as the role of the data controller(s), the necessity for a data protection impact assessment (hereinafter DPIA) in cases of large-scale data processing, the role of the data protection officer, and the rights of the data subjects. This chapter mainly focuses on the lawful basis of explicit consent for the use of personal data and human tissue, and on the exceptions to consent as a legal ground for processing.

In the new Dutch Code of Conduct, the lawful basis of explicit consent is taken as a point of departure. Subsequently, the exceptions are explained.[321] The Code includes standards for

1. processing data and human tissue, including personal data and human tissue of deceased patients;
2. processing personal data and human tissue in scientific research; and
3. processing personal data and human tissue with the purpose of answering a question with regard to illness, (public) health, and/or the system of health care and health protection.

The summary term for said research is health research. The GDPR does not provide a definition of scientific research.[322] In recital 159 GDPR, a broad interpretation of scientific research is provided. I use the definition included in the Dutch Code of Conduct, with a reference to the 2018 Dutch Code of Conduct for research integrity.[323] In the GDPR, personal data, including health data, are broadly defined. The GDPR does not apply to the personal data of deceased persons.[324] Those data fall under the professional medical secrecy, also when a patient has died. The Dutch Code of Conduct uses the umbrella term 'participant' for the person whose personal data or human tissue are made available for scientific research. The participant is always a 'data subject' pursuant to article 4 (1) GDPR. I refer to 'the patient' in this chapter, based on a case study. This patient is also a data subject pursuant to the GDPR and a participant in light of the Code. This latter concept of a participant is broader, a

[321] Art. 6 (1) (a) GDPR in conjunction with art. 9 (2) (a) and (j) GDPR and art. 24 UAVG. See Beleidslijn inzake het verzamelen van onderzoeksdata en doorgifte buiten EU vanwege COVID-19 of 16 April 2020. Also M.C. Ploem, T. Rigter & J.K.M. Gevers, Medisch data-onderzoek in het AVG-tijdperk: een zoektocht naar de juiste regels, *TvGR* (44) 2020 (2), 162-181. And, S. Rebers et al., Zeggenschap over nader gebruik van lichaamsmateriaal: patient is het best gediend met 'geen bezwaar'- procedure, *Nederlands tijdschrift voor geneeskunde* 2012:156:A4485.

[322] Recital 159 in conjunction with articles 9 (2) (j) and 89 GDPR.

[323] The definition reads as follows (p.16): *"Generating knowledge through systematic research and reflection, observation and experimentation that is in accordance with the relevant methodological and ethical standards of the sector, and conforms to good practice. Health research is also always scientific research."* Also, Dutch Code of Conduct for Research Integrity 2018, knaw.nl/shared/resources/actueel/bestanden/nederlandse-gedragscode-wetenschappelijke-integriteit-2018-nl, p. 7, derived from the *European Code of Conduct for Research Integrity* (Berlin: Allea, 2017).

[324] Art. 4 (1) in conjunction with art. 4 (15) GDPR. See also recital 35 GDPR, in which the sources of personal health data are listed. See Article 29 Working Party (01248/07/NL. WP 136). Advice 4/2007 on the concept of personal data, 20 June 2007. This includes video images.

generic concept also comprising the subject pursuant to the Dutch Medical Research (Human Subjects) Act (*Wet medisch-wetenschappelijk onderzoek met mensen*, hereinafter WMO), and the 'donor' in the draft Wzl.[325]

4.1.1. Case study

Patient X is referred from regional hospital A to academic hospital B for further treatment. He has been diagnosed with skin cancer. Ten years ago, he was treated for a similar condition in academic hospital C. Both academic hospitals offer health care and carry out scientific research, both in respect to his health data and the human tissue collected during treatment. At various points, Patient X is asked to give his consent for the secondary use of his health data and human tissue for scientific research; alternatively, under specific circumstances, the health care institution that will carry out research may invoke one of the exceptions included in the WGBO, the Wzl, and the UAVG. In this chapter, I discuss the provisions in legislation and regulations that are relevant in the context of this case study.

4.1.2. The legal framework

The lawful basis of explicit consent is included in the GDPR.[326] In the WGBO, consent is also the point of departure for the performance of the medical treatment contract.[327] For 'information on the patient or access to the medical records' for the benefit of scientific research, the WGBO includes an exception to the consent requirement, provided that specific conditions are met.[328] For using data regarding 'anonymous human tissue and parts collected from the body' for purposes of scientific research, the WGBO includes only a provision for anonymous residual material.[329] For the case study on Patient X, this means that only human tissue collected from him during the diagnosis or treatment may be used anonymously for further scientific research. In the draft Wzl, the void about the further use of human tissue is expected to be solved; article 4:467 WGBO will cease to exist upon the entry into force of the Wzl.[330] Explicit consent is also the point of departure for using both identifiable and anonymous residual material in the draft Wzl. A derogation may apply in specific cases.[331]

[325] Dutch Code of Conduct for Health Research, 11.
[326] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), *OJEU* 4 May 2016, L 119 (hereinafter GDPR). Also art. 22 of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine) (Council of Europe, 1997). See also articles 10 and 11 Dutch Constitution.
[327] Articles 7:446 et seq. WGBO, in particular art. 7:450 (1) WGBO that defines the consent requirement.
[328] Articles 7:457 and 7:458 WGBO.
[329] Art. 7:467 WGBO.
[330] Parliamentary Paper 35844, Regels voor handelingen met lichaamsmateriaal, welke worden verricht voor andere doeleinden dan geneeskundige behandeling of diagnostiek van de donor (Wzl), on 2, 27 May 2021, https://zoek.officielebekendmakingen.nl/dossier/kst-35844-2.html. At present, a new draft of the Wzl is prepared.
[331] Inter alia pursuant to art. 15 (1) 1 draft Dutch Authority over Human tissue Act.

Explicit consent is also key in the Dutch Code of Conduct; derogations may apply in specific situations. The Dutch Code of Conduct focuses on medical scientific research that seeks to answer a question with regard to illness, (public) health, and/or the system of health care and health protection, irrespective of the origin of the data. In a formal sense, the Dutch Code of Conduct thus addresses the controllers, i.e., research and other institutions, including health care providers processing or supplying personal data or human tissue for health research.[332] This means that the data may have been collected specifically for scientific research, or may comprise existing personal data that are made available for scientific research.[333] This latter category of personal data is also referred to as health data that are 're-used for scientific research'.[334]

For Patient X in the case study, said regulations and legislation mean that in principle, his explicit consent is required for the secondary use of his health data for scientific research. He gives explicit consent for the use of his personal data, and the use of his human tissue collected during treatment and diagnostics. The data controller, for example an academic hospital where scientific research is carried out, may derogate from this rule in specific situations. I discuss the exceptions to explicit consent in more detail in section 4.3 (in the context of the secondary use of health data for scientific research) and in section 4.5 (when I discuss several other exceptions from the WMO and the draft Wzl).

This chapter mainly focuses on the secondary use of health data for scientific research. Medical-scientific research with individuals pursuant to the WMO is also mentioned in sections 4.2 and 4.5. In this latter research under the WMO, people are subjected to medical interventions. For instance, a medical intervention takes place in the framework of medication research or when a blood sample is taken, or rules of conduct are imposed upon the individual, in the form of questionnaires that he may find burdensome or stressful, and/or which may violate subjects' physical and/or mental integrity. This type of research is assessed by a Medical Research Ethics Committee (*Medisch-Ethische Toetsingscommissie,* hereinafter METC) and the written consent of the subject in question is required.[335]

[332] Dutch Code of Conduct for Health Research, 22.
[333] Dutch Code of Conduct for Health Research, 13.
[334] Niet-WMO-plichtig onderzoek en ethische toetsing – Verkenning in opdracht van het Ministerie van VWS, 14 February 2020. Antoni van Leeuwenhoekziekenhuis & MLC Foundation. R. Scholte et al., Hergebruik van patiëntgegevens voor wetenschappelijk onderzoek: op weg naar eenduidige spelregels, *Tijdschrift Gezondheidswet* (97) 2019 (3/4), 55-58.
[335] For the consent requirement in prospective research with an intervention and a specific research question, see art. 1(v) in conjunction with art. 69 (1) (a) WMO. D.P. Engberts & L.E. Kalkman-Bogerd (eds.), *Gezondheidsrecht* (Houten: Bohn Stafleu van Loghum, 2009). Also, CCMO: ccmo.nl/onderzoekers/wet-en-regelgeving-voor-medisch-wetenschappelijk-onderzoek/uw-onderzoek-wmo-plichtig-of-niet. Research falls under the WMO if it satisfies the following two requirements: a) it concerns medical-scientific research with people and b) individuals are subjected to acts, or behavioural rules are imposed upon them.

4.1.3 The lawfulness of processing

The processing of personal data is lawful if at least one of the legal grounds for processing in article 6 GDPR has been met. The UAVG must be observed in addition to article 9 GDPR for the processing of special categories of personal data, including personal data for the benefit of health research. The elements of consent as one of the legal grounds for processing data in article 6 GDPR constitute the following. The consent of the data subject (in this case: the patient) is freely given, specific, informed, and unambiguous.[336] The Article 29 Working Party issued guidelines on the concept of consent in 2017, which were revised by the European Data Protection Board, hereinafter EDPB) in May 2020.[337] The EDPB provides that consent is an appropriate legal ground for processing data only if the data subject can exercise control over the processing of his personal data and has a real choice to accept, or objects to accept, the conditions, without any consequences. Recital 33 GDPR specifies the consent requirements for research purposes regarding detail ('granularity') and specificity.[338]

When applied to the case study, these provisions imply the following. By giving his consent, Patient X provides the option of processing his health data to be re-used for scientific research. Recital 33 GDPR recognizes that at the outset of research, the research purpose may not be identified in detail, even though personal data are collected. The EDPB interprets recital 33 in such a way that there is a limited scope for a broad interpretation, provided that Patient X is either asked for his consent anew in the next phases of the research, or he regularly receives (where applicable, new) information during the various phases of research.[339] The Dutch Code of Conduct chooses the second option: the provision of information to Patient X in the event that he takes part in long-term research, for example. However, the Dutch Code of Conduct provides four conditions to be met with this (broader) consent.[340] Firstly, Patient X must regularly be informed during the course of the research. Secondly, a review must take place whether the course of the research is still in line with Patient X's reasonable expectations. Thirdly, the patient must give his consent anew if the course of the research is not in line with his reasonable expectations. Fourthly, patient X must

[336] Recital 30 and art. 4 (11) GDPR. See also the European Data Protection Board (EDPB), successor of the Article 29 Working Party and an independent European body incorporated under the GDPR (see articles 68-76 GDPR): Guidelines 05/2020 on consent under Regulation 2016/679, par. 11. EDPB: Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, para 25, 2 February 2021.

[337] Article 29 Working Party, Guidelines 05/2020 on consent under Regulation 2016/679 of 10 April 2018 and WP 259 revision 01of 28 November 2017, as last revised by the European Data Protection Board on 4 May 2020, version 1.1: Guidelines 05/2020 on consent under Regulation 2016/679.

[338] V. Chico, The impact of the General Data Protection Regulation on health research, *British Medical Bulletin* 128 (2018) (1), 109-118.

[339] EDPB, Guidelines 05/2020 on consent, paras. 158 and 160. Dutch Code of Conduct, chapter 5.

[340] Dutch Code of Conduct, chapter 5.

provide additional consent for sub-research that may have further consequences for him. In the next section 4.2, the explicit consent given by Patient X is discussed.

4.2. Explicit consent as a point of departure in the Dutch Code of Conduct for Health Research

The Dutch Code of Conduct takes the explicit consent of article 6 (1) (a) in conjunction with article 9 (2) (a) GDPR as a point of departure. In drafting the Dutch Code of Conduct, consent in article 7:457 and the exception in article 7:458 WGBO were taken into account. I discuss this in more detail in section 4.3. The adjective 'explicit' in the GDPR relates to the manner in which the data subject's consent is obtained.[341] Applied to the case study, explicit consent means the following. On the one hand, Patient X must actively perform an act that shows his consent. An example is written but also an electronic signature, sending a form in writing and verbal consent are forms of explicit consent. On the other hand, the data controller, for example academic hospital B in the case study, must be able to show for each form of consent that the consent was actually given by X. Hospital B has a duty to inform Patient X. His consent should be given freely and must be specific, informed, and unambiguous.[342] In addition, Patient X should be able to withdraw his consent at any time, in the same way that it was given.[343]

Explicit, informed consent is relevant with regard to data received directly from Patient X or human tissue collected from X. This relates to Patient X's control over the processing of new patient data, such as questionnaires, data for the research subject to the requirements of the WMO, and additional collections of human tissue. In these situations, the collections are not part of the care provided: they relate to the mental or physical integrity of the patient. This is also the case in the event of whole genome sequencing, research with a great likelihood of yielding clinically relevant additional findings, the creation of cell lines from human tissue, purely commercial research, and lastly, research in which data sharing may have considerable consequences for the protection of the patient's data.[344] Where the purpose of the research can only be broadly described and several research methods are used, informed consent may be requested under specific circumstances.[345] This may relate to long-term cohort research (see section 4.3). In that case, explicit consent is requested before the start of

[341] Guidelines 05/2020 on consent, 18.
[342] Recital 42 in conjunction with article 7(1) and 7(3) GDPR. The controller bears a double burden of proof: not only to show that specific consent was granted, and for what it was granted, but also to prove that the consent meets the requirements made thereof. See Parliamentary Papers II 1997/98, 25892, no 3, p. 67 (Explanatory memorandum Wbp). See also the Report of the Dutch DPA of 1 September 2014, *Onderzoek naar de toestemming voor de uitwisseling van medische persoonsgegevens via het Landelijk Schakelpunt (z2012-779)*.
[343] Art. 7 (3) GDPR.
[344] Chapter 5 Dutch Code of Conduct.
[345] Section 5.5 Dutch Code of Conduct (conditions for re-use).

the research, and the patient or ex-patient, participating in the research, is informed as fully as possible during the research. He may also object to the further use of his data in research.

Explicit, separate consent must also be asked from the patient if his data are re-used for different research.[346] The patient then gives separate consent a) for the secondary use of his data for other research and b) to be approached for further (different) research. However, explicit consent cannot be requested in every situation. I discuss this in section 4.3. Applied to the case study, the implications are as follows. For instance, academic hospitals B and C undertake multi-center skin cancer research. The hospitals request the consent of patients that are (or were) treated in the hospital in question. Simply put, the hospital that primarily draws up the research protocol is the data controller: it determines the purpose and the means of research. If the hospital where Patient X is being treated, hospital B, draws up the research protocol, then hospital B is responsible for asking X's consent. If both hospitals determine purpose and means, there is joint responsibility. The data are exchanged using a data sharing agreement or data transfer agreement, whereby the requirements of articles 24, 26, 28, and 32 GDPR must be satisfied with respect to, for example, data minimization, technical and organizational measures, transparency of processing, and the embedding of patients' rights. In the case study, hospitals B and C will agree on which hospital requests the patient's consent to avoid that both hospitals approach Patient X.

If a patient were to die in the meantime, his health data may be re-used for scientific research. His data may not be used if he did not give his consent or if he objected to such secondary use. For human tissues, a distinction is made in the draft Wzl between materials collected during and after the patient's life. For human tissue, explicit consent applies without exception.[347] The further use of human tissue, for instance immortalized cell lines, may result in questions raised within our society if explicit consent has not been obtained. Further rules are provided by governmental decree.[348]

4.3. Consent modalities in the context of re-using health data for scientific research in the Dutch Code of Conduct

If patient health data are re-used for scientific research, the Dutch Code of Conduct follows the provisions in articles 7:457 and 7:458 WGBO as national, sectoral legisla-

[346] Section 5.5 Dutch Code of Conduct (conditions for re-use) and chapter 9 (use and re-use of research data and human tissues for future research).
[347] Parliamentary Papers II, 2020/21, 35844, on 3 (Explanatory memorandum, Regels voor handelingen met lichaamsmateriaal, welke worden verricht voor andere doeleinden dan geneeskundige behandeling of diagnostiek van de donor (Wzl). As noted, the Wzl is subject to another review and round of consultation in the spring of 2024. See also M.C. Ploem & J.C.J. Dute, Wetenschappelijk onderzoek na overlijden: goed geregeld? *TvGR* 40 (2016) (8), 498-512. See in particular art. 6 draft Wzl about the definition of human tissue.
[348] Art. 6 (4) draft Wzl.

tion. The various layers of the legal basis of consent are set out in more detail in the Dutch Code of Conduct pursuant to articles 7:457 (consent) and 7:458 (exception to consent) WGBO. As noted above, consent constitutes the principal standard.[349] A general exception is made for specific care providers, i.e., the data controllers that systematically supply patient data or human tissue for various forms of scientific research.[350] Examples of these are the academic hospitals or the Netherlands Cancer Institute – Antoni van Leeuwenhoek hospital, where, in addition to care, scientific research is also performed. Another example is the provision of personal data for the benefit of quality registration with which scientific research is also carried out. However, the EDPB provides that the scope offered in recital 33 GDPR cannot be interpreted to mean that the obligation regarding the specificity of the consent no longer applies.[351] A solution is the patient's consent to a specific research domain that includes his illness or related medical conditions. Another solution may be the exception offered in article 7:458 WGBO.

In line with this layered structure, the Dutch Code of Conduct thus provides, in addition to the option of consent of article 7:457 WGBO, the option of no objection of article 7:458 WGBO. In addition, article 24 UAVG presents details of article 9 (2) (j) GDPR and, as such, a legal ground for the processing of health data. The controller can provide the personal data if consent cannot reasonably be requested (see article 7:458 (1) (a) WGBO) or if requesting consent cannot reasonably be required (see article 7:458 (1) (b) WGBO). Subsequently, the Dutch Code of Conduct elaborates under what circumstances consent cannot reasonably be requested or requesting consent cannot reasonably be required.[352] The following three cumulative conditions pursuant to article 24 UAVG must be met: a) the research serves a public interest; b) requesting explicit consent proves to be impossible or requires a disproportionate effort; and c) adequate safeguards are provided to prevent disproportionate infringement of the data subject's privacy. Article 7:458 (2) WGBO provides that information may be supplied only if a) the research serves a public interest; b) the research cannot be conducted without the information in question; or c) the patient has not explicitly objected to the information being supplied. It is worth noting that the expression of no objection is not included in article 24 UAVG.

Thus, the care providers mentioned above, the data controllers who systematically provide patient data or human tissue, ask the patient's consent or, alternatively, the patient can voice his objection to the processing of his data for the purpose of scientific research to someone other than the health care professionals directly involved in

[349] Chapter 5 Dutch Code of Conduct.
[350] Section 5.7 Dutch Code of Conduct.
[351] EDPB, Guidelines 05/2020 on consent under Regulation 2016/679, paras 7.2, 35 et seq.
[352] Section 5.4 and 5.5 Dutch Code of Conduct.

his treatment. Although the Dutch Code of Conduct prefers consent, it also includes the option that patients have the choice to voice their objection. In that latter case, care providers that also conduct scientific research will have to show why requesting consent is not feasible. In addition, the consent or the objection voiced by the patient must relate to his illness or related medical conditions, of the patient's illness or treatment demand.[353] The data controller should honor the general duty to provide information and the research must be carried out in the public interest.

In the event that data are re-used in different research than the research for which the patient gave his consent or did not voice his objection, the data controller must investigate whether the patient can be informed about this other research and whether that research is sufficiently in line with the consent granted by him earlier.[354] If this is not the case, the controller must substantiate why requesting consent is impossible or requires disproportionate effort. Nevertheless, the data may be used for different research, if the information about this research is publicly disclosed and is sufficiently in line with participants' expectations based on the information received earlier, about which they gave their consent.

In sum, the Dutch Code of Conduct, while referring to the WGBO, leaves room for a broader, multi-layered consent and a no-objection system in relation to the secondary use of health data for scientific research. However, the research in question should serve the public interest and the controller must offer optimal transparency.[355] The use of patient data should meet the patient's reasonable expectations by having a bearing on his illness or related medical conditions that include the one for which the patient is or was being treated. Lastly, the data controller should honor the principle of privacy by design of article 25 GDPR.

4.4. The relationship between consent in the WGBO, the draft Wzl, the GDPR and the UAVG with respect to the secondary use of health data for scientific research

The next issue regarding the secondary use of health data for scientific research concerns the relationship between consent pursuant to articles 7:457 and 7:458 WGBO, and article 14 draft Wzl, respectively, and consent as a legal ground for processing data in article 6 (1) (a) in conjunction with article 9 (2) (a) GDPR. Firstly, I observe that the WGBO, including articles 7:457 and 7:458 WGBO, entered into force on 1 April 1995. Moreover, the most recent amendment of 2020 did not consider these articles.

[353] Referred to as 'illness or related medical conditions' in the Draft Dutch Code of Conduct.
[354] Chapter 9 Dutch Code of Conduct.
[355] On the interface of public interest, scientific research and the privacy of the individual, see, inter alia, E.M.M. Hoytema van Konijnenburg, A.H. Teeuw & M.C. Ploem, Data research on child abuse and neglect without informed consent? Balancing interests under Dutch law, *European Journal of Pediatrics* 174 (2015) (10), 1573-1578.

The GDPR entered into effect on 25 May 2016, after which a transition period of two years began. On 25 May 2018, the GDPR became applicable. The Dutch legislator adopted a policy-neutral approach in the UAVG regarding provisions that already applied pursuant to the Wbp. Article 24 UAVG, an elaboration of article 9 (2) (j) GDPR, is identical to article 23 (1) (a) and (2) Wbp.

Subsequently, recital 33 GDPR leaves room for a broader form of consent at first sight. However, the EDPB asserts that the scope of granularity of the consent request cannot constitute an unbridled form of consent.[356] Given his broad consent regarding medical-scientific research, whether a patient expresses his autonomy, freedom of choice and self-determination is a question that should be considered from various perspectives, both on the patient side and on that of the data controller.[357] The EDPB notes that the GDPR provides for other legal grounds for processing data for the benefit of scientific research, for example in articles 6 (1) (e) or 6 (1) (f) GDPR.[358]

I would argue that recitals 33 and 50 GDPR in conjunction with articles 5 (1) (b) second sentence and 89 (1) GDPR leave enough room for consent regarding the secondary use of health data for scientific research. Re-using health data for scientific research is consistent with the original purpose, as a result of which no separate legal lawful basis is required. The data subject, the patient in the case study, should be given the opportunity to give his consent for specific research areas or in relation to his illness or related medical conditions. Accordingly, this more general request for consent should be as specific as possible. An example of a more general consent request is the consent patients are asked to give for the secondary use of their health data for scientific research at the Netherlands Cancer Institute – Antoni van Leeuwenhoek hospital, upon their first visit.[359] However, the lawful basis of consent in the GDPR leaves no room for merely a no-objection system, whereby patients are informed and, subsequently, may voice their objection. In that respect, a different legal ground for processing data pursuant to the GDPR, such as the public interest in conjunction with article 89 (1) GDPR, would be more apt. I also suggest a further elaboration in

[356] EDPB, Guidelines on consent, par. 11. See also EDPB: Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, par. 25, 2 February 2021.
[357] C. Ploem et al., Privacywetgeving en wetenschappelijk onderzoek, *Huisarts en wetenschap* (2020) (2), 3-4, henw.org/articles/privacywetgeving-en-wetenschappelijk-onderzoek. See also D. Hallinan, Broad consent under the GDPR: an optimistic perspective on a bright future, *Life Sciences, Society and Policy* 16 (2020) (1), 1-18.
[358] Recital 154, Guidelines on consent, 35.
[359] *AVL vraagt patieënt expliciet toestemming voor wetenschappelijk onderzoek/Gegevensuitwisseling/Gegevensuitwisseling in de zorg*. Also R. Stüssgen et al., *Zorggegevens voor onderzoek: bezwaar of toestemming? De wet en de praktijk* (Utrecht: Nivel 2019). Also avl.nl/onsonderzoek-het-nederlands-kankerinstituut/toestemming-wetenschappelijk-onderzoek/.

sectoral legislation of another lawful basis included in the GDPR, in conjunction with article 24 UAVG.[360]

Furthermore, the Dutch health legislation leaves room for a no-objection system, if the conditions of proper information provision, transparency, and respect for patients' rights are satisfied.[361] The applicable legislation in this case comprises the WGBO, the draft Wzl, and the policy-neutral interpretation of article 24 UAVG, whereby the parameters of article 89 (1) GDPR are honored. I also refer to article 44 UAVG, in which exceptions in the rights of data subjects are mentioned that apply if processing takes place for scientific or statistical purposes. The Dutch legislator has chosen the standard of the WGBO in conjunction with article 24 UAVG for the provision of patient data for health research.[362] Hence, good public information, transparency, governance, and accountability of the data controller are essential components in a system of consent, and in some situations a no-objection system whereby the patient is transparently and fully informed.[363] On the one hand, consent is the point of departure (see article 7:457 WGBO and article 14 draft Wzl); on the other, there is the option to derogate from this (see article 7:458 WGBO, article 15 draft Wzl in conjunction with article 24 UAVG).[364] It is essential that the patient be informed in a suitable fashion and in comprehensible language. In addition, he must have the option at any time to withdraw his consent or voice his objection.[365] Patients are informed with a patient information leaflet (PIL), information on the internet about the research in question, and videos shown at the hospital, for example. The patient may withdraw his consent or raise an objection at any time. From the moment he does, his data will no longer be used for research.

[360] Inbreng op wetsvoorstel Wet zeggenschap lichaamsmateriaal by FMS, NFU, COREON, Health-RI of 24 September 2021, coreon.org/zorgen-juridisch-kader-gebruik-lichaamsmateriaal-wzl/. See also the technical briefing on the Wzl of 29 September 2021, in which the sectoral legislation was discussed: tweedekamer.nl/debat_en_vergadering/commissievergaderingen/details?id=2021A05976.

[361] E. Vermeulen et al., Opt-out plus, the patients' choice: preferences of cancer patients concerning information and consent regimen for future research with biological samples archived in the context of treatment, *Journal of Clinical Pathology* 62 (2009) (3), 275-278. See also M.C. Ploem et al., Privacywetgeving en wetenschappelijk onderzoek, *Huisarts en wetenschap* 63 (2020) (2), 30-32. M.C. Ploem, T. Rigter & J.K.M. Gevers, Medisch data-onderzoek in het AVG-tijdperk: een zoektocht naar de juiste regels. *Tijdschrift voor Gezndheidsrecht* (2020) (2), 162-181.

[362] Parliamentary Papers II 2017/18, 34851, no 3, 91-92.

[363] Letter of the Minister of Health, Welfare and Sport to the Dutch House of Representatives dated 8 January 2019 (reference 1457289-185057-PG), 8. See also the letter of BBMRI-NL and Coreon to the Minister of Health, Welfare and Sport of 23 June 2017 (response to internet consultation on draft Wzl).

[364] Art. 24 (b) UAVG, 7:458(2)(a) WGBO. See also Letter to the House of Representatives of the Minister for Health, Welfare and Sports in re response to the secondary use of data, 4 October 2019, rijksoverheid.nl/documenten/kamerstukken/2019/10/04/kamerbrief-over-reactie-artikel-fdoversecundair-gebruik-data. Also J. Gerritsen. & P. Verhoef, *Datasolidariteit voor gezondheid – Verbeterpunten met oog voor ieders belang* (The Hague: Rathenau Institute, 2020).

[365] E. S. Dove, The EU General Data Protection Regulation: Implications for International Scientific Research in the Digital Era, *Journal of Law, Medicine & Ethics* 46 (2018), 1013-1030. See also WMA Declaration of Helsinki, Brazil, 2013, section 32.

In my view, this combination of consent and a no-objection system evidences a veritable balancing act. On the one hand, the Dutch Code of Conduct walks the tightrope of consent pursuant to the GDPR and the UAVG. On the other, it dances to the tune of the exceptions pursuant to the WGBO, the draft Wzl, and the UAVG. Therefore, I welcome a further exploration of other possible legal grounds for the secondary use of health data for scientific research. Comparative surveys in the member states of the European Union show that different legal grounds for health research are honored in some member states.[366] Thus, the lawful bases of the public interest and legitimate interests, as laid down in article 6 (1) (e) or (f) together with article 9 (2) (j) and article 89 (1) GDPR merit further attention, as mentioned in section 3.2.1 above. Chapter 5 will elaborate on the developments in the UK as regards the lawful bases of the public interest and legitimate interests as well. Furthermore, I encourage an exploration of unanimous sectoral legislation on this matter to enhance health research in the interest of public health and health research.[367]

4.5. Four other exceptions to the lawful basis of consent in the Dutch Code of Conduct

In addition to the exceptions that apply for the secondary use of health data for scientific research, the Dutch Code of Conduct includes four other exceptions to consent as a legal ground for processing data, which I briefly mention here. These exceptions are part of Dutch legislation. Firstly, there is the controller's legal duty. If the controller has a legal duty to provide personal data for the benefit of scientific research or statistics, e.g., pursuant to the Dutch Public Health Act (*Wet publieke gezondheid*, hereinafter Wpg), the lawful basis of consent does not apply. For instance, a physician is obliged, pursuant to the Wpg, to notify the Dutch municipal health service (*Gemeentelijke Gezondheidsdienst*, hereinafter GGD) of an infectious disease.

Secondly, in an emergency, it may not be possible either to request consent from the patient for, or for the patient to voice his objection to, the processing of his data. The request for consent or the confirmation of no objection by the patient will have to be made at a later stage in such a case. However, for research regarding a patient's physical integrity, or where considerable consequences will ensue relating to the protection of the participant's data, explicit consent must always be requested. Applied to the case study of Patient X, this may have the following effects. Let us imagine that Patient X goes into cardiac arrest during surgery, after which further research is immediately

[366] European Commission, Assessment of the EU Member States' rules on health data in the light of GDPR, including the Annex with country fiches of all EU MS. Specific Contract No SC 2019 70 02 in the context of the Single Framework Contract Chafea/2018/Health/03.

[367] T. Hooghiemstra & M. Lokin, Persoonsgegevens zijn niet altijd taboe in medisch onderzoek, *NRC*, 11 May 2021. Also, the contribution by the Royal Dutch Medical Association (KNMG) of 8 October 2021 with regard to the draft Wzl: knmg.nl/advies-richtlijnen/actualiteit-opinie/nieuws/nieuwsbericht/inbreng-knmg-wetzeggenschap-lichaamsmateriaal.htm.

carried out. If Patient X is not responsive, he cannot give his consent – but even if he is more or less responsive, his consent will not have been freely given. In this situation, X's postponed consent can be used.[368]

Thirdly, consent need not be requested from the next of kin unless there is a situation in which the explicit consent of the (deceased) participant had to be asked each time. This applies for the secondary use of human tissue that might cause societal unrest. Fourthly, pursuant to the GDPR, the patient does not have to give his consent if the data are supplied anonymously. The GDPR does not apply to anonymous data, although the processing of pseudonymized data is considered processing of personal data in the GDPR.[369]

4.6. Conclusion

This chapter answered sub-question 3 that reads as follows:

> *In what way does the lawful basis of consent serve as a proper legitimation for re-using health data for scientific research and in what way may other lawful bases legitimize this use?*

The Dutch Code of Conduct provides for a layered structure of consent: explicit, specific consent, explicit, general (broad) consent and the exceptions to the lawful basis of consent as included in article 7:458 WGBO and article 24 UAVG. The latter provisions include a no-objection system. Where (explicit) consent pursuant to the GDPR may not provide for a solution for data sharing in secondary health research, then the WGBO provides for a solution in the two exceptions of article 7:458 (1) WGBO.

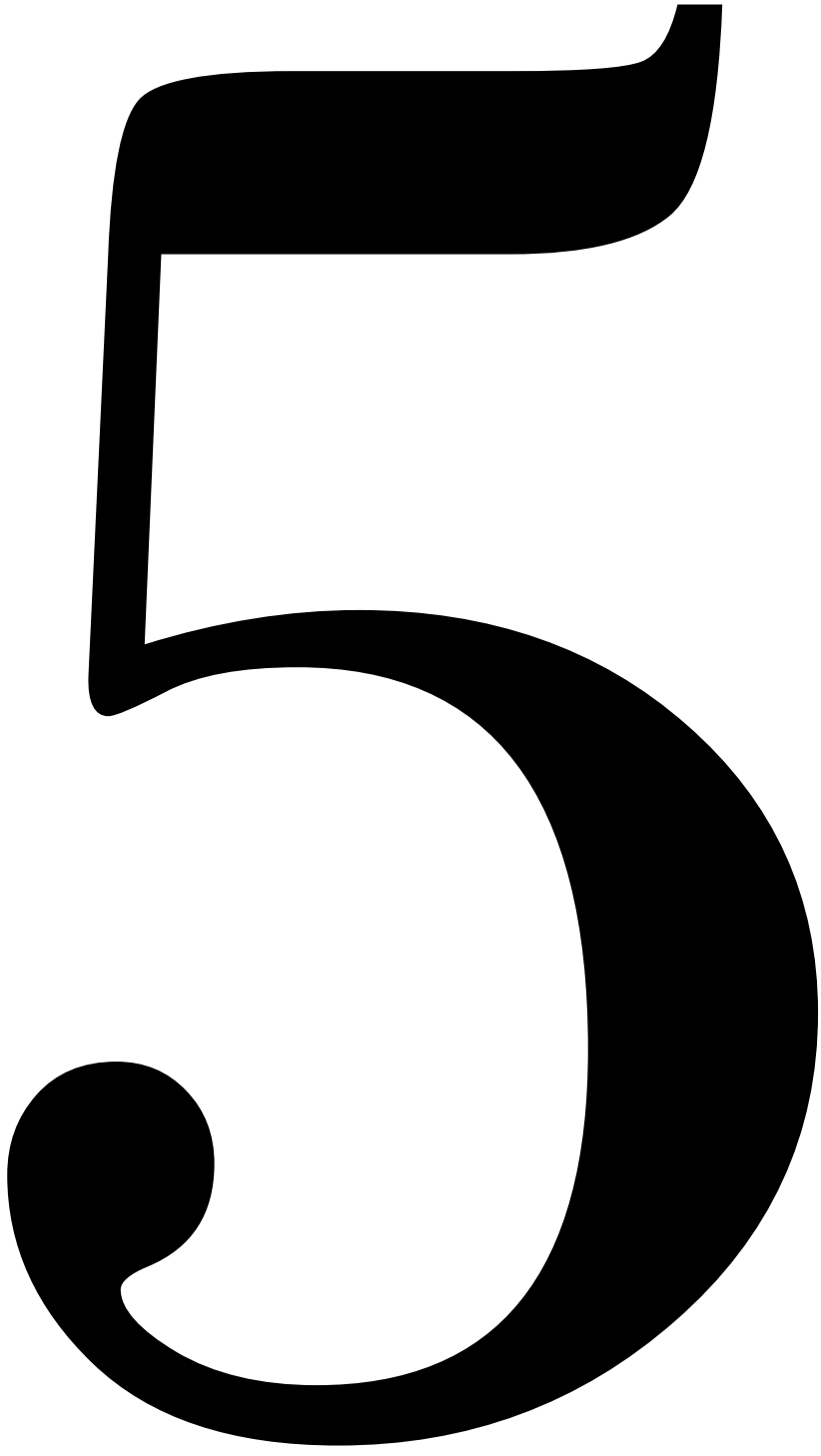
In the first situation, requesting consent is not reasonably possible and the research does not disproportionately prejudice the patient's privacy. In the second, requesting consent cannot reasonably be required, and the physician will prevent in all reasonableness that the personal data are identifiable to individual patients. However, the conditions of article 7:458 (2) and (3) WGBO should be observed. Article 17 Wzl includes similar exceptions as included in the WGBO to the consent for using human tissue. Article 24 UAVG further details the lifting of the prohibition on the processing of special personal data pursuant to article 9 (2) (j) GDPR.

The following can be concluded about the lawful bases to the secondary use of health data. Firstly, a different legal ground for scientific research in the GDPR could ap-

[368] Draft Dutch Code of Conduct, legal substantiation, 20.
[369] Recitals 26, 28, 29, and 156 GDPR and articles 4 (5), 11, 25 (1), 32 (1), and 89 (1) GDPR.

ply, such as the lawful basis of the public interest.[370] I consider that article 24 in conjunction with 44 UAVG may offer appropriate details. Secondly, the Dutch Code of Conduct consists of a detailed connective legislative web that incorporates elements from the UAVG, the WGBO, the WMO, and the draft Wzl. The Code balances between safeguarding the patient's personal data and his rights as a data subject on the one hand, and furthering health research, on the other. I support any voices from the field that call for sectoral legislation in this area, which would embody that connective web into an act. Lastly, it is questionable whether the intended transition and solution for situations in practice has been achieved with the self-regulation in the Dutch Code of Conduct.

[370] Art. 6 (1) (e) in conjunction with art. 9 (2) (i) (j) GDPR. See also art. 5 (1) (b) and art. 89 (1) GDPR.



Proposal for a new data regime in the UK: an avenue to be explored by the EU

5. Proposal for a new data regime in the UK: an avenue to be explored by the EU[371]

This chapter answers sub-question 4 that reads as follows:

In what way do the developments in the United Kingdom serve as an avenue to be explored in the European Union with regard to the further use of health data for secondary health research?

[371] I.R. Kist, Proposal for a new data regime in the UK: an avenue to be explored by the EU, *European Data Protection Law Review* 8 (2022) (2), 295-301. DOI https://doi.org/10.21552/edpl/2022/2/18.

5.1. Introduction

When the UK formally left the European Union on 31 December 2020 at 11 PM after a transition period of one year, the GDPR was retained in domestic UK law as the UK GDPR. However, the UK is at liberty to keep the framework under review. The UK GDPR applies alongside an amended version of the Data Protection Act (DPA) 2018.[372] Thus, the main principles, rights and obligations have remained the same even after the beginning of 2021. At present, however, the so-called retained EU law, which includes the UK GDPR, may undergo significant amendment. In its document *Data: a new direction*, published by the Department for Digital, Culture, Media & Sport (DCMS) on 10 September 2021, the UK set off on a new and different path from the EU.[373] The primary aim is to reduce regulatory burdens and to lessen the resources required for compliance. A parallel development has been the UK's National Data Strategy, announced in June 2018 by the Secretary of State for the Department for Digital, Culture, Media & Sport (DCMS), which aims at unlocking the power of data across the government and wider economy. This strategy also aims at building citizen trust in the data ecosystem and at supporting the UK towards a world-leading data economy. Furthermore, on 31 January 2022, the UK government announced the 'Brexit Freedoms Bill'.[374] The Bill was included in the Queen's Speech in May 2022 and received Royal Assent on 29 June 2023 following agreement of both Houses in Parliament.[375] Two other bills were also announced in the Queen's Speech, i.e., the Data Reform Bill and the Bill of Rights.[376] The legislative developments in the UK could have implications for the free flow of data from the EU to the UK.[377]

[372] The UK GDPR means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018. https://www.legislation.gov.uk/ukdsi/2019/9780111177594/pdfs/ukdsi_9780111177594_en.pdf. Data Protection Act, https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted. Accessed 6 June 2022.

[373] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1022315/Data_Reform_Consultation_Document__Accessible_.pdf. Accessed 6 June 2022. Also, House of Commons, European Scrutiny Committee, Oral evidence: Retained EU Law: Where next? HC 1113, 9 February 2022. And UK Government, *National Data Strategy*, updated 9 December 2020, Department for Digital, Culture, Media & Sport, https://www.gov.uk/government/publications/uk-national-data-strategy/national-data-strategy. Accessed 6 June 2022.

[374] The Brexit Freedoms Bill is part of the European Union (Withdrawal Agreement) Act 2020, https://www.legislation.gov.uk/ukpga/2020/1/contents. Accessed 6 June 2022.

[375] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1074113/Lobby_Pack_10_May_2022.pdf. Accessed 6 June 2022. Also, https://www.parliament.uk/business/news/2023/february-2023/lords-debates-retained-eu-law-revocation-and-reform-bill/. Accessed 22 January 2024.

[376] In the meantime, the UK government introduced the Data Protection & Digital Information Bill (No. 2) on 8 March 2023. This Bill withdrew the Data Protection the Data Protection & Digital Information Bill that was introduced in June 2022. https://bills.parliament.uk/bills/3430/. Accessed 22 January 2024. The Bill of Rights was withdrawn on 27 June 2023. https://bills.parliament.uk/bills/3227. Accessed 22 January 2024.

[377] Responses to the consultation: UK Government, Data: a new direction, https://www.gov.uk/government/consultations/data-a-new-direction. Accessed 7 June 2022.

This chapter addresses the proposed changes to data protection law in the UK and the UK National Data Strategy.[378] It focuses particularly on the proposed changes for scientific research. Thus, this analysis does not include all amendments as proposed. The chapter starts with an outline of the limitations and deficiencies to scientific research in the UK GDPR (section 5.2). Next, it elaborates on the proposed amendment (section 5.3). An argument will be made that the amendment is an avenue to be explored by the EU with its potential benefits for scientific research. The chapter then elaborates on potential risks to the data protection landscape and the data subject. Subsequently, the implementation of the GDPR in the Netherlands with regard to scientific research will be used as an example (section 5.4). The latest EU developments will be briefly referred to as well, before ending with a conclusion (section 5.5).

5.2. UK GDPR – Limitations and deficiencies of scientific research

5.2.1. Barriers to responsible innovation and data flows

The interpretation of the law, as well as general definitions in the law without explanatory case law (yet) or regulatory guidance, have resulted in the full capacity of data sharing not always being used. Furthermore, the elaborations on the lawful basis for the re-use or secondary use of research data have resulted in an over-reliance on asking consent from individuals. Seeking (additional) consent may hamper the efficiency of research and may place a burden on the individual, i.e., the data subject. Additionally, increasing technological innovations, including the use of artificial intelligence and the vast amount of data require clearance about this use with consistent rules. Moreover, the UK GDPR includes both the recitals and the articles of the law. However, some recitals related to scientific research have not been adopted in the plain text of the UK GDPR. Hence, the relevant clauses on international data transfers, in particular as regards adequacy regulations (article 45 UK GDPR), appropriate safeguards (article 46 UK GDPR), and derogations (article 49 UK GDPR), place restrictions on these transfers, and, consequently, on international, multi-center research.[379]

5.2.2. Barriers to scientific research

In addition to these barriers to responsible innovation and data flows, there are specific barriers to scientific research. The recitals and provisions on scientific research are dispersed across the UK GDPR and the Data Protection Act 2018, whereas the content of the recitals is not always incorporated into the plain text of the UK GDPR. As a result, researchers are unaware of which legal obligations they must fulfill and whether exemptions to the general rules apply to their research. Guidance by the Information Commissioner's Office (ICO) alone will not suffice to solve the uncertainty and

[378] Policy paper, updated 9 December 2020, https://www.gov.uk/government/publications/uk-national-data-strategy. Accessed 6 June 2022.
[379] P. Breitbarth, A risk-based approach to international data transfers, *European Data Protection Law Review* 4 (2021), 540-549.

ambiguity in the law.[380] Thus, legal reform is necessary in this respect. Furthermore, an additional, separate lawful basis for research, or clarity about the use of the lawful bases of the public interest or legitimate interests, may prove useful to organizations that undertake scientific research.

Additionally, the further processing of personal data, i.e., re-using the data for another research purpose, has been subject to lively debate.[381] Article 5 (1) (b) UK GDPR states that further processing of personal data for scientific or historical research purposes shall not be considered incompatible with the initial purposes, provided that the necessary safeguards are in place.[382] Moreover, although the broader conditions for determining compatibility of the purposes for further processing are enshrined in article 6 (4) UK GDPR, it cannot be deduced from this clause when personal data may be re-used for another purpose than that for which they were collected in the first place. Secondly, it is unclear whether personal data may be re-used by a different controller than the original controller that collected the data in the first place, and whether this collection by the second controller constitutes further processing. Thirdly, the question arises whether the further processing is subject to a new determination of the lawful basis, both in cases where the further processing is either compatible or incompatible with the original purpose as referred to in article 5 (1) (b) together with article 6 (4) UK GDPR.

There is lively debate surrounding the concept of broad consent.[383] While it has been acknowledged that an individual gives his consent for broad(-er) areas of scientific research, the scope of consent is subject to discussion. A second issue concerns the reconciliation of the concept of broad consent with the elements of valid consent as defined in article 4 (11) UK GDPR, i.e., that the consent must be freely given, specific, fully informed, and unambiguous. The question arises what constitutes 'broad' in broad consent. Furthermore, the lawful bases of the public interest and legitimate interests have yet to be fully explored as regards scientific research (as well as other domains where personal data are processed).

Artificial intelligence (AI) and machine learning have become important components of scientific research.[384] The use of data in this field requires that specific attention be

[380] https://ico.org.uk/for-organisations/dp-at-the-end-of-the-transition-period/data-protection-and-the-eu-in-detail/. Accessed 6 June 2022.
[381] European Data Protection Supervisor, A Preliminary Opinion on data protection and scientific research, 6 January 2020, https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf. Accessed 6 June 2022.
[382] Recital 50 GDPR. The GDPR is saved into UK law through section 3 of the European Union (Withdrawal) Act 2018 ("EUWA"). This includes the recitals to the GDPR.
[383] E. Gefenas et al., Controversies between regulations of research ethics and protection of personal data: informed consent at a cross-road, *Medicine, Health Care and Philosophy* (2022) (25), 23-30 https://doi.org/10.1007/s11019-021-10060-1.
[384] UK Government, *National AI Strategy*, https://www.gov.uk/government/publications/national-ai-strategy, published on 22 September 2021. Accessed 7 June 2022.

paid to its collection, curation, storage, and removal. The UK GDPR and the Data Protection Act 2018 are technology-neutral, although the UK GDPR distinguishes between the use of data for research and non-research purposes. The fact that the data protection framework does not distinguish between the different uses of data within an AI process may result in uncertainty about the lawful basis and the purpose(s) of data processing. Furthermore, a distinction is necessary in the various phases of an AI process, from development to deployment. Additionally, clarification is required about the circumstances surrounding when personal data will be regarded as anonymous. Since the UK GDPR only applies to personal data that can be re-identified, directly or indirectly, this determination is important to delineate the applicable law to data processing.

5.2.3. Rule-based regulatory compliance

Although one of the main principles as set out in article 5 UK GDPR concerns the accountability of the controller, a rule-based system of regulatory compliance has been established. This system, together with a specific number of requirements that organizations must fulfill to demonstrate compliance, places an unnecessary burden on organizations as well as data subjects, since energy is devoted to demonstrating compliance rather than to developing better practices and, thus, protecting the personal data and data subject's rights. For instance, article 30 UK GDPR requires a record of processing activities by the organization and article 35 UK GDPR requires a Data Protection Impact Assessment (DPIA) in case of processing personal data which is likely to result in a high risk to individuals. Furthermore, article 36 UK GDPR requires prior consultation in case an organization has identified a high risk for data processing that cannot be mitigated, and articles 37 to 39 UK GDPR require the appointment of a data protection officer. Furthermore, articles 33 and 34 UK GDPR set out the rules for reporting a data breach. Only those breaches where a risk to individuals is not material are exempted from notification. However, the scope of a non-material breach remains unclear. All clauses referred to above fall within a system of rule-based regulatory compliance, rather than a risk-based approach.

5.3. Proposal for a UK GDPR amendment

5.3.1. Reducing barriers to responsible innovation and data flows

The UK government realizes that AI technology, big data research, and machine learning are of prime importance to innovations. At the same time, these innovations require a robust approach to data protection. The government proposes a further dialogue on the scope of transparency and fairness as regards data processing to these ends, where a balance can be found among these innovations as well as in responsible and trustworthy AI developments. For instance, data processing may be necessary in order to detect biases and to mitigate risks. If this data processing is subject to

the explicit consent from the data subjects, the AI application may not represent a complete data population. Thus, the AI application itself may become biased. The government proposes that this processing constitutes a legitimate interest pursuant to article 6 (1) (f) UK GDPR, so that the AI system can monitor, detect, and correct biases. The government proposes particular attention to be drawn to the use of sensitive data in this respect, i.e., regarding the purpose for which the data are collected and the appropriate safeguards that are in place to mitigate the risks of secondary use. The government aims at furthering public trust in data collection for innovation.

Thus, the government proposes further clarity on data minimization, such as pseudonymization, and a clear distinction between anonymized and pseudonymized data. Whereas pseudonymized data fall within the scope of the UK GDPR, anonymized data do not. The government proposes a relative approach in this respect.[385] Furthermore, the government proposes a risk-based approach to adequacy regulations in international data flows. Additionally, in case an adequacy decision has not been given, the government proposes alternative transfer mechanisms where the data subject's rights are respected. The government intends to facilitate more detailed, practical support in determining and addressing risks with regard to these transfers. One of these alternative transfer mechanisms includes the certification scheme and the government proposes a common, inter-operable approach based on the principles of accountability. Lastly, the government proposes that the derogations enunciated in article 49 UK GDPR be invoked in case of repetitive data transfers as well.

5.3.2. Reducing barriers to scientific research

The UK government proposes that research-specific provisions be consolidated and concentrated to clarify the large amount of provisions and their correlations. In this respect, a definition of scientific research is desired in the provisions of the UK GDPR, rather than an explanation in recital 159 UK GDPR. As regards the lawful basis or bases of scientific research, the government considers the following. First, the lawful basis of the public interest (article 6 (1) (e) UK GDPR) could be another lawful basis to be relied upon by university research projects, in addition to the lawful basis of consent. Second, a separate lawful basis for scientific research could reduce the burden for organizations seeking a proper lawful basis for their research, if the safeguards as enshrined in article 89 (1) UK GDPR be adhered to at all times.

Next, as regards the re-use or further processing of personal data for a purpose other than the original collection of data, the government proposes to clarify the concept of (broad) consent, as well as offer a clarification on article 5 (1) (b) of the UK GDPR

[385] Judgment of the Court (Second Chamber) of 19 October 2016, Patrick Breyer v Bundesrepublik Deutschland. Case C-582/14. ECLI:EU:C:2016:779.

on the compatibility of the further use of data for research purposes. In concrete terms, the government proposes that the further use of data for scientific research is always compatible with the original purpose, and that it is always lawful pursuant to article 6 (1) of the UK GDPR. In this respect, the government reiterates the necessity of transparency to the data subjects whose data are used, and the technical and organizational measures to be taken by the controller in order to guarantee the data subject's rights and freedoms.

As regards the re-use of data for a purpose different from that for which they were collected, the government proposes that the further processing for an incompatible purpose may be allowed when the processing safeguards an important public interest. To this end, the government proposes a clarification on article 6 (4) of the UK GDPR. Similarly, the government proposes clarity on the further processing by a different controller. At present, controllers are uncertain whether they can do so lawfully, while ensuring fairness and transparency. Additionally, a similar uncertainty exists regarding the lawful basis of the further processing. For example, if the new purposes for processing are incompatible with the original purpose, controllers question whether the further processing can be permitted. The government proposes that the further processing indeed be permitted, whether it be incompatible or compatible with the original purpose, if the further processing be based on a law that safeguards an important public interest.

With respect to the lawful bases of data processing, the government concludes that the lack of clarity and certainty regarding the use of the different lawful bases in article 6 UK GDPR may have resulted in an over-reliance on the lawful basis of consent pursuant to article 6 (1) (a) UK GDPR, and far less reliance on the lawful basis of the legitimate interests pursuant to article 6 (1) (f) UK GDPR. To this end, the government refers to the Data Protection Act 2018, which includes an exhaustive list of legitimate interests relating to which consent from the data subjects need not be asked.

5.3.3. Risk-based regulatory compliance

The government proposes a more flexible and risk-based accountability framework, based on privacy management programs implemented by the organizations themselves and on the scope of the data processing activities. Furthermore, the government proposes that specific legal requirements in the current UK GDPR be removed, as referred to in sections 5.3.1 and 5.3.2 above. Examples are the register of data processing activities, the requirement of a data protection officer, the data protection impact assessment, and the prior consultation with the Information Commissioner's Office. To this end, the government enhances tailor-made approaches by the organizations

in their specific circumstances with the common aim of identifying, mitigating, and minimizing privacy risks of data processing. As regards data breaches, the government proposes that only those data breaches be reported that are likely to result in a risk to the rights and freedoms of the data subject. In short, the government proposes a proactive approach from the organizations to demonstrate accountability and transparency while the burden of demonstrating compliance is reduced at the same time.

5.3.4. Analysis: the UK's changes to the retained EU law

The foregoing seems to suggest that the proposed reforms benefit data sharing in the pursuit of scientific research.[386] However, in my view a few points merit consideration. First, if the UK government significantly alters, and partly removes, retained EU law through the Brexit Freedoms Bill and the Data Reform Bill, the question arises how the new UK legislation will relate to the GDPR. A deviation from the EU's data protection regime may have an impact on the UK to maintain EU adequacy. I applaud the desire for innovation, scientific research as well as clarity in the data protection legal landscape and, hence, data sharing. At the same time, these changes might erode the UK's data protection regime overall and the data subject's rights in particular. The Information Commissioner's Office, in its response to the DCMS Consultation,[387] argued that "innovation is enabled, not threatened, by high data protection standards."[388] Furthermore, new legislation could result in a further divergence between the UK and EU GDPR. The free flow of data, both within the EU and between the EU and the UK, serves as an engine for economic growth. Both the EU and the UK have an interest in the free flow of data and, therefore, the UK's adequacy remains pivotal. A balance must be found between the data protection landscape vis-à-vis the free flow of data to further scientific research and innovations.

5.4. Potential benefits of the UK GDPR amendment for scientific research: the example of the Netherlands

I would argue that the holy grail of the UK GDPR amendment can be found in the risk-based approach as a guiding principle throughout the proposal, together with the attention given to accountability, transparency, and trust. This approach would also benefit scientific research in the Netherlands, a data-intensive economy where both national and international collaboration are prerequisites for enhancing scientific research. Thus, the proposed changes referred to above with regard to international data flows, a clarification on pseudonymization and anonymization, a broader use of

[386] UK Government, The benefits of Brexit, https://www.gov.uk/government/publications/the-benefits-of-brexit. Accessed 7 June 2022.
[387] Department for Digital, Culture, Media and Sport.
[388] Information Commissioner's Office, Response to DCMS consultation "Data: a new direction", 06 October 2021. https://ico.org.uk/media/about-the-ico/consultation-responses/4018588/dcms-consultation-response-20211006.pdf. Accessed 7 June 2022.

other lawful bases in addition to the lawful basis of consent, a solid AI strategy, and risk-based regulatory compliance, will prove useful for the organizations that process personal data as well as for the data subjects whose data must be protected.

The UAVG is policy-neutral.[389] The provisions pursuant to the previous Dutch Data Protection Act (*Wet bescherming persoonsgegevens,* hereinafter: Wbp)[390] have been incorporated into the new legislation, as far as they are compatible with the GDPR. The UAVG is currently under revision.[391] The GDPR is technology-neutral, while new developments progress rapidly. For instance, the COVID-19 pandemic has shown the necessity once again for international, multi-center data sharing to foster scientific research and to combat life-threatening diseases. A new light shed on the GDPR and the UAVG may increase efficiency in data sharing, whereas the data subjects and their data are equally protected. Furthermore, risk-based regulatory compliance will yield similar results in the Netherlands, as described above in the UK. It will enhance efficacy and efficiency in organizations that process personal data.

In the meantime, new developments are taking place in Europe. The European strategy for data includes new European legislation. On 25 November 2020, the European Commission published a proposal for a regulation on data governance.[392] The Data Governance Act (DGA) entered into force on 23 June 2022 and became fully applicable in the EU on 24 September 2023, following a transitional period of 15 months. The EU aims to create a single European market for data to guarantee the free flow, share, and re-use for the benefit of individuals, researchers, corporate entities, and public administrations. The Data Governance Act creates the processes and structures to facilitate data use.

The Data Act also clarifies who can create value from data and under what conditions.[393] The Data Act entered into force on 11 January 2024.[394] On 3 May 2022, the European Commission presented a proposal for a regulation on the European

[389] Enacted on 16 May 2018, https://wetten.overheid.nl/BWBR0040940/2021-07-01. On this, cf. Paul Breitbarth, GDPR Implementation Series Netherlands: The UAVG (2018) 4(3) EDPL 360-365.
[390] Enacted on 6 July 2000, https://wetten.overheid.nl/BWBR0011468/2018-05-01. Replaced by the GDPR on 25 May 2018.
[391] Tweede Kamer (Lower House of Dutch Parliament), vergaderjaar (year of session) 2019–2020, 32 761, nr. 164. https://www.tweedekamer.nl/kamerstukken/brieven_regering/detail?id=2020Z10112&did=2020D21909. Accessed 6 June 2022.
[392] Proposal for a Regulation of the European Parliament and of the Council on European data governance (Data Governance Act, DGA), COM/2020/767 Final, 25 November 2020.
[393] Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act), COM (2022) 68 Final Brussels, 23 February 2022.
[394] https://digital-strategy.ec.europa.eu/en/news/european-data-act-enters-force-putting-place-new-rules-fair-and-innovative-data-economy. Accessed 22 January 2024.

Health Data Space.[395] The EHDS is one of nine European data spaces identified in the European Commission's 2020 European Strategy for Data. It builds on the Data Governance Act and the Data Act. These acts are horizontal in nature, while the EHDS Regulation includes specific sectoral measures in the area of health, both as regards the use of data for health care (primary use) and the re-use of health data (secondary use). These deliverables aim to regulate both the free flow and use of data and to expand the rights of citizens to access and portability of health data. In that view, the EU developments are promising. Yet, the proposals do not address specific questions about the use of data for scientific research. The European Commission raised these questions at an earlier stage.[396] The UK government addresses these particular questions in more detail.

5.5. Conclusion

This chapter answered sub-question 4 that reads as follows:

> *In what way do the developments in the United Kingdom serve as an avenue to be explored in the European Union with regard to the further use of health data for secondary health research?*

The proposals by the UK government are a good starting point for a further elaboration in the EU in general and the Netherlands in particular for the following four reasons. Firstly, the risk-based approach has been included throughout the proposal, together with the attention drawn to accountability, transparency and trust granted by the data controller as regards data sharing.

Secondly, the lawful basis of the public interest (article 6 (1) (e) UK GDPR) could be another lawful basis to be relied upon by university research projects. Additionally, a separate lawful basis for scientific research, together with the safeguards of article 89 (1) UK GDPR, could reduce the burden for organizations seeking a proper lawful basis for their research. The use of the lawful basis of the public interest or a separate legal ground for scientific research may solve the predominant focus on the legal ground of consent. As regards the lawful basis of consent, the concept of (broad) consent is further clarified. Furthermore, the further use of data for scientific research

[395] European Health Data Space Regulation, Proposal for a regulation - The European Health Data Space (europa.eu). Accessed 9 May 2022. https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en#governance-of-the-european-health-data-space. Accessed 13 April 2022. Legislative train schedule on https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-european-health-data-space. Accessed 13 April 2022. A Commission's presentation for the European Public Service Union of 3 February 2022: https://www.epsu.org/sites/default/files/article/files/EHDS%20presentation.pdf. Accessed 13 April 2022. Hereinafter EHDS.

[396] European Data Protection Board, Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research. Adopted on 2 February 2021, https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf. Accessed 7 April 2022.

is considered compatible with the original purpose. To this end, transparency to the data subjects and measures taken by the controller are of importance.

Thirdly, the further processing for an incompatible purpose could be allowed if the processing safeguards an important public interest. Article 6 (4) UK GDPR merits further clarification to this end. Thus, the further processing may be permitted, whether it be incompatible or compatible with the original purpose if the further processing were based on a law that safeguards an important public interest. The UK government concludes that the lack of clarity and certainty regarding the use of the different lawful bases in article 6 UK GDPR may have resulted in an over-reliance on the lawful basis of consent pursuant to article 6 (1) (a) UK GDPR, and far less reliance on the lawful basis of the legitimate interests pursuant to article 6 (1) (f) UK GDPR.

Fourthly, a risk-based approach to international data transfers will facilitate international data sharing. Adequacy decisions are one way to enable international data sharing. Alternative transfer mechanisms where the data subject's rights are respected could be of value as well. One of these alternative transfer mechanisms includes a certification scheme, based on the principle of accountability on behalf of the data controller. Furthermore, the derogations enunciated in article 49 UK GDPR should be invoked in case of repetitive data transfers as well.

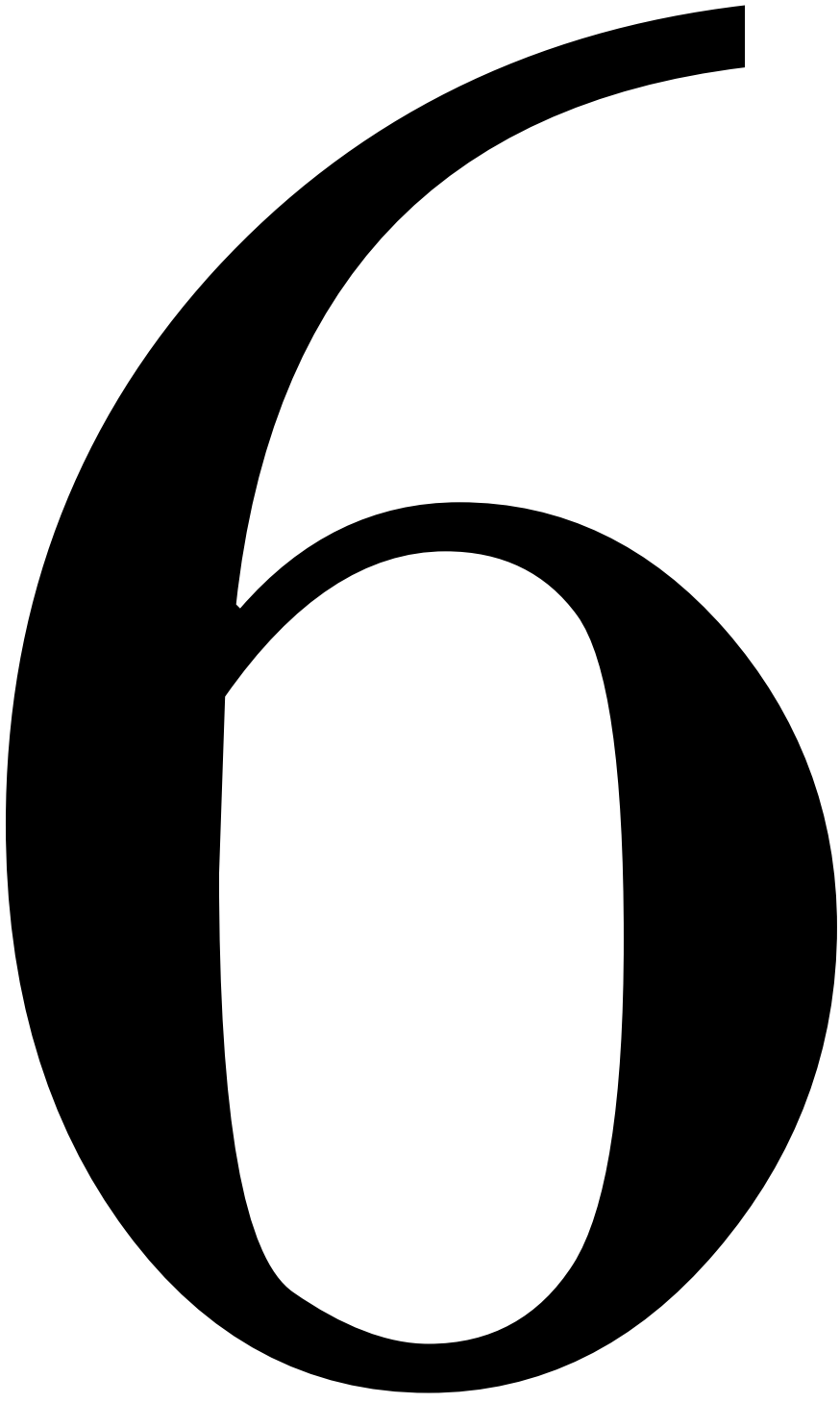
However, the proposals also leave room for further discussion. For example, the proposals refer to the processing when "it safeguards an important public interest." Further elaboration on what constitutes "an important public interest" is desirable. Similarly, the proposal refers to processing "in the substantial public interest" in the case of sensitive personal data. A complete overview of those data that may be processed "in the substantial public interest" has not yet been finalized.

Secondly, the proposals for international transfer mechanisms, other than those based on an adequacy decision raise further questions. For example, one of the approaches includes the empowerment of organizations to create their own transfer mechanism. The UK follows the data protection regime of New Zealand in this respect, and it raises questions about the minimum criteria to be met as well as the boundaries to this flexibility. One must bear in mind, however, that new approaches may have an impact on the UK's adequacy status itself. A further analysis on the free flow of data on the one hand, and safeguarding the interests of the data subjects on the other, is needed.

Thirdly, as regards the lawful bases for processing, the UK government proposes that the lawful bases of the public interest and legitimate interests be scrutinized in case

of the (further) use of personal data for scientific research. At the same time, the government proposes that a separate, new lawful basis for scientific research, together with the safeguards of article 89 UK GDPR, be examined. The European landscape, with its wide variety of implementation legislation of the GDPR and, likewise, the use of lawful bases for the further use of personal data for scientific research, may not be served with yet another lawful basis. Rather, a more flexible, risk-based approach to the use of the existing lawful bases may yield similar results. Nevertheless, recent developments in both the UK, the European Union and the Netherlands point towards the use of other lawful bases for scientific research. The developments of the EHDS and Wzl underpin this.

Lastly, risk-based regulatory compliance not only requires a different approach from the organizations that process data, but also from the data protection authorities that monitor compliance. Furthermore, the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) play an important role in this respect as well. Thus, a different approach in the UK requires another role and, therefore, reform of the Information Commissioner's Office. A different approach to regulatory compliance in Europe requires another role and reform of the national data protection authorities in the first place. Furthermore, a new design of both the roles of the EDPB and EDPS may be required as well. Nevertheless, the UK's National Data Strategy on scientific research certainly is an avenue to be explored by the EU since it addresses the challenges both the EU and UK currently face. In that sense, one can look forward to the developments in the UK as well as those on the mainland to see whether they reach the welcome goals of furthering scientific research and protecting the data subject.



Closing the gaps in patients' data protection rights: a glance into the future with a Dutch case study

6. Closing the gaps in patients' data protection rights: a glance into the future with a Dutch case study[397]

This chapter answers sub-question 5 that reads as follows:

In what way does the existing data protection and health legislative framework protect the individual's autonomy, his health data, and his position as a care receiver where commercial companies deliver health services?

Abstract

This chapter discusses the legislative framework of data protection and health law in today's world, where the individual has become an active player in governing his health.[398] The individual's protection within the traditional treatment relationship between care provider and care receiver has been subject to substantial changes amidst technological and health innovations. The traditional, clinical health setting is complemented with actors from a non-clinical background, such as commercial companies that provide health care deliverables. New mechanisms for data protection and safeguarding a data subject's rights are required. The European Health Data Space Regulation is a good starting point, since it enables individuals to obtain a copy of their health data, to share and rectify these. However, we observe three gaps in the individual's data protection and his position vis-à-vis commercial companies: in the domain of legislation, in governance, and in the interaction between care provider and care receiver. The individual plays a role as a patient, but also as an individual with a particular lifestyle who uses wearables and buys commercial DNA tests. The individual's monitoring of his own health with devices does not necessarily fall within the scope of existing European and Dutch legislation on data protection and health.

[397] R. Dekker & I.R. Kist, Closing the gaps in patients' data protection rights: a glance into the future with a Dutch case study, *European Data Protection Law Review* 3 (2022) (8), 331-345. Keywords: European Health Data Space, fundamental rights, individual and informational self-determination, technological innovations

[398] In this chapter, words importing the masculine shall include the feminine and words importing the singular shall include the plural or vice versa. For easier readability, we continue with words importing the masculine.

6.1. Introduction

We elaborate on the new role played by the individual in his relationship with commercial companies that provide health deliverables. Health deliverables include any medical device as defined in the medical device regulation (MDR).[399] However, not all devices fall within the scope of the MDR since some of these devices focus on general health and well-being rather than on a medical purpose. In any event, the MDR includes a reference to data protection, i.e., the current General Data Protection Regulation (GDPR).[400] The individual must give his explicit consent for the processing of health data on health deliverables. In practice, research has shown that the companies of health deliverables do not always comply with the GDPR provisions.[401] Furthermore, though the individual seemingly exercises more control over his health and health data in monitoring this himself, his data may be further processed by other parties with a different purpose. As a result, his control over his data is compromised.[402]

In this chapter, the individual's role is illustrated with an innovative example followed by a glance into the future. We consider that some forms of data processing by these commercial companies have not yet been fully covered by law, either at an international or European or national level.[403] Consequently, the individual runs the risk that his data will be processed for other purposes than the original purpose or that they will be transferred to third parties, whereas the individual has neither given his consent nor has he been properly informed about this further processing.[404] His health data could be spread worldwide without his knowledge.[405]

[399] Article 2 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance), Medical Device Regulation, hereinafter MDR.
[400] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), hereinafter GDPR. The MDR explicitly refers to data protection in article 110 (1).
[401] H.B. van Kolfschooten, The mHealth Power Paradox: Improving Data Protection in Health Apps through Self-Regulation in the European Union. In I. G. Cohen, T. Minssen, W. N. Price II, & C. Robertson (eds.), *The Future of Medical Device Regulation: Innovation and Protection* (Cambridge University Press, 2022), 63-76.
[402] European Data Protection Board (EDPB) – European Data Protection Supervisor (EDPS) Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, adopted on 12 July 2022. EDPS, Preliminary Opinion 8/2020 on the European Health Data Space, 2020. P. Quinn, The EU commission's risky choice for a non-risk based strategy on assessment of medical devices, *Computer Law & Security Review* 33.3 (2017), 361-370.
[403] C.S. Schneble et al., All our data will be health data one day: the need for universal data protection and comprehensive consent, *Journal of Medical Internet Research* 22 (2020) (5), e16879. And, Commission Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps Accompanying the document Green Paper on mobile Health ("mHealth"), 2014, https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:52014SC0135. Accessed 7 September 2022.
[404] C.M.L. Zegers et al., Mind your data: privacy and legal matters in eHealth, *JMIR Formative Research* 5 (2021) (3), e17456.
[405] M. Becker, Understanding users' health information privacy concerns for health wearables, 2019 https://pdfs.semanticscholar.org/c4a5/206eafcf533565f936ce5a70b8b11226f43d.pdf. Accessed 14 July 2022.

The existing data protection and health legislation has been implemented at the EU and national level by and among member states.[406] Health legislation governs the relationship between care provider and care receiver.[407] However, health innovations are often introduced by commercial non-state organizations. These organizations process and transfer health data from individuals, yet a treatment relationship, legally speaking, does not exist between these organizations and the individual. We consider that in these situations, the individual's consent, as a legitimation for processing his health data, may not suffice. The individual needs additional legislative protection, for instance a guarantee that particular data processing activities be prohibited by law, such as the commercial exploitation of his health data.[408]

Similarly, the health care professional finds himself in a new role. He continues to act pursuant to rules pertaining to professional medical secrecy and with his professional autonomy.[409] However, he is unable to exercise control over the personal data that have been collected and processed beyond traditional health care institutions. Whereas the health professional has a duty of care to the patient and his data in the traditional provider–patient relationship, the guardianship of his data has shifted towards the individual himself vis-à-vis commercial companies.

In the light of these innovations, we observe gaps in the existing data protection and health legislation with an impact on the individual's autonomy and control over his data. The GDPR applies but the data processing does not fall within the scope of the treatment relationship between the care provider and the care receiver. Thus, national health law does not automatically govern the data processing by commercial companies outside the traditional clinical realm. We investigate how said technological health services create a legislative and governance gap, both for the individual and the care provider. Furthermore, we analyze how the European Health Data Space

[406] European Commission, Assessment of the EU Member States' rules on health data in the light of the GDPR, Specific Contract No SC 2019 70 02 in the context of the Single Framework Contract Chafea/2018/Health/03. BBMRI-ERIC, Statement by BBMRI-ERIC on "A European Health Data Space", and Response by BBMRI-ERIC to "European Health Data Space" (EHDS) Questionnaire (Public Consultation), https://www.bbmri-eric.eu/. Accessed 11 September 2022.

[407] In this chapter, we consider that the care provider is a healthcare professional pursuant to national health law, in particular the WGBO. However, we focus on commercial companies that also deliver healthcare services but do not automatically fall within the scope of Dutch health law.

[408] Article 4 (13), (14), and (15) together with article 9 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), hereinafter GDPR.

[409] Article 7:453 (WGBO); Article 99 Wet op de beroepen in de individuele gezondheidszorg (de wet BIG), Dutch Law on Individual Healthcare Provisions, hereinafter BIG.

(EDHS) constitutes a basis for filling these gaps to ensure that the processing of health data by commercial companies is legally solidified.[410]

6.1.1. Scope

We elaborate on the active role the individual plays in monitoring his health by making use of commercial tools and services. Hence, commercial companies also process and transfer his health data beyond the traditional care provider–care receiver relationship. This also occurs in the light of DNA testing, for instance. Although we do not cover the topic of genetic profiling and automatic decision-making here, we consider that these topics also deserve further analysis in view of the individual's autonomy and data protection.

We focus on data protection law, and we aim to strike a balance between data protection and health law when we consider the individual in two different health contexts. First, the individual is a patient in a clinical setting with the relationship between the care provider and care receiver. Second, the individual is an active participant who monitors his health beyond the traditional clinical realm. We illustrate the legislative and governance gaps and overlap with an example of an individual who lives in the Netherlands within the Dutch legal and health context. The Dutch context serves to highlight the correlation between data protection and health law, as well as the interaction between European and national data protection and health law.

6.1.2. Aim and research question

Individual self-determination and autonomy are two pillars of data protection and health law.[411] Nevertheless, these principles must be scrutinized with the new role the individual plays in the processing of health data provided by commercial companies beyond the traditional, legally safeguarded, care provider–care receiver relationship. Our aim in this chapter is twofold. Firstly, we aim to strike a balance between data protection and health law since we consider that both legal domains serve to safeguard the individual and his health data. Secondly, we elaborate on the European Health Data Space as a starting point to overcoming the legislative and governance gaps and overlap.

[410] BBMRI-ERIC, Statement by BBMRI-ERIC on "A European Health Data Space", 4 February 2021, https://www.bbmri-eric.eu/wp-content/uploads/statement-on-european-health-data-space.pdf. Accessed 14 July 2022. EDPB/ EDPS, Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, adopted on 12 July 2022, https://edpb.europa.eu/system/files/2022-07/edpb_edps_jointopinion_202203_europeanhealthdataspace_en.pdf. Accessed 14 July 2022. L. Abboud et al., Towards European Health Data Space, Summary of Milestone 5.1 & 5.2 Annex A | Case studies: different governance and health data systems in Europe, 28 September 2021.

[411] Article 8 Charter of Fundamental Rights of the European Union, 2012/C 326/02. See section 6.2 below for the legal background. Also, A.C. Hendriks et al., Het recht op autonomie in samenhang met goede zorg bezien, *Tijdschrift voor Gezondheidsrecht* (2008) (32), 2-18.

We aim to answer the following sub-question in this chapter: *In what way does the existing data protection and health legislative framework protect the individual's autonomy, his health data, and his position as a care receiver where commercial companies deliver health services?*

In unraveling this question, we will elaborate on the influence of health innovations by commercial companies on the individual's autonomy and control over his health data. Furthermore, we will discuss which gaps and overlaps can be observed in the existing legislative and governance framework. Subsequently, we will elaborate on the role that the European Health Data Space (EHDS) can play in overcoming these gaps and overlap.

We begin this chapter with the legal research methodology (section 6.1.3) followed by the theoretical and legal background of this chapter (section 6.2). We analyze the individual's autonomy and control over his data from a data protection perspective (sections 6.2.1 and 6.2.2), and we elaborate on his autonomy within technological health innovations (section 6.2.3). Next, we introduce a case study (section 6.2.4.) upon which we illustrate the gaps we observe in data protection with the health services provided by commercial companies (section 6.3). We continue with the relationship between the care provider and the care receiver, which has gained new impetus (section 6.3.1). We also focus on the role played by commercial companies that offer health services (section 6.3.2). Subsequently, we analyze the gaps and overlaps, i.e., the legislative gap (section 6.4.1) and the governance gap and overlap (section 6.4.2). In addition, we elaborate on the role of the European Health Data Space as a point of departure to a transition in this field. We conclude by answering the research question of this chapter (section 6.5).

6.1.3. Legal research methodology

Firstly, the methodology applied in this chapter is doctrinal legal research.[412] The chapter analyzes the letter of the law, and both primary and secondary sources of law are scrutinized. Case law is also included. Secondly, the chapter analyzes the interpretation and implementation of the law in practice.[413] To this end, a Dutch case study serves to exemplify the challenges to health data protection amidst technological innovations. We have explicitly chosen a case study in one of the EU member states, i.e., the Netherlands, to elaborate on the interaction between international, European and national law on the one hand, and the relationship between data protection and health law on the other. In principle, Dutch data protection and health law provide

[412] J.B.M. Vranken, Methodology of legal doctrinal research, in M.A.A. Hoecke (ed.), *Methodologies of legal research. Which kind of method for what kind of discipline* (Hart Publishing, 2010), 111-121.
[413] P. Langbroek et al., Methodology of Legal Research: Challenges and Opportunities, *Utrecht Law Review* 13 (2017) (3), 1-8.

for the lawful basis of explicit consent for the use of health data.[414] The patient's implied consent applies when one or more health care provider(s) is (are) also directly involved in the care and cure of the patient.[415] The Netherlands has a long-standing history of the patient's informed consent for processing and transferring his health data and is a European pioneer in patients' rights.[416] The Dutch WGBO dates to 1994 and the case study sheds light on the interaction between national health law and the GDPR. The WGBO was implemented at a time when the internet had just been introduced to humankind, while the GDPR was implemented in a world surrounded by technological innovations.[417] Currently, the European Health Data Space aims to facilitate the creation of a European Health Union, as well as to enable the EU to make full use of the potential offered by a safe and secure exchange, use and re-use of health data.[418]

6.2. Legal background

We consider that health innovations influence the patient's autonomy and the control over his data.[419] Before we analyze the position of the individual and his health data, we outline the concept of self-determination in the context of health law and data protection law. We do so from the perspective of the care receiver. We note that the individual's autonomy and control over his personal data are subject to change since he engages in legal relations with commercial companies that deliver health care services. National health law does not automatically apply to these (international) commercial companies. At the same time, the care receiver can no longer rely on the professional medical secrecy for safeguarding his health data in a situation beyond the traditional care provider–care receiver relationship for the following two reasons. Firstly, the care receiver gives his consent to the processing of his personal data outside the realm of traditional health care and hence beyond the traditional legal framework where the health provider may not share the patient's data with others unless a specific legal ground applies. Secondly, the care provider–care receiver relationship with

[414] Article 24 UAVG, https://wetten.overheid.nl/BWBR0040940/2021-07-01. Article 7:450 WGBO.
[415] Article 7:457 (1) WGBO.
[416] European Commission, Patients' Rights in the European Union Mapping eXercise, PRE-MAX Consortium March 2016, 26.
[417] W. Schäfke-Zell, Revisiting the definition of health data in the age of digitalized health care, *International Data Privacy Law* 12 (2022) (1), 33-43.
[418] European Health Data Space Regulation, https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en. And, https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en#governance-of-the-european-health-data-space. Legislative train schedule on https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-european-health-data-space. And, A Commission's presentation for the European Public Service Union of 3 February 2022: https://www.epsu.org/sites/default/files/article/files/EHDS%20presentation.pdf. Accessed 13 April 2022. Hereinafter: EHDS.
[419] M. Karampela et al., Connected health user willingness to share personal health data: questionnaire study, *Journal of Medical Internet Research* 21 (2019) (11), e14537.

shared decision-making is absent in the relationship between the individual and the commercial companies.[420] We turn to this impact in section 6.2.3 below.

6.2.1. Individual self-determination: the individual's autonomy

In health care, the notion of individual self-determination is closely related to the patient's freedom, i.e., the protection against the limitation of his autonomy and his (physical and mental) integrity, and, subsequently, the freedom to choose and to determine for himself which health care he receives. Additionally, self-determination with regard to his medical records is described as his capacity to determine, in principle, to what extent his personal data may be processed and transferred to foster a self-determined life.[421]

At an international and European level, individual self-determination is affirmed, inter alia, in article 8 Charter of Fundamental Rights of the European Union, article 8 European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR), and in article 1 International Covenant on Economic, Social and Cultural Rights.[422] The European Court of Human Rights has also acknowledged that article 8 ECHR includes the positive obligation of the individual's autonomy, rather than solely the negative right to freedom of the individual.[423] Explicit reference to individual self-determination is included in the Oviedo Convention and the UN Convention on the Rights of Persons with Disabilities.[424] However, these conventions are specifically directed at state actors, whereas commercial companies are non-state actors.[425]

[420] M.J. Taylor & J. Wilson, Reasonable expectations of privacy and disclosure of health data, *Medical Law Review* 27 (2019) (3), 432-460.
[421] T. Hooghiemstra, *Informationele zelfbeschikking in de zorg* (2018), 15.
[422] Council of Europe, Convention for the Protection of Human Rights and Fundamental Freedoms, Council of Europe Treaty Series 005, Council of Europe, 1950. Hereinafter ECHR. United Nations (General Assembly). International Covenant on Economic, Social, and Cultural Rights. Treaty Series, 999, 171, 1966. See E. Milligan & J. Jones, Rethinking Autonomy and Consent in Health Care Ethics, 2017, Intech Open. V.A. Entwistle et al., Supporting Patient Autonomy: The Importance of Clinical-Patient Relationships, *Journal of General Internal Medicine* 25 (7), 741-745. Also, D. Hallinan, The Genomic Data Deficit: on the Need to Inform Research Subjects of the Informational Content of Their Genomic Sequence Data in Consent for Genomic Research, *Computer Law & Security Review* 37 (July 2020), 105427, 1-10.
[423] ECHR 7 July 1989, 10454/83 (Gaskin/United Kingdom); ECHR 13 February 2003, 42326/98 (Odièvre/France). Cordula Dröge, 'Positieve Verpflichtungen der Staaten in der Europäischen Menschenrechtskonvention', Beitrage zum ausländischen öffentlichen Recht und Völkerrecht, Band 159, 2003, pp. 379-392. European Court of Human Rights, Guide on Article 8 of the European Convention on Human Rights: Right to respect for private and family life, home and correspondence. Updated on 31 August 2021.
[424] Council of Europe, Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164). The Netherlands have not ratified the Oviedo convention. United Nations General Assembly, Convention on the Rights of Persons with Disabilities: resolution / adopted by the General Assembly, 24 January 2007, A/RES/61/106. See H. Nys et al., Patient rights in EU Member States after the ratification of the Convention on Human Rights and Biomedicine, *Health Policy* 83 (2007) (2-3), 223-235.
[425] F. Thouvenin, Informational Self-Determination: A Convincing Rationale for Data Protection Law? *JIPITEC* 12 (2021) (4), 246-256, https://www.jipitec.eu/issues/jipitec-12-4-2021/5409. Accessed 12 April 2021.

6.2.2. Informational self-determination: the individual's control over his data

We consider the following in light of the European legal framework on informational self-determination. The concept of consent, as a corollary to self-determination, is not expressly included in the Council of Europe Convention 108 or in the non-binding OECD Guidelines on the Protection of Privacy and Trans-border Flows of Personal Data.[426] The OECD Guidelines only indirectly refer to the principle of consent in article 7, whereas Council of Europe Convention 108 refers to consent once in article 14 as regards the assistance to data subjects who are residents abroad. However, article 5 of this convention includes the requirement of fair and lawful processing and, thus, that a legitimate purpose and a lawful basis exist. The European Charter on Fundamental Rights has not formulated the right to data protection as a right to informational self-determination.[427]

The Data Protection Directive (DPD) connects the individual's privacy as well as other fundamental rights and interests of the individual, and echoes the right to informational self-determination to some extent.[428] However, the directive does not explicitly anchor a principle or a right to informational self-determination. The principle can be observed via the principle of consent by the individual and the rights he can invoke to express his control over his data. Examples are the right of access, the right of rectification, and the right to object.[429] Thus, the individual is able to exercise a certain degree of control over his personal data.

The GDPR also promotes the individual's control over his data, but like the DPD does not include an absolute, enforceable right to self-determination.[430] The GDPR combines the free flow of data and the necessity of trust by an individual in the data controller.[431] The individual must have control over his own personal data and he is

[426] Council of Europe, Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data 1981, ETS No. 108. OECD Guidelines on the Protection of Privacy and Trans border Flows of Personal Data, 2002, OECD Publishing, Paris.
[427] P. Hustinx, European Leadership in Privacy and Data Protection. *Hacia un nuevo regimen europeo de protección de datos/ Towards a new European Data Protection Regime* (Valencia, 2015). E. Dove, The EU General Data Protection Regulation: Implications for International Scientific Research in the Digital Era, *Journal of Law, Medicine & Ethics* 46 (2018) (4), 1013-1030.
[428] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data OJ L 281, 23 November 1995.
[429] Article 7 (a) DPD (on consent), article 12 (a) DPD (on the right of access), article 12 (b) DPD (on the right of rectification) and article 14 DPD (on the right to object).
[430] Recital 7 GDPR. E.M.L. Moerel & J.E.J. Prins, Het recht op zelfbeschikking is een illusie, *Homo Digitalis* (NJV 2016-1) 2016/1.4.3. F. Thouvenin, Informational Self-Determination: A Convincing Rationale for Data Protection Law? *J. Intell. Prop. Info. Tech. & Elec. Com. L.*, 12 (2021), section 1.
[431] B. van der Sloot, Do data protection rules protect the individual and should they? An assessment of the proposed General Data Protection Regulation, *International Data Privacy Law* (2014) (4), 315. B. van der Sloot, Privacy as a human flourishing: Could a shift towards virtue ethics strengthen privacy protection in the age of Big Data? *JIPITEC* 5 (2014), 230. Also M. Mostert et al., Big Data in medical research and EU data protection law: challenges to the consent or anonymise approach, *European Journal of Human Genetics* 24 (July 2016) (7), 956-60.

autonomous in his decision-making.[432] He expresses his free will with his explicit consent.[433] Furthermore, the individual has a number of rights he can invoke, i.e., the right of access, the right to rectification, the right to erasure, the right to restrict processing, the right to data portability, the right to object and the right not to be subject to a decision based solely on automated processing.[434] However, individuals are not always aware of or informed about their data protection rights when purchasing a wearable.[435] Thus, while the GDPR provides for a general data protection framework in theory, practice shows that the actual protection of the individual's privacy and health data protection is prone to the risk of further data processing beyond the original purpose, his own knowledge, and without his consent. Though the GDPR applies to those organizations outside the EU that render services and data to individuals in the EU, practice shows that organizations offering wearables on the EU market do not always comply with the EU legislative framework.[436]

Informational self-determination is closely related to the individual's autonomy.[437] In 1983, the German Constitutional Court developed the notion of informational self-determination as stemming from the core value of human dignity (article 1 of the German Constitution) and the so-called personality right (article 2 of the German Constitution).[438] This ruling presumes the capacity of the individual to determine, in principle, the processing and sharing of his personal data. Based on the newly defined right to informational self-determination, the individual himself, and only himself, shall decide when and within which limits the information about his private life may be communicated to others.[439]

[432] Recitals 5, 6, 7 and article 1 GDPR. European Data Protection Supervisor, https://edps.europa.eu/data-protection_en. Accessed 12 April 2022:

[433] European Data Protection Board, Guidelines 05/2020 on consent under Regulation 2016/679 Version 1.1, adopted on 4 May 2020; European Data Protection Supervisor, Preliminary Opinion 8/2020 on the European Health Data Space, 17 November 2020.

[434] Chapter 3, articles 12 – 23 GDPR: rights of the data subject.

[435] T. Mulder & M. Tudorica, Privacy policies, cross-border health data and the GDPR, *Information & Communications Technology Law* 28 (2019) (3), 261-274. Also F. Lucivero, K.R. Jongsma, A mobile revolution for healthcare? Setting the agenda for bioethics, *Journal of Medical Ethics* 44 (October 2018) (10), 685-689.

[436] H.B. van Kolfschooten, The mHealth Power Paradox: Improving Data Protection in Health Apps through Self-Regulation in the European Union, in I. G. Cohen, T. Minssen, W. N. Price II, & C. Robertson (eds.), *The Future of Medical Device Regulation: Innovation and Protection* (Cambridge University Press, 2022), 66 – 68.

[437] T. Hooghiemstra, (2018). *Informationele zelfbeschikking in de zorg*. SDU. Also, A. Rouvroy & Y. Poullet, The right to informational self-determination and the value of self-development: reassessing the importance of privacy for democracy, in S. Gutwirth et al. (ed.), *Reinventing data protection?* (Springer, 2009), 45.

[438] Judgment of the Bundesverfassungsgericht of 15 December 1983, First Senate, Case 83. ECLI:DE:BVerfG:1983:rs19831215.1bvr020983. G. Hornung & C. Schnabel, Data protection in Germany I: The population census decision and the right to informational self-determination, *Computer Law & Security Report* 24 (2009) (1), 84-88.

[439] The Court considered informational self-determination to derive from the fundamental (German) right to personality, as laid down in the German Constitution. See also C-73/07 Satakunnan Markkinapörssi Oy and Satamedia v. Finland, App. No. 931/13, 2017, ECLI:CE:ECHR:2017:0627JUD000093113, at 137, where the Court recognized that article 8 of the European Convention on Human Rights 'provides for the right to a form of informational self-determination'.

New European legislation is to be implemented as deliverables to the European strategy for data.[440] In short, the legislation comprises the following deliverables. On 25 November 2020, the European Commission published a proposal for a regulation on data governance.[441] The Data Governance Act (DGA) entered into force on 23 June 2022 and became fully applicable in the EU on 24 September 2023, following a transitional period of 15 months The EU aims to create a single European market for data to guarantee the free flow, sharing, and re-use for the benefit of individuals, researchers, corporate entities, and public administrations. The Data Governance Act creates the processes and structures to facilitate data.

The Data Act then clarifies who can create value from data and under what conditions.[442] The Data Act entered into force on 11 January 2024 and it will become applicable in September 2025.[443] The Data Act particularly addresses the use of data generated by Internet of Things (IoT) devices. On 3 May 2022, the European Commission presented a proposal for the European Health Data Space Regulation (EHDS). The EHDS is one of nine European data spaces identified in the European Commission's 2020 European Strategy for Data. It builds on the Data Governance Act and the Data Act. These acts are horizontal in nature, i.e., they also apply to the mutual relationship between consumers and companies, whereas the EHDS Regulation includes specific sectoral measures in the area of health, both as regards the use of data for health care (primary use) and the re-use of health data (secondary use). These deliverables aim to regulate both the free flow and use of data and to expand the rights of citizens to access and portability of health data.

At a national level, Dutch legislation serves to enhance the interoperability and exchange of data in the health sector. The *Wet elektronische gegevensuitwisseling in de zorg* (Dutch Act concerning the flow of electronic data interchange) was addressed by both chambers of Parliament and entered into force on 1 July 2023.[444] However, this act governs the 'when' and 'how' of data exchange, and does not address the position of the individual or the lawful bases of the data processing in particular. In conclusion,

[440] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A European strategy for data, COM/2020/66 Final, 19 February 2020.
[441] Proposal for a Regulation of the European Parliament and of the Council on European data governance (Data Governance Act), COM/2020/767 Final, 25 November 2020.
[442] Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act), COM (2022) 68 Final Brussels, 23 February 2022. EDPB-EDPS Joint Opinion 2/2022 on the Proposal of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act), adopted on 4 May 2022.
[443] https://digital-strategy.ec.europa.eu/en/policies/data-act. Accessed 21 January 2024.
[444] Kamerstukken II 35 824 nr. 2 (Parliamentary Papers II 35 824 nr. 2) Regels inzake het elektronisch delen en benaderen van gegevens tussen zorgverleners in aangewezen gegevensuitwisselingen (Wet elektronische gegevensuitwisseling in de zorg), https://www.tweedekamer.nl/kamerstukken/wetsvoorstellen/detail?id=2021Z07327&dossier=35824. Accessed 13 April 2022. Ministerie van Volksgezondheid, Welzijn en Sport, (Dutch Ministry of Health, Welfare and Sport), Herijking Grondslagen voor gegevensuitwisseling in de zorg (Recalibrating the lawful bases for data exchange in health care), 9 May 2022.

a wide array of international, European, and national (implementation) legislation aims to protect the individual and his health data. However, a separate right to informational self-determination has not been acknowledged.[445] New legislation aims at safeguarding both the individual and his data as well as the free flow of data.

6.2.3. Challenges to Individual and informational self-determination in the light of health innovations

With regard to the legal framework as described above, the individual reaches decisions about his health (i.e., he gives expression to his individual self-determination) and exercises control over his health data (i.e., he gives expression to his personal autonomy and informational self-determination).[446] Individual self-determination applies, inter alia, to the relationship between the care provider and care receiver.[447] The right is reflected in the patient's informed consent and safeguarded by the medical professional secrecy.[448] The requirement of the patient's informed consent serves two elements. First, it serves the patient's defensive right to say 'no' to a certain treatment. Second, it serves the patient's positive right to choose a medical treatment. Health services delivered beyond the traditional care provider–care receiver relationship have an impact on the traditional relationship and on the protection of the individual's health data.

Both the individual role and the role of the traditional care provider change with commercial companies that deliver health services. In his traditional role, the care provider is bound by professional secrecy and professional autonomy. He is the guardian of the patient's data and self-determination as regards medical treatment. The patient can voice his rights, for instance to access his medical records or choose a medical treatment. Although the individual may have access to the results of health deliverables from a commercial company, the traditional legal relationship between the care provider and care receiver is absent. In the traditional relationship, national health law protects the patient, whereas the commercial companies do not automatically fall within the traditional health care system.

In the traditional roles, the right to individual and informational self-determination is expressed by means of shared decision-making to create a balance in the provision

[445] In the Netherlands, the right to informational self-determination was subject to debate in 2010, as the Dutch State Committee brought it forward. See G. Overkleeft-Verburg, het grondrecht op eerbiediging van de persoonlijke levenssfeer, in A.K. Koekkoek et al., *De Grondwet, Een systematisch en artikelsgewijs commentaar* (Deventer, 2000), 155-179. B.J. Koops, Digitale grondrechten en de Staatscommissie: op zoek naar de kern, *Tijdschrift voor Constitutioneel Recht* (2011), 168-185.
[446] T. Hooghiemstra, Informational Self-determination, Digital Health and New Features of Data Protection, *European Data Protection Law Review* 2019 (2), 160-174.
[447] Verdict by the Dutch Supreme Court, 18 March 2005, Baby Kelly, NJ 2006, 606. ECLI:NL:HR:2005:AR5213.
[448] O. O'Neill, Some limits of informed consent, *Journal of Medical Ethics* 29 (2003), 4-7. M. Taylor & J. Wilson, Reasonable expectations of privacy and disclosure of health data, *Medical Law Review* 28 (2020) (2).

of care.[449] The following example sheds light on the different roles played by both the care provider and care receiver in the light of commercial companies that deliver health services. Additionally, the challenges to the individual and informational self-determination are addressed.

6.2.4. Dutch case study: Mrs. Johnson's diagnosis

Mrs. Johnson (43 years old) lives in Amsterdam. She watches a commercial about a genetic self-test that may inform her about a potential risk she runs for developing colorectal cancer. She buys the test with commercial technology Company X (a company that operates in various other sectors beyond health and which hosts other services as well) in non-EU country Y. The result shows that she carries a genetic variant with an increased risk of colorectal cancer. Upon receiving the test result, she also receives advice about her health and potential beneficial changes to her lifestyle. Mrs. Johnson learns that Company X has also invented an algorithm that can estimate her chances of developing colorectal cancer, based on her blood levels provided by a wearable.[450] Mrs. Johnson buys the wearable monitor from Company X. Company X asks Mrs. Johnson's consent for data processing of the blood levels to enhance the algorithm and, subsequently, to provide her with even better information about her health status. Based on the results created by the algorithm, she receives feedback that certain biomarkers in her blood have reached a certain level. She is advised to contact her general practitioner (GP). After a few days of emotional turbulence, she contacts her GP to find support and treatment. She also buys a smartwatch from Company X to monitor her health, which information she shares with Company X. Company X processes these data and informs her about adapting her lifestyle when the data give rise to this. A health practitioner, affiliated with but not employed by Company X, occasionally monitors these data. Ever since, Mrs. Johnson receives adverts from other companies about devices to monitor her health. When she shares the data gathered on her device with her GP, the GP expresses his concerns that premature conclusions may have been drawn after all.

This example illustrates the position of the individual and the health care professional within innovations and underpins the relationship between data protection and health law. The traditional care provider–care receiver relationship is subject to change that emerges from the dynamics of innovations. Traditional rights that aim to safeguard the individual's self-determination such as shared decision-making, as well as professional medical secrecy, are inextricably linked to the traditional care provider–care receiver relationship. In these new situations, the individual uses his own devices and draws

[449] H.J.J. Leenen et al., *Handboek Gezondheidsrecht* (The Hague, 2020, 8th ed.), 101.

[450] It may sound like a fictional reality, but in fact, Elisabeth Holmes tried to impress the world with such tests. Though this was in vain and trials followed, the future may bring similar innovations. See https://www.washingtonpost.com/technology/2021/11/16/blood-startups-theranos/Accessed 11 July 2022.

his own conclusions. Therefore, the specific protection of individual rights in the traditional health care relationship is absent. In the following section 6.3, we analyze and identify the changes of these dynamics in health care from a data protection and health law perspective.

6.3. Health data protection: what has changed?

The individual has become an active player in governing his health. We consider that the health innovations, and hence the different roles the care provider and care receiver play, give rise to changes. At an international, European, and national level, legislation provides for the individual's protection in health. The WGBO in particular protects his health care rights as a patient at a national level.[451] The act dictates that the individual is regarded as a patient when the treatment qualifies as a medical treatment, as a result of which he is entitled to a number of patient rights.[452] For instance, he must be informed about his treatment about which he can reach an informed decision based on shared decision-making.[453] Thus, individual self-determination is reflected in the individual's informed consent as regards his medical treatment. However, as an individual, in his relationship with commercial companies that deliver health care, his rights are not safeguarded pursuant to Dutch health law, since the traditional care provider–care receiver relationship is absent.

Moreover, the health care professional fulfills an essential role in determining to what extent the individual is able to express his self-determination via his consent to the data processing. Based on the protection that the individual receives as a patient within the current legal framework, a gap arises when we consider the example of Mrs. Johnson. She independently shares her health information with Company X. It may very well be that these data are processed anywhere around the world by organizations such as Company X without the intervention of a medical professional.

We continue to elaborate on two factors that influence the safeguards for the individual and his health data. The first factor concerns the changing relationship(s) between the care provider and the individual, where more health innovating companies have entered the scene, and where the individual no longer fulfills the role of patient but he is also an active participant in monitoring his health. The second factor follows from the first and concerns the data protection of the individual's health data.

[451] Article 7:446 – 7:468 WGBO.
[452] Article 7:446 WGBO.
[453] Article 7:448 WGBO.

6.3.1. The changing relationship between the traditional care provider and the individual

In the traditional relationship between the care provider and the individual, the patient has access to his medical records and may exercise his rights as a data subject pursuant to the GDPR.[454] In other words, he may express his right to informational self-determination.[455] His rights as a patient are also guaranteed in national health law.[456] Health legislation protects both the patient's position and the confidential relationship between care provider and care receiver. The bond of trust between them is a key factor when the patient seeks medical advice. Within the professional medical secrecy, the care provider guarantees that the care receiver may share his health data without fear of disclosure of this confidential data.[457] In other words, the care provider may not share the patient's health data in the traditional relationship unless a legal ground exists.[458]

A breach in professional medical secrecy is justified a) with the patient's consent, b) pursuant to a legal obligation or task, or c) in case of a conflict of interest while balancing the facts and circumstances by the care provider.[459] When the care provider breaches the professional medical secrecy in case of a conflict of interest, he must ascertain that he has done his utmost to obtain the patient's consent, and that further damage can only be averted by breaching the professional medical secrecy. In all instances, the care provider must perform a balancing test whether or not he breaches the professional medical secrecy.[460] The patient can only rely on these safeguards when the WGBO applies, i.e., when a treatment relationship qualifies as a medical treatment. Furthermore, the care provider carries out the treatment in the execution of his medical profession.[461]

In the example of Mrs. Johnson, we consider the following. First, Company X does not automatically fall under the scope of the WGBO. Secondly, by analyzing the conclusions reached with an algorithm, Company X informs Mrs. Johnson about a health risk based on the data from her wearable. In this example, the 'diagnosis' can be (and perhaps should be) regarded as an act in the field of medicine, but the traditional care provider–care receiver relationship remains absent since Company X does not meet the requirements of a health provider, i.e., a medical professional,

[454] Articles 12 – 23 GDPR.
[455] T. Hooghiemstra (2018). *Informationele zelfbeschikking in de zorg*. SDU, 15.
[456] Articles 7:446 – 7:467 WGBO.
[457] HR 19 November 1985, NJ 1986, 533, with annotation 't Hart. ECLI:NL:HR:1985:AC9105.
[458] Kamerstukken II 21561 nr. 3 (Parliamentary Papers II 21 561 nr. 3 MvT) 39.
[459] Articles 7:448 (3), 7:450, 7:457 (1) and 7:466 WGBO.
[460] KNMG richtlijn (Royal Dutch Medical Association - Guidelines) Omgaan met medische gegevens (KNMG 2021) 23.
[461] Article 7:446 WGBO and H.J.J. Leenen, Handboek gezondheidsrecht, 2020,108.

pursuant to the Dutch WGBO.[462] Consequently. Mrs. Johnson cannot exercise her right to self-determination via her patient's rights. Similarly, she is not protected by the professional medical secrecy from her care provider.

We reach the following preliminary conclusions. The new role carried out by the individual in monitoring his health results in a lack of legislative and operational protection. Since the individual is no longer regarded as a patient pursuant to existing Dutch national law, he lacks the legal protection pursuant to health law. In the example in section 6.2.4 above, even though Mrs. Johnson may have consented to the data processing of Company X, she has not consented to the further processing by third parties, or the sale of her data to other companies. We elaborate on the new relationship and the data protection in the following section.

6.3.2. The individual's health data and his position as a care receiver in a commercial context

Innovative health companies offer tests, treatments and monitoring via algorithms.[463] For instance, the number of genetic, direct-to-consumer tests is emerging. These tests serve various purposes related to health and lifestyle.[464] On the one hand, the individual may gather more information about his health, beyond the traditional treatment relationship. This may be considered a positive development. On the other hand, the medical professional is absent, which may jeopardize the individual's health and his data.

In accepting health services, the individual is generally in a disadvantaged position of health knowledge and expertise, and is unaware in what way his data are (further) processed. The bond of trust is not safeguarded in the commercial setting, because professional medical secrecy does not apply in this new relationship. Data protection is a general concern in DNA testing.[465] Consumers, by accepting the general conditions from the commercial company, may be unaware that they have consented to the further use of their data, albeit anonymized.[466] The concept of freely given, specific,

[462] Article 7:446 (2) (3). And M. van der Mersch, Nieuwe E-health toepassingen, zijn de patiëntenrechten aan innovatie toe? (Preadvies Vereniging voor Gezondheidsrecht 2018) 112 & Memorie van Antwoord (Reply to the statement of objections), Kamerstukken II 1989/90 (Parliamentary Papers II), 21561, nr. 6-55.

[463] Digital healthcare: patient first (22 April 2021) https://dealroom.co/uploaded/2021/04/Healthtech-Dealroom-Inkef-Capital-MTIP-final-smol.pdf?x23070. Accessed 9 February 2022.

[464] C. Ploem, M. Cornel & S. Gevers, Commercieel aanbod van DNA-tests: ruim baan voor vrije markt en zelfbeschikking? (2019) 32 *NJB* 2364. T. Rigter et al., Kansen en risico's van DNA-zelftesten (RIVM-2020-0196) 13.

[465] J.S. Roberts et al., Direct-to-consumer genetic testing: user motivations, decision making, and perceived utility of results, *Public Health Genomics* (2017), 36-45. And E.M. Gerrits et al., Direct-to-consumer genetic tests in de spreekkamer, *Nederlands Tijdschrift voor Geneeskunde* (2019) D4131, 163.

[466] Recital 26 GDPR. See AEPD and EDPS Joint Paper, 10 Misunderstandings related to anonymisation, 2021, https://edps.europa.eu/system/files/2021-04/21-04-27_aepd-edps_anonymisation_en_5.pdf. Accessed 11 July 2022. G. Schneider, Disentangling health data networks: a critical analysis of Articles 9(2) and 89 GDPR, *International Data Privacy Law* 9 (2019) (4), 253-271.

informed, and unambiguous consent is eroded, aside from the question of whether DNA data can be completely anonymized at all.[467]

Company X does not automatically fall within the scope of national health law, as a result of which a national quality control framework and a specific, sectoral enforcement mechanism do not automatically apply either. The WGBO dictates that the care provider supplies the patient with proper information, based on his estimation what he needs.[468] Enforcement mechanisms, linked to the quality and safety of care, are important pillars for the patient's right to health and self-determination. Sanctions could be applied pursuant to civil law, disciplinary law, administrative law, and criminal law.[469] In the new health context, similar enforcement mechanisms remain absent since this kind of health services are provided beyond the traditional clinical realm.[470] In our view, the EHDS is a point of departure for filling the legislative gap. At the same time, we observe that the EHDS has significant overlap with other European legislation, such as the GDPR, the MDR, the Data Act, Data Governance Act, and AI Act.[471] The EHDS and Data Governance Act introduce a new governance structure, with a European Digital and Health Data Board. In our view, the patchwork of regulations creates both a governance gap and an overlap. We turn to the potential role of the EHDS in this matter in section 6.4.2 below.

We conclude that the health context for the individual has changed. We consider that the individual and his health data deserve equal protection in new relationships, no matter what role he adopts and no matter which care provider or commercial company he addresses. We observe a legislative gap (section 6.4.1) and a governance gap and overlap (section 6.4.2).

6.4. Filling the gaps: data protection in health innovations

The traditional care provider no longer controls the data processing by commercial companies beyond the traditional framework. Additionally, the individual lacks the bond of trust he enjoys in the traditional care provider–care receiver relationship, and the commercial companies are not bound by the professional medical secrecy. We

[467] M. Suriyar, I. Schlünder, Challenges and Legal Gaps of Genetic Profiling in the Era of Big Data, *Frontiers in Big Data* 2019, https://doi.org/10.3389/fdata.2019.00040. Accessed 12 July 2022.
[468] A. Hendriks et al., *Thematische wetsevaluatie Zelfbeschikking in de zorg* (ZonMw 2013) 158-161.
[469] Article 7:457 WGBO, 272 Wetboek van Strafrecht (Dutch Criminal Code), 218 Wetboek van Strafvordering (Dutch Code of Criminal Procedure) and 88 Wet BIG.
[470] T. Rigter et al., Kansen en risico's van DNA-zelftesten, RIVM-2020-0196, 18.
[471] Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain union legislative acts, COM/2021/206 final, 2021. M. Kop, EU Artificial Intelligence Act: The European Approach to AI, Vienna Transatlantic Technology Law Forum, Transatlantic Antitrust and IPR Developments, Stanford University, 2/2021. Ministerie van Volksgezondheid, Welzijn en Sport (Dutch Ministry of Health, Welfare and Sport), Kamerbrief Waardevolle AI voor Gezondheid (Letter to Parliament, Valuable AI in Health care), 9 May 2022.

observe a legislative gap as well as a governance gap and overlap in the relationship between the commercial company that provides health services and the individual.

6.4.1. Filling the legislative gap: protecting the individual and his data by commercial companies

We consider that the lawful basis of explicit consent, as one of the legitimations for the processing of health data, does not suffice in the role played by the individual vis-à-vis the commercial company. The individual is not able to assess the consequences of his consent and the risks involved in the data processing. Thus, other lawful bases must be considered that protect the individual in the new context. Next, we propose specific legislation with the following aims. This legislation must set norms for particular forms of data processing that must be prohibited, i.e., the mere exploitation of the (further) use of health data for commercial purposes without a licensing system and qualitative controls. Although we recognize that the individual is already surrounded by the new health context and acts accordingly by purchasing tests and monitoring his health, we argue that the legislative framework must fill the gap with respect to these new forms of data processing.

The individual's protection in the traditional health system has always been extensive, i.e., to protect the individual who finds himself in a dependent position. Thus, the legal system entrusted the state actors with the accountability and transparency towards the individual, where the individual reaches an autonomous decision, where his data are protected and the individual's rights respected.

The GDPR provides for a general data protection framework and the WGBO provides for the individual's protection in the traditional care provider–care receiver relationship. In traditional health law, safeguards have been implemented to protect the patient and his data. Commercial companies are not bound, legally speaking, to guarantee similar protection.[472]

We consider that the current legislative framework, at an international, European, and national level, does not fill the legislative gap. We observe that the boundaries of individual self-determination are stretched by the individual with his consent to commercial companies. Although we observe that the individual's health data are protected by national health law and, generally, by the GDPR, we observe that the individual's data protection is incomplete in the relationship between himself and commercial companies. We question whether the accountability and transparency principles in

[472] T. Rigter et al, T. Kansen en risico's van DNA-zelftesten (RIVM-2020-0196), 18.

the GDPR are fully realized in the data protection by commercial companies.[473] In our view, the European Health Data Space Regulation is a point of departure in the integral protection of the individual's position and health data. In the following section, we turn to the role of the EHDS as a starting point to foster human dignity in general, and to further the individual's rights to data protection and control over his health data. We observe both a governance gap and an overlap that require further attention to foster the integral protection of the individual's position.[474]

6.4.2. Filling the governance gap and overlap

The EHDS is part of the Digital Single Market Strategy[475] and the new generation of data regulations, i.e., the Data Act, the Digital Services Act, the Digital Markets Act, the Artificial Intelligence Act, and the Data Governance Act. In providing a framework for the use of electronic health data, the EHDS builds on the Data Governance Act and the Data Act.[476] These acts are horizontal in nature, i.e., they also apply to the mutual relationship between consumers and companies. The EHDS Regulation includes specific sectoral measures in the area of health, both as regards the use of data for health care (primary use) and the re-use of health data (secondary use).[477] As a horizontal framework, the Data Governance Act only lays down generic conditions for the secondary use of public sector data without creating a genuine right to the secondary use of such data. The Data Act enhances the portability of certain user-generated data, which can include health data but does not include rules for all health data. The EHDS complements these proposals and includes specific rules for the health sector. These rules cover the exchange of electronic health data and may affect provider of data sharing services formats that ensure the portability of health data, cooperation rules for data altruism in health, and complementarity on access to private data for secondary use.[478]

[473] T. Karjalainen, All Talk, No Action? The Effect of the GDPR Accountability Principle on the EU Data Protection Paradigm, *European Data Protection Law Review* 1 (2022), 19-30.
[474] Expertmeeting on 'Zeggenschap, eigenaarschap en persoonsgegevens. Overwegingen en suggesties voor beleid' (control, ownership and personal data. Considerations and policy advice), 29 October 2021. And Brief van de minister van Volksgezondheid, Welzijn en Sport aan de Voorzitter van de Tweede Kamer der Staten-Generaal (letter from the Minister of Health, Welfare and Sport to the Chairman of the Parliament), 27529, nr. 276 and 277 as regards the legislative proposal Wegiz, 9 and 19 May 2022. Eerste Kamer der Staten-Generaal, Wet elektronische gegevensuitwisseling in de zorg, verslag van een deskundigenbijeenkomst, 2021 – 2022, 31765, 12 November 2021.
[475] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Digital Single Market Strategy for Europe COM (2015) 192 final. And, A European Strategy for Data: Shaping Europe's Digital Future, https://digital-strategy.ec.europa.eu/en/policies/strategy-data, with reference to: Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A European Strategy for Data, COM/2020/66 final. Accessed 10 September 2022.
[476] EHDS, explanatory memorandum, 4.
[477] EHDS, explanatory memorandum, 4-5.
[478] EHDS, explanatory memorandum, 4-5.

The central goal of the EHDS is to provide the individual with more control over his health data.[479] It builds on the GDPR that provides for safeguards in relation to data subject's rights over their health data. The EHDS aims to foster a genuine single market for digital health services while strengthening the right to data protection.[480] For instance, a further harmonization in the rights by individuals over their data is proposed by including a general right to data portability, as opposed to the GDPR where this right is limited.[481] Additionally, the EHDS includes an explicit right to direct access to one's health data, free of charge.[482]

The proposal is based on the Treaty on the Functioning of the European Union (TFEU).[483] The EU not only aims at protecting the individual's health data and giving the individual more control over his data, but it also fosters a framework with free data flows.[484] The EHDS and the Data Governance Act provide for a new governance structure, to which we turn now. Up until now, a national governance structure has guaranteed the supervision and monitoring of the health care system. With the new governance structure, a European Digital and Health Data Board (EHDS Board) is created which will be entrusted with promoting the collaboration between digital health authorities and health data access bodies.[485] This EHDS board will operate parallel to the existing European and national monitoring system, i.e., the European Data Protection Board (EDPB), European Data Protection Supervisor (EDPS), and the national Data Protection Authorities (DPAs). Additionally, the Data Governance Act introduces the European Data Innovation Board (Board), which serves to interact with the existing framework.[486] This Board shall be established in the form of an Expert Group, consisting of the representatives of competent authorities of all the member states, the European Data Protection Board, the Commission, relevant data spaces, and other representatives of competent authorities in specific sectors.[487] The Board shall encapsulate the data protection as enshrined in article 27 Data Governance Act. To this end, the Board shall advise and assist the Commission in developing a consistent practice of public sector bodies and competent bodies processing requests for the re-use of the categories of data referred to in article 3 (1). One or more of these competent bodies shall be designated by member states as a national duty. This competent body may be sectoral, to support the public sector bodies which grant

[479] EHDS, 21.
[480] Article 16 Treaty on the Functioning of the European Union.
[481] EHDS, explanatory memorandum, 6.
[482] Article 1 (subject matter and scope) together with article 3 (rights of natural persons in relation to the primary use of their personal electronic health data) and article 34 (purposes for which electronic health data can be processed for secondary use) of the Commission proposal for a Regulation on the European Health Data Space.
[483] Articles 16 and 114 TFEU.
[484] GDPR, Recitals 1, 2, 4-7 together with article 1 GDPR.
[485] EHDS, 19.
[486] Recital 40 Data Governance Act.
[487] Article 26 (1) Commission Proposal for a Regulation on the European Health Data Space.

access to the re-use of the categories of data referred to in article 3 (1) in the exercise of that task.[488]

Regarding the governance model created by the proposal of the EHDS, the tasks and competences of the new public bodies must be scrutinized, particularly taking into account the tasks and competences of national Supervision Authorities, the EDPB, and the EDPS in the field of processing personal (health) data. The EDPB-EDPS Joint opinion on the Proposal for a Regulation on the European Health Data Space observes the existence of an overlap in competences that should be avoided.[489] Furthermore, the fields and requirements for cooperation should be specified.[490] For instance, a difference is observed in the language between article 1 (4) EHDS, which reads as follows.

> "*(…) This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data (…).*"

And article 1 (2) Data Governance Act, which reads as follows:

> "*(…) [T]his Regulation is without prejudice to specific provisions in other Union legal acts regarding access to or re-use of certain categories of data, or requirements related to processing of personal or non-personal data. Where a sector-specific Union legal act requires public sector bodies, providers of data sharing services or registered entities providing data altruism services to comply with specific additional technical, administrative or organizational requirements, including through an authorization or certification regime, those provisions of that sector-specific Union legal act shall also apply.*"[491]

Thus, it can also be argued that the national Data Protection Authorities will retain their oversight competence over commercial companies offering health services, apps and the like to patients. In view of the above, we observe a governance overlap and refer to the need as expressed in the EDPB-EDPS Joint Opinion for a clear coordination between the EDPB, the envisaged EHDS Board chaired by the European Commission and the national Data Protection Authorities.[492]

[488] Article 7 (1) Data Governance Act.
[489] EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space.
[490] EDPB-EDPS Joint Opinion 03/2022, 4.
[491] Article 1 (2) Data Governance Act. EDPB- EDPS Joint Opinion 03/2022, paras 28 – 30, at 10.
[492] EDPB-EDPS Joint Opinion 03/2022, paras 117 – 121, at 29-30.

In principle, health care is governed by the member states and the proposal on the EHDS does not aim to regulate how health care is provided by member states.[493] However, a European health union has become even more apparent with the recent challenge of COVID-19 and global non-state actors in the health field. Additionally, the evaluation of the digital aspects of the Cross-border Health care (CBHC) Directive reviewed the current situation of fragmentation, differences, and barriers to access and use of electronic health data.[494] The evaluation shows that action by member states alone may prove insufficient and hamper the rapid development and deployment of digital health products and services, including artificial intelligence.[495] The EHDS takes a step forward and allows for the use of electronic health data for public health in the public interest, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health and care and of medicinal products or medical devices. It also serves scientific or historical research and statistical purposes.[496]

Although this new generation of data regulations aims at safeguarding the individual and his data as well as the free flow of data, a separate right to informational self-determination has not been acknowledged.[497] Besides, as we concluded earlier, the health context for the individual has changed. Nevertheless, the individual's human rights and his health data deserve equal protection in new relationships, no matter which role he adopts and no matter which care provider or commercial company he addresses. The boundaries of individual self-determination are stretched by the individual in relation to commercial companies. Though we understand that the individual's health data are protected by national health law and, generally, by the GDPR, we observe that the individual's data protection is incomplete in the relationship between commercial companies and the individual. Member states alone cannot counterbalance the commercial companies that operate at a global level to protect the individual, his health data, and his position as a care receiver in the new context. Here, we observe a governance gap that must be overcome.

[493] Commission proposal for a Regulation on the European Health Data Space, 8.
[494] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. And European Commission, Study supporting the evaluation of the Directive 2011/24/EU to ensure patients' rights in the EU in cross-border healthcare, 13 May 2022, https://health.ec.europa.eu/publications/study-supporting-evaluation-directive-201124eu-ensure-patients-rights-eu-cross-border-healthcare_en. Accessed 12 September 2022.
[495] Commission proposal for a Regulation on the European Health Data Space, 8.
[496] Commission proposal for a Regulation on the European Health Data Space, 7.
[497] In the Netherlands, the right to informational self-determination was subject of debate in 2010, as the Dutch State Committee brought it forward. M. Overkleeft-Verburg, Artikel 10. In A.K. Koekkoek et al., *De Grondwet – een systematisch en artikelsgewijs commentaar* (Deventer: W.E.J. Tjeenk Willink 2000), 177. Also, B.J. Koops, Digitale grondrechten en de Staatscommissie: op zoek naar de kern, *Tijdschrift voor Constitutioneel recht*, March 2011.

To analyze this gap, we took a conceptual look at the EHDS. Though the EHDS does not provide for a global answer, it does provide for additional data protection of the individual and his health data beyond the realm of the traditional care provider–care receiver relationship. In our opinion, the EHDS is a starting point to foster human dignity in general, including addressing the individual's rights to data protection and control over his health data. A European governance structure is created with the EHDS and can be seen as a starting point to bridge the gap between the national autonomy of member states also in health law. The EHDS aims to protect the health data of individuals, and is not limited to protecting the patient's data only.

We reach the following preliminary conclusions. Firstly, both the EHDS and the Data Governance Act create opportunities for the protection of the individual and his health data beyond the traditional care provider–care receiver relationship. Secondly, although member states are given the opportunity to designate a sectoral monitoring body or bodies, we observe a missing link in the relationship between data protection in general and the individual's protection of his health data and safeguarding of his rights. We would argue that a next step is necessary, one that combines individual self-determination (as enshrined in health law) and informational self-determination (as enshrined in data protection law). In this respect, we consider that data protection authorities should cooperate more closely with (cross-) sectoral bodies to strike a balance between the individual and informational self-determination, and to reach a solution to the governance overlap.[498]

6.5. Conclusion

In this chapter, we elaborated on the fifth sub-question:

> *"In what way does the existing data protection and health legislative framework protect the individual's autonomy, his health data, and his position as a care receiver where commercial companies deliver health services?"*

Firstly, the WGBO protects the patient in existing health law, i.e. in the relationship between the care provider and care receiver. The care provider guarantees that the care receiver can share his health data without the fear of disclosure of his confidential data, as part of the professional medical secrecy. The care provider may not share the patient's health data in the traditional relationship unless a breach to the professional medical secrecy is justified. Additionally, the traditional health system is based on the patient's informed consent in the context of shared decision-making.

[498] Recital 41 and article 1(2) Data Governance Act, article 1 (4) EHDS.

The situation is quite the opposite in the new health context where the individual plays a different, active role in monitoring his health beyond the traditional care provider – care receiver relationship. In this new situation, the bond of trust between the care provider and care receiver is absent. The individual uses his own devises and draws conclusions about his health. In this context, he gives his consent to the processing of his personal data outside the realm of traditional health care, beyond the traditional legal framework. Since the individual is no longer safeguarded as a patient, the boundaries of individual self-determination are stretched by the individual and by the commercial companies that deliver health services. We conclude that the legislation must set norms for these forms of data processing beyond the traditional clinical realm. In addition, some forms of data processing must be prohibited where the individual runs a serious risk, such as the mere exploitation of the (further) use of health data for commercial purposes without a licensing system and qualitative controls.

Secondly, the individual's autonomy is not fully protected because of a legislative gap in the current legal framework. The individual's health data are protected by Dutch health law in the traditional care provider–care receiver relationship and, generally, by the GDPR. The individual's data protection is incomplete in the relationship between the commercial company and the individual. The legislation was set up by and between member states, whereas these developments take place beyond the traditional clinical realm by commercial companies. The member states alone cannot safeguard the individual's autonomy and control over his health data with the new, active role he himself plays. The individual runs the risk that his health data are processed for other purposes and by third parties.

Thirdly, we observe a governance gap and overlap in the individual's protection in health law – which safeguards the individual's self-determination and autonomy – and the individual's data protection – which safeguards the control over his personal data and informational self-determination. A next step is necessary to safeguard the individual's self-determination (as enshrined in health law) and his informational self-determination (as enshrined in data protection law). In our view, the European Health Data Space (EHDS) can play a pivotal role in the individual's protection of his health data for reasons as outlined below.

The EHDS creates a European governance structure and can be a driving force behind the aim of protecting the individual and his health data in a broader sense. Thus, the EHDS is a good point of departure for a) enhancing data protection, b) striking a balance between data protection and health law, and c) setting the agenda for a European governance framework in health. However, we also observe some difficulties

in the European ambitions, since health law – within the traditional clinical realm – is governed by member states. When it concerns national health matters, the EHDS must leave room for the supervisory systems within member states. We recommend a further analysis of the interaction between European data protection and national health law.

Additionally, we observe that the EHDS and Data Governance Act do not provide for sectoral supervision. We consider that national data protection authorities should cooperate more closely with sectoral health bodies to strike a balance between the individual's protection in data protection and health law, based on the governance structure offered by the EHDS. Thus, the governance structure should be broadened to safeguard both the individual's position and his data both in the traditional and innovative health contexts. Furthermore, clarity must exist as regards those bodies handling data protection issues. When both European supervisory authorities and national bodies address data protection issues, then the risk of conflicting contributions arises – with the possible result of legal uncertainty.

To conclude, the innovations call for joint action at the European and national levels to safeguard the individual's position and his data in health beyond the traditional care provider–care receiver relationship. We recommend a further legal analysis of the interaction between individual self-determination (in health law) and informational self-determination (in data protection law). We also recommend a sectoral supervisory body that monitors the individual's self-determination in health and his control over his health data. The EHDS creates a European governance structure that can be considered a starting point to bridge the gap between the national autonomy of member states in health law as well. Member states cannot counterbalance the commercial companies that operate at a global level. The EHDS can close the gaps in the individual's data protection rights in health, beyond his role as a patient in the traditional clinical setting.

Conclusions, recommendations and final considerations for future research

7. Conclusions, recommendations and final considerations for future research

This thesis was prompted by the problematic exchange of health data, both within the Netherlands and beyond. At least four issues are at the root of this, i.e.:[499]

a) the diverse interpretations of essential elements of consent;
b) the use of various legal bases within the European Union for the processing of health data;
c) the mere focus on protecting individual rights and interests while obstructing the free flow of data and, hence, the societal interest;
d) the shift away from a risk-based approach towards rule-based regulatory compliance.

Therefore, I aimed at answering the following main research question:

> *In what way can a balanced approach be found for the exchange of health data that serves the data protection of the individual and patient on one hand, and the furtherance of health research in the interest of society, on the other?*

This chapter starts with an answer to the main research question (section 7.1). Then, seven recommendations are shared (section 7.2). This chapter ends with six final considerations for further research (section 7.3).

[499] Chapter 1: Introduction.

7.1. Answering the main research question

The short answers to the main research question are as follows. A balanced approach can be found in the following four ways. Firstly, a broader interpretation of the concept of consent is possible to facilitate secondary health research in the Netherlands and the European Union. Although consent is an autonomous concept of EU law, which must be interpreted uniformly throughout the EU, member states interpret and implement the legal ground of consent in various ways. This obstructs the use of health data for secondary research purposes.

In the Netherlands, the lawful basis of consent is used following the provisions in the GDPR and UAVG.[500] Furthermore, the WGBO contains conditions for the further use of health data by others than the health care provider.[501] The GDPR provides for explicit consent as an exemption to the prohibition of the processing of health data. Recital 33 GDPR allows for some granularity of consent for research purposes.[502] Though the EDPB considers that the granularity should not be stretched too far, it does not further clarify what could fall within this broader scope.[503] In sum, a first answer is that the lawful basis of consent could be used for secondary health research provided that the granularity of consent is further explicated.

Secondly, the use of other lawful bases besides consent can be a solution in the Netherlands and the European Union for the legitimation of secondary health research.[504] The lawful bases of the public interest[505] as well as the legitimate interests[506] are used in the European Union.[507] A separate legal ground for secondary research purposes has not been included in the GDPR and could be a solution to resolve the issue of

[500] Article 6 (1) (a) together with article 9 (2) (a) and article 89 (1) GDPR; article 22 together with 24 UAVG.
[501] Article 7:457 and 7:458 WGBO.
[502] Recital 33 GDPR: *"(…) Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognized ethical standards for scientific research (…)."*
[503] EDPB, Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, 2 February 2021, para 26, at 7:
"(…) [T]he EDPB points out that, as stated in the EDPB Guidelines 05/2020 on consent under regulation 2016/679 (§153 and following), even though, for the cases where purposes for data processing within a scientific research project cannot be specified at the outset, Recital 33 allows as an exception that the purpose may be described at a more general level, the GDPR cannot be interpreted to allow for a controller to navigate around the key principle of specifying purposes for which consent of the data subject is asked. Therefore, when research purposes cannot be fully specified, a controller must seek other ways to ensure the essence of the consent requirements are served best, for example, to allow data subjects to consent for a research purpose in more general terms and for specific stages of a research project that are already known to take place at the outset."
R. Becker et al., Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers? *European Journal of Health Law*, 29, 1-29. https://doi.org/10.1163/15718093-bja10094.
[504] Chapters 3 and 4, in particular sections 3.2.2, 3.3, 3.3.2, 3.5, 4.3 and 4.5.
[505] Article 6 (1) (e) together with article 9 (2) (j) and article 89 (1) GDPR.
[506] Article 6 (1) (f) GDPR.
[507] European Commission, Assessment of the EU Member States' rules on health data in the light of GDPR, including the Annex with country fiches of all EU MS. Specific Contract No SC 2019 70 02 in the context of the Single Framework Contract Chafea/2018/Health/03. Also, E.B. van Veen, R.A. Verheij, Further use of data and tissue for a learning health system: the rules and procedures in The Netherlands, compared to Denmark, England, Finland, France and Germany, MLCF/Nivel, Utrecht, May 2022.

a proper lawful basis for secondary health research purposes.[508] Additionally, with the developments of the EHDS, provisions have been included as regards the use of data for healthcare and research purposes, referred to in the EHDS as the primary and secondary use.[509] For efficient data sharing among member states, it is desired that the member states allow for the use of different lawful bases for the exchange of health data for research purposes.[510] In the Netherlands, an amendment of article 24 UAVG, as well as articles 7:457 and 7:458 WGBO would be needed if the EHDS is adopted with the provisions on the secondary use of data.[511] This would also require an amendment of the draft Wzl. In sum, a second answer is that lawful bases other than consent legitimize the use of health data for secondary research purposes. Mutual recognition by the member states is a key factor in the use of different legal grounds for secondary research purposes. An amendment in the Dutch legislation is needed as regards the secondary use of data if the EHDS is adopted.

Thirdly, a balance can be found in the individual's autonomy and (informational) self-determination vis-à-vis the accountability of the health institution that processes his data, and the attention drawn to the free flow of data.[512] In health care and research, the individual exercises control over his data with the expression of his consent. However, he may not always be able to oversee the consequences of the expression of his will. In health care, a balance can be found in the triangle of care with the involvement of the care provider, the formal or informal representative and the care receiver when the individual is not or no longer capable of expressing his consent.[513] In health research, the balance can be found in the acknowledgement that the GDPR does not have as its objective

> *"(…) [t]o grant data subjects control over their personal data as a right in itself, or that data subjects must have the greatest control possible over those data."*[514]

[508] As explored in the United Kingdom in the proposals to the revision of the UK GDPR. See Chapter 5 supra.
[509] European Commission. (2022d, May 3). Proposal for a Regulation of the European Parliament and of the Council of 3 May 2022 on the European Health Data Space (Text with EEA relevance), articles 2 (2) (d) and (e).
Also, European Data Protection Board, Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, 2 February 2021, para 18, at 6.
[510] EDPB, 2 February 2021, footnote 509, para 16, at 6:
"It is advisable that controllers should as far as possible make an effort to limit the consequences of different Member States' legal regimes for processing health data for scientific research purposes, for instance by optimizing and thus harmonizing the rights of data subjects irrespective of the Member State they live in."
[511] Veenbrink, J. M., van de Gronden, J. W., & Glas, L. R. (2022). *Juridisch Advies over het voorstel voor een Verordening betreffende de Europese ruimte voor gezondheidsgegevens (European Health Data Space)*, 58.
[512] Hooghiemstra, T. (2018). *Informationele zelfbeschikking in de zorg*. SDU.
[513] Chapter 2, in particular sections 2.4 and 2.5.
[514] UI v Österreichische Post, Opinion of Advocate General Campos Sánchez-Bordona (Court of Justice of the European Union, 2022). ECLI ECLI:EU:C:2022:756, paras 73 – 74.

Furthermore, the GDPR aims at protecting individual rights together with the free flow of data.[515] Thus, a third answer is to find the balance between the individual's autonomy and self-determination vis-à-vis the free flow of data. The triangle of care, with the involvement of the individual, the care provider and the formal or informal representative may be a solution in health care when the individual is unable to express his will about his health and the necessary care for him. In health research, the accountability of the health institution is shown with the technical and organizational measures taken.[516] Furthermore, with the use of other lawful bases than consent, the focus is shifted from the individual's consent towards the public or legitimate interests of the data controller.[517] Additionally, the GDPR itself provides for the balance between the data protection rights on the one hand, and the free flow of data, on the other.[518]

Fourthly, a balance can be found in a risk-based rather than a rule-based approach by supervisory authorities.[519] To this end, clarification is required as regards the roles of the supervisory authorities. In Dutch health care and research, both general and sectoral supervisory authorities monitor compliance with general data protection legislation (GDPR, UAVG) and sectoral health legislation (inter alia, proposal for a regulation on the EHDS, WGBO, draft Wzl, Wlz). In Europe, with the development of the EHDS, yet another supervisory mechanism is established, the Health Data Access Bodies.[520] The relationship between the European and Dutch supervisory authorities, as well as between the Dutch authorities, deserves clarification as to the respective roles, tasks and functions. Furthermore, the data controller has to show compliance with, inter alia, data protection impact assessments,[521] records of processing activities[522] and data breaches.[523] A balance can be found in the development of best practices for fair, transparent, and lawful data processing by the data controllers and, hence, a more risk-based approach by the supervisory authorities. Thus, a fourth answer is that monitoring authorities could focus on risk-based rather than rule-based

[515] Article 1 (1) GDPR: *"This Regulation lays down rules relating to the protection of natural persons with regard to the processing of personal data and rules relating to the free movement of personal data."*
[516] Article 24 (1) and (2) together with article 32 (1) GDPR.
[517] For instance article 6 (1) (e) GDPR: *"(…) [P]rocessing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller"*, or article 6 (1) (f) GDPR: *"(…) [P]rocessing is necessary for the purposes of the legitimate interests pursued by the controller (…)."*
[518] Recital 4 GDPR: *"The processing of personal data should be designed to serve mankind. The right to the protection of personal data is not an absolute right; it must be considered in relation to its function in society and be balanced against other fundamental rights, in accordance with the principle of proportionality (…)."* And, Recital 6 GDPR: *"(…) Technology has transformed both the economy and social life, and should further facilitate the free flow of personal data within the Union and the transfer to third countries and international organizations, while ensuring a high level of the protection of personal data (…)."*
[519] Section 5.3.3 supra.
[520] Article 37 EHDS. See section 6.4.2 supra.
[521] Article 35 GDPR.
[522] Article 30 GDPR.
[523] Article 33 (5) GDPR.

monitoring. Furthermore, the different roles, tasks and functions of these supervisory authorities should be clarified.

The following sections contain a more detailed answer to the main research question with a focus on the following components. I start with the legal framework (section 7.1.1) upon which I continue with the legitimation for the use of health data (section 7.1.2). Then, I focus on the individual rights on the one hand and the free flow of data on the other (section 7.1.3). Lastly, I reach conclusions on monitoring compliance (section 7.1.4).

7.1.1. The legal framework

A balanced approach can be found in the GDPR itself. The GDPR provides for a general legal framework and does not prescribe a particular interpretation. Then, new developments take place with the proposal for a Regulation on the European Health Data Space. This Regulation aims at promoting the exchange of and access to different types of electronic health data, including electronic health records, genomics data, patient registries to further health care and research.[524] Additionally, the Data Act and Data Governance Act have entered into force since the start of this thesis.

In the Netherlands, the Dutch Act on Quality Registrations (*Wet Kwaliteitsregistraties Zorg*) is currently prepared. In the field of research, the draft Dutch Authority over Human tissue Act (*Wet zeggenschap lichaamsmateriaal, Wzl*) is prepared and a renewed proposal for an amendment is foreseen in the spring of 2024. In view of most recent developments of the EHDS and the lawful basis of processing for secondary use, the plenary debate was postponed in 2023. If the EHDS is adopted, then article 24 UAVG, as well as articles 7:457 and 7:458 WGBO would need to be amended. Lastly, the initiatives by the executive power, i.e., the Dutch Ministry of Public Health, Welfare, and Sport, in cooperation with representatives from the field who joined their efforts in Health-RI and the Royal Netherlands Standardization Institute (*Nederlands Normalisatie Instituut, NEN*), have presented the first results.[525]

7.1.2. The legitimation for the use of health data

A balanced approach to the legitimation for the use of health data serves to enhance the exchange of data for clinical and research purposes. The legitimation with the lawful basis of consent for the use of health data for clinical and research purposes is not always adequate for the following reasons. Firstly, the four elements of consent cannot always be satisfied.[526] Secondly, a comprehensive interpretation of consent among EU

[524] Explanatory memorandum EHDS: *"(…) [T]he uneven implementation and interpretation of the GDPR by Member States creates considerable legal uncertainties, resulting in barriers to secondary use of electronic health data."*
[525] https://www.health-ri.nl/lees-en-kijk-materiaal. Accessed 29 January 2024.
[526] Article 4 (10) GDPR.

member states is absent, as the meaning and scope of consent differ in the Union. Thirdly, the percentage of consent given among particular diseases, populations, and minority groups, for instance, differs. As a result, a biased research population may exist. Fourthly, the individual is not always capable to express his will with consent.

Furthermore, the individual's consent does not exempt the controller from implementing appropriate safeguards for the data processing. Each data processing must be carried out in accord with the general data protection principles of article 5 GDPR. In short, the controller is responsible for safeguarding these principles. The processing must take place based on a lawful basis. Additionally, the individual's rights must be respected. Again, regardless of which lawful basis is used, the controller must fulfill these obligations. Thus, the focus should not be primarily on determining the proper legal basis for the data processing, but rather on the underlying assessment and guarantee that the data controller respects legal principles and human values.

In some member states of the European Union, recourse can be had to another lawful basis, such as the public interest or legitimate interests.[527] In the United Kingdom, a separate lawful basis for (health) research is considered.[528] The developments of the EHDS are of particular importance, as well as the recent developments in the Netherlands.[529] These recent developments in the Netherlands are promising with a new amendment to the proposal of the Wzl and the advice from the Dutch Data Protection Authority on the excess mortality rates during the COVID-19 pandemic.[530] If the Dutch proposal of the Wzl will be amended in view of the EHDS, then articles 7:457 and 7:458 WGBO, as well as article 24 UAVG, would need to be amended as well. In the course of time, integral sectoral health legislation in the Netherlands is an option for establishing a separate lawful basis for secondary health research.

As regards the further processing for research purposes, the data controller, i.e. the health institution in this thesis, must demonstrate that the processing is based on a lawful basis.[531] The controller must show compliance with the principles enshrined in article 5 GDPR, and must adopt the institutional and technical safeguards.[532] Thus, the special regime regarding the further processing for research purposes may not constitute a derogation from the data subject's rights.

[527] Article 6 (1) (e) together with article 9 (2) (i) or (j) and article 89 (1); article 6 (1) (f) together with article 89 (1) GDPR.
[528] Chapter 5 supra.
[529] Section 7.1.1 supra. A Letter to Parliament is expected in the spring of 2024 in the Netherlands. This letter will address, inter alia, data sharing in the interest of secondary research purposes.
[530] Autoriteit Persoonsgegevens, Adviesverzoek onderzoek oversterfte, 13 februari 2023. https://www.autoriteitpersoonsgegevens.nl/uploads/imported/advies_ap_onderzoek_oversterfte.pdf. And, https://www.eerstekamer.nl/behandeling/20230223/brief_regering_verzoek_uitstel/document3/f=/vm11ejjmm2sk.pdf. Accessed 29 January 2024.
[531] Article 6 and 9 together with article 89 (1) GDPR.
[532] Article 24, 32 and 89 (1) GDPR. European Data Protection Supervisor, A Preliminary Opinion on data protection and scientific research, 6 January 2020, 17.

7.1.3. Individual rights or interests and the free flow of data

The rights to data protection and privacy are not absolute. These rights must be seen in conjunction with the free flow of data and the protection of other human rights or interests. The general framework of the GDPR leaves room for a comprehensive interpretation of concepts. Furthermore, the individual rights or interests are not guaranteed only by the lawful basis of consent. Other lawful bases must equally safeguard these rights and interests. Moreover, regardless of which lawful basis is used, the controller must fulfill its obligations in chapter III GDPR on the rights of the data subject.

Additionally, the individual's rights must be safeguarded in today's innovative developments and the new position that the individual plays in monitoring his own health. The traditional relationship between the care provider and care receiver is absent.[533] The EHDS may provide additional safeguards. This act focuses on data protection on the one hand and the necessity of and the challenges to the exchange of data for health care, research, and innovations on the other. Innovative developments are already taking place and require innovative answers to both the individual and his data.

A comprehensive interpretation of the concepts is both legally possible and necessary in the search for a balanced approach between data protection and the free flow of data. Concepts in the law are interpreted differently among member states and within the member states themselves. The concepts need not only be interpreted from the perspective of individual self-determination, autonomy, and the rights or interests of the individual, but also from the perspective of the free flow of data and the furtherance of health research. Thus, data processing of health data for care and research purposes is in the best interest *of* a specific patient, and in the societal interests *for* all patients.

7.1.4. Monitoring compliance

Lastly, a balanced approach is required to monitoring compliance by the Data Protection Authority and other (sectoral) supervisory mechanisms. This requires a risk-based approach from the authorities to serve both the individual rights or interests and the free flow of data. One of the main principles in the GDPR concerns the accountability of the controller.[534] However, a rule-based system of regulatory compliance rather than a risk-based system has been established.

The data controllers must demonstrate compliance with, for instance, a record of data processing activities (article 30 GDPR) and data protection impact assessments (article

[533] Chapter 6 supra.
[534] Article 5 GDPR.

35 GDPR). Additionally, prior consultation with the supervisory authority must take place where a data protection impact assessment indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk (article 36 GDPR). The appointment of a data protection officer must be notified as well (articles 37 – 39 GDPR). Furthermore, the controller is obliged to notify the Data Protection Authority of all data breaches unless a breach does not pose a material risk to the rights and freedoms of the individual (articles 33 and 34 GDPR). These requirements place a burden on both the organizations and the individuals, since time is devoted to compliance rather than to the development of best practices for fair, transparent, and lawful data processing.

With the new legislative developments of the EHDS and AI Act, questions are raised by the EDPB and EDPS on the interaction between (additional) supervisory bodies established within the EHDS and AI Act and the existing supervisory bodies established by the GDPR and national, sectoral health legislation.[535] In the Netherlands, the Dutch Health care Inspectorate (*Inspectie Gezondheidszorg, IGJ*) and the Dutch Health care Authority (*Nederlandse Zorgautoriteit, NZA*) monitor health care. The Dutch Data Protection Authority provides advice and carries out supervision of data protection.

Overall, a wide array of supervisory and monitoring mechanisms have been established in the applicable legislation and are forecast to be established with the future legislative development of the EHDS. The EHDS proposes a governance structure aiming at closer cooperation between national data protection authorities and sectoral health bodies. In the Netherlands, the Dutch Ministry of Public Health, Welfare and Sport launched the Program HDAB-NL on 23 December 2023.[536] Clarification about the different roles, tasks and functions is needed in such a manner that the health care and research institutions know what is expected and which authority they can consult for further questions.

7.2. Recommendations

In the context of this thesis, I offer the following seven recommendations to the European and Dutch legislature, as well as to the supervisory authorities in data protection and health law.

[535] EDPB - EDPS Joint Opinion 5/2021 on the proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act), 18 June 2021. Also, EDPB - EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, 12 July 2022.

[536] https://www.gegevensuitwisselingindezorg.nl/actueel/nieuws/2023/12/04/vws-start-programma-health-data-access-body-hdab-nl. Accessed 29 January 2024.

Recommendation 1: Emphasize the burden of control by the data controller

Firstly, I recommend that the data controller acknowledges and emphasizes its burden of control as regards data processing. The individual is neither able to exercise sufficient control over the processing of his data, nor is he able to implement the necessary technical and organizational measures. Therefore, regardless of which lawful basis is used for data processing in health care and research, the data controller must take the necessary technical and organizational measures. It must meet the principles of fairness, necessity, and proportionality, as well as data quality (recitals 32, 33, 42, and 43, article 5 GDPR). In addition, the controller must be able to demonstrate that consent is given (recital 42, articles 4 (11) and 7 GDPR). Furthermore, the data controller must inform the individual in a clear, transparent manner about the data processing. The information provided to the individual must be comprehensible and easily accessible, for instance on the internet, via information leaflets or video-screens at the data controller's premises. The individual should not carry the weight of his consent as a legitimation for the processing of his health data. The controller is accountable for the data processing regardless of the lawful basis applied.

Recommendation 2: Mutually agree on the use of various lawful bases for secondary research purposes

Secondly, I recommend that a further analysis be carried out whereby other lawful bases, in addition to consent, serve as a proper legitimation for the secondary use of health data in research, and under which conditions these lawful bases can be applied. In the European Union, other lawful bases than consent are used by member states that may serve as potential solutions in the Netherlands as well. A coherent European approach has not yet been achieved, as the GDPR allows member states to adopt various and diverging implementation laws. Nevertheless, the fact that the processing of health data for research across Europe is carried out pursuant to different perceptions of consent, as well as other legal bases, does not necessarily mean that the individual's rights receive better protection in country X than in country Y. Yet, these differences complicate trans-border data flows between the EU and elsewhere.

I recommend that member states acknowledge the use of different legal grounds based on which the data exchange for health research takes place. This requires mutual trust between the research institutions that the rights and interests of the individual are safeguarded, while the controller undertakes the necessary technical and organizational measures, regardless of which lawful basis is applied. It also requires mutual trust between the member states as regards the choice of a lawful basis and specific member state laws. Some member states have specified, prescribed, or excluded the

lawful bases for processing health data for scientific research in specific member state law. Other member states have explicated in member state law whether an exemption on article 9 (1) may be based on article 9 (2) (g), (i) or (j) in conjunction with article 6 (1) (a), (e), or (f) GDPR. Since a European Code of Conduct does not seem feasible in the short run, I recommend that the potential lack of homogeneity among member states be solved with the mutual acknowledgement of different lawful bases used for the secondary use of health data for research. Furthermore, the developments in the EHDS should be aligned with the current legal framework of the GDPR, AI Act, Data Act and Data Governance Act.

Recommendation 3: Aim for a comprehensive interpretation of the lawful basis of consent

Thirdly, I recommend that the lawful basis of consent be interpreted in a comprehensive manner. Suffice it to say that the elements of consent, i.e., the freely given, explicit, informed, and unambiguous consent, require an interpretation that coincides with reality and cultural differences.

In health care, I recommend that careful attention be given to the capacity of the individual and, therefore, the expression of his consent. With his consent, the individual expresses his free choice and self-management in the care given to him. However, he may withhold himself from required care when he expresses his will, for instance in the case of individuals developing dementia. In these situations, the triangle of care with the involvement of the individual, health provider, and representative deserves further attention. In practice, this not only requires a legislative amendment, but also a procedural and system change since the access to the electronic health record takes place with the individual's consent himself. A formal or informal representative may request authorization to access his health record but again, consent from the individual himself must be given. Then, the vicious circle of consent is complete.

In the case of health research, the element "informed" may not be completely achieved when the research was initiated. The researcher may not be aware of findings that become known at a later stage and that may form the basis for new research. Asking repetitive consent may place a burden on the individual, particularly in the case of longitudinal studies, which can last for several decades. The individual's consent is also reflected in the trust and the reasonable expectations based on his relationship with the controller, i.e., the health research institution.[537]

[537] Recital 50 GDPR.

Recommendation 4: Separate the lawful basis of consent from the assumption of the individual's full control over his data

Fourthly, I recommend that a fair balance be achieved in practice between data protection rights and the free flow of data. To this end, I recommend that the lawful basis of consent be separated from the assumption that the individual has full control over his personal data. The individual, in his role as patient or client who receives medical care and whose data could be of value for health research, may very well not read, let alone understand privacy statements or balance the pros and cons of his consent. The GDPR (articles 12 – 22) grants the individual a number of rights as regards his personal data, rights that he can exercise towards the data controller. However, this does not mean that he actually owns or controls the data himself or that the GDPR grants the individual full control over his data.

Recommendation 5: Explain concepts in European legislation

Fifthly, I recommend that the concepts of secondary use, further processing, public interest and research in the GDPR be further detailed, preferably by the EDPB. The interpretation of the GDPR framework substantially differs among member states. This has resulted in fragmentation rather than a common approach to the interpretation and use of health data. Additionally, I recommend that similar concepts used in the GDPR, the EHDS, and the AI Act be explained. Confusion arises when there is a different scope or interpretation of similar concepts used in the GDPR, EHDS, and AI Act. These concepts warrant further clarification, also as regards the relationship between the general GDPR and the specific EHDS and AI Act.

As regards the EHDS in particular, I recommend further clarification of the concepts of 'primary use of health data' and 'secondary use of health data', in line with the EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space. For instance, health data from diagnostics and care are used to improve the quality of care and for public registries. The data may also serve as an important source for secondary research. Furthermore, the individual who monitors his own health may also present the data collected from his wearable to the health provider. The question arises when the data are processed for primary use and when they are collected for secondary use. The GDPR does not include the EHDS concept of "secondary use of health data." Instead, it uses the concept of "further processing of personal data." The concept of "further processing" refers to the purpose for which the controller originally processed the data.

Recommendation 6: Aim for a risk-based approach in monitoring and supervision

Sixthly, I recommend that the risk-based approach, which has been included in the GDPR, be given new impetus by the supervisory authorities. In practice, data controllers have to demonstrate compliance with the obligation to record data processing activities (article 30 GDPR), Data Protection Impact Assessments (article 35 GDPR) and to record data breaches (article 33 (5) GDPR). Furthermore, the presence of a data protection officer is required (articles 37 – 39 GDPR). Although the obligations have proved useful, they do not ensure that the individual rights or interests are guaranteed. I recommend that the data controller focus more on the balance between the individual rights or interests and the free flow of data, while fulfilling the obligations enunciated in article 5 GDPR. The return to a risk-based approach by the data controller also requires a shift by the data protection authorities.

Recommendation 7: Aim for a closer cooperation between Data Protection Authorities and sectoral supervisory mechanisms

Seventhly, I recommend that the Data Protection Authorities in the Netherlands and the European Union cooperate more closely with sectoral, health care supervisory bodies. This way, the individual is protected from both the data protection and health law perspectives. Since the individual plays an active role in monitoring his own health and sharing data beyond the traditional care provider–care receiver context, I recommend that the governance structure be extended to safeguard his position in both contexts. The governance structure offered by the EHDS can be a starting point to closing the gaps in the individual's data protection rights regarding health beyond his role as a patient in the traditional setting. In addition, the EHDS can also provide a framework to close the gap between the supervisory mechanisms in health and the general data protection authorities.

7.3. Final considerations for future research

Although I identified a considerable number of pending questions while working at the Netherlands Cancer Institute – Antoni van Leeuwenhoek hospital, questions that comprise a valuable basis for my thesis, I have not been able to connect all the capillaries. In delineating my thesis, I purposely left open a number of questions that would benefit from further research. Therefore, I end this study with six final considerations for future research.

Firstly, future research is recommended on the principles of solidarity and reciprocity in secondary health research.[538] The starting point for this research could be the Universal Declaration of Human Rights (UDHS), which was adopted by the General Assembly of the United Nations in 1948, where article 27 (1) states that

> *"Everyone has the right (…) to share in scientific advancement and its benefits (…)."*

Furthermore, the GDPR seeks to harmonize the protection of fundamental rights and freedoms of natural persons in respect of processing activities and to ensure the free flow of personal data among member states. In health research, personal data, either directly or indirectly identifiable to the individual, are of crucial importance to advancing science. Today's patients and their data form the basis of tomorrow's research. Their data sharing may not cure those patients, but may cure those of future generations indeed.

Research could be carried out to determine how the individual may, could or perhaps should serve the common good in sharing his personal data for secondary health research. Data processing of health data for care and research purposes is in the best interest *of* a specific patient, and in the societal interests *for* all patients. The other side of the same coin comprises the limits to economic gain with these personal health data. Data registers of health data and biobanks are valuable sources for investors and, therefore, a driving force behind the global health data economy. Further research could analyze the limits to the individual solidarity and reciprocity as regards data sharing in health.

In a broader perspective, such further research fits into the debate on how privacy and data protection should be regulated, particularly as regards the discrepancy between the so-called Individual Control Model and the Societal Structure Model. The Individual Control Model aims

> *"(…) to empower individuals with rights to help them control the collection, use, and disclosure of their data.*[539]

The Societal Structure Model starts

[538] B. Prainsack, (2018). The "we" in the "me" solidarity and health care in the era of personalized medicine. *Science, Technology, & Human Values*, 43(1), 21-44. R. Yotova, & B.M. Knoppers, (2020). The right to benefit from science and its implications for genomic data sharing. *European Journal of International Law*, 31(2), 665-691.

[539] D.J. Solove & W. Hartzog (2024). Kafka in the Age of AI and the Futility of Privacy as Control (January 5, 2024). *104 Boston University Law Review* (2024, Forthcoming), at 2. Available at SSRN: https://ssrn.com/abstract=4685553 or http://dx.doi.org/10.2139/ssrn.4685553. Accessed 11 February 2024.

> *"(…) [w]ith the recognition that privacy is not purely (or even primarily) an individual interest; instead, privacy should be protected for the purpose of promoting societal values such as democracy, freedom, creativity, health, and intellectual and emotional flourishing."* [540]

Furthermore, the Individual Control Model presupposes the individual control over their data, whilst the individual cannot completely control his data, especially in today's world where the individual is surrounded by technological innovations:

> *"Turning to modern digital technologies, individual control is often an illusion. People don't exercise control in a meaningful way. Merely being in a command center with various switches, buttons, and levers is mere theater unless people have the ability and knowledge to operate the controls. The individual's ability to exercise control always exists within a larger power structure."* [541]

Secondly, future research is recommended into the elements of informed (ethical) consent as enunciated in the Clinical Trials Regulation, and the elements of consent in the GDPR, especially with regard to new legislative developments in the Netherlands. For instance, the draft Wzl has incorporated the four elements of consent from the GDPR. Research could be carried out to determine when informed (ethical) consent or when GDPR consent is privileged to legitimize the use of health data for research purposes. Furthermore, the elements of consent and the way in which this consent is expressed by the patients deserve further attention. Lastly, an alternative legal ground could be considered in the Netherlands, as regards the (further) use of data for scientific research. The EHDS has paved the road for more integration in the field of health at EU level. These developments will influence the legal developments in the Netherlands as well.[542]

Thirdly, future research is recommended on the interaction between latest European legislative initiatives (EHDS, AI Act, Data Act, and Data Governance Act) and the Dutch legislative developments (inter alia, the draft WzL). Additionally, future research is recommended on the interaction between the GDPR, the UAVG, and specific, sectoral health legislation. This future research could also include a further

[540] D.J. Solove & W. Hartzog, footnote 539, at 7.
[541] D.J. Solove & W. Hartzog, footnote 539, at 11.
[542] Organization for Economic Co-operation and Development. (2021). Toward an integrated health information system in the Netherlands. Draft interim brief and recommendations, at 29:
"Revisions may be needed to legacy legislations that are posing unnecessary obstacles to an integrated health information system, such as revisions to the Medical Treatment Contracts Act (Wgbo) to allow for lawful alternatives to consent for data exchange and uses in the public interest; to legislation authorizing the Central Bureau of Statistics to allow it to act as a central hub for access to health datasets; and to regulations related to consumers and markets that prevent health care collaborations and data integration."

elaboration on terminology in the current legislation, as well as and compared to the legislative proposals in the Netherlands and Europe.

Fourthly, future research is recommended on the mission and tasks carried out by data protection authorities and sectoral supervisory bodies. Supervisory authorities have been established in the health sector, both European and national, and both general and specific. In the Netherlands, the Dutch Health care Inspectorate (*Inspectie Gezondheidszorg en Jeugd*, IGJ) and the Dutch Health care Authority (*Nederlandse Zorgautoriteit*, NZA) supervise the health care sector, while the Dutch Data Protection Authority (DPA) supervises data protection in general. Furthermore, the Dutch Data Protection Authority carries out supervision as regards the AI Act as well. A European Health Data Space Board will also be created as regards the re-use of health data, which builds on the framework introduced by the Data Governance Act. This future research could not only unravel the patchwork of monitoring mechanisms in Europe and among member states, but it could also elaborate on the question of how these authorities could design risk-based rather than rule-based regulatory compliance.

Fifthly, future research is recommended regarding the individual's own role in monitoring his health. The processing of health data by commercial service providers may pose a risk to personal data protection. In Chapter 6, my co-author and I analyzed the traditional relationship between the care provider and receiver. This relationship is absent when the individual engages into monitoring his own health whilst buying self-tracking devices. Future research could further unravel the individual autonomy, self-determination and informational privacy amidst the use of new technologies.

Lastly, further research is recommended regarding the proper communication strategy for informing a patient population, a nation's population, or any other population in the EU, about the use of his data for clinical and research purposes. Regardless of which lawful basis is chosen for the legitimation of the exchange of data, the population should be reached in the most efficient way and with the best informative tools. This research should consider cultural influences, different educational backgrounds and literacy of the European citizens. A tailor-made communication strategy for different target groups contributes to a feeling of trust and willingness to share health data.

8. Bibliography

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9. Index of cases

Presented in chronological order

Court of Justice of the European Union

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Orange Romania SA v Autoritatea Națională de Supraveghere a Prelucrării Datelor cu Caracter Personal (ANSPDCP) (Court of Justice of the European Union, 2020). ECLI:EU:C:2020:901.

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Germany

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The Netherlands

1590 Besch (Hoge Raad der Nederlanden, 1985). ECLI:NL:HR:1985:AC9105

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Staat der Nederlanden tegen Clara Wichmann C.S. (SGP-Uitspraak) (Hoge Raad der Nederlanden, 2010) ECLI:NL:PHR:2010:BK4549

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Millecam (Hoge Raad der Nederlanden, 2013). Conclusie in cassatie: ECLI:NL:PHR:2013:BY4859

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Presented in chronological order

European Data Protection Board, formerly the Article 29 Working Party

Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (WP 131), adopted on 15 February 2007.

Article 29 Data Protection Working Party, Opinion 4/2007 on the concept of personal data (WP. 136), adopted on 20 June 2007.

Article 29 Data Protection Working Party, Opinion 15/2011 on the definition of consent (WP 187), adopted on 13 July 2011.

Article 29 Data Protection Working Party, Opinion 03/2013 on purpose limitation (WP 203), adopted on 2 April 2013.

Article 29 Data Protection Working Party, Opinion 06/2014 on the notion of legitimate interests of the data controller under Article 7 of Directive 95/46/EC, (WP 217), adopted on 9 April 2014.

European Data Protection Board, Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (Art. 70.1.b)). Adopted on 23 January 2019.

European Data Protection Board, Guidelines 1/2019 on Codes of Conduct and Monitoring Bodies under Regulation 2016/679, 4 June 2019.

European Data Protection Board, Guidelines 05/2020 on consent under Regulation 2016/679, version 1.1, adopted on 4 May 2020.

European Data Protection Board, Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, adopted on 2 February 2021.

EDPB Guidelines 04/2022 on the calculation of administrative fines under the GDPR, Version 2.1, adopted on 24 May 2023.

European Data Protection Supervisor
European Data Protection Supervisor, Opinion 4/2015. Towards a new digital ethics. Data, dignity and technology, 11 September 2015.

European Data Protection Supervisor, EDPS Guidelines on assessing the proportionality of measures that limit the fundamental rights to privacy and to the protection of personal data, 19 December 2019.

European Data Protection Supervisor, A Preliminary Opinion on data protection and scientific research, 6 January 2020.

European Data Protection Supervisor, Preliminary Opinion 8/2020 on the European Health Data Space, 17 November 2020.

Agencia Española de Protection de Datos & European Data Protection Supervisor (2021). Joint Paper, 10 Misunderstandings related to anonymization.

European Data Protection Supervisor, *Data protection*.

European Data Protection Supervisor, *The EDPS quick-guide to necessity and proportionality*.

Joint Opinions by the European Data Protection Board and European Data Protection Supervisor
European Data Protection Board – European Data Protection Supervisor Joint Opinion 5/2021 on the proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act), 18 June 2021.

European Data Protection Board – European Data Protection Supervisor Joint Opinion 02/2022 on the Proposal of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act), 4 May 2022.

European Data Protection Board – European Data Protection Supervisor Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, 12 July 2022.

11. List of professional activities and affiliations

Professional activities[543]

2018 - present:

• Data protection officer at the Netherlands Cancer Institute. The advices to both clinicians and researchers have served as a foundation for identifying and defining the scope of this thesis. Furthermore, I am the first point of contact for patients as regards privacy-related questions. I give workshops to colleagues and I participate in meetings of moral deliberations.

2019:

• 25 – 26 March 2019: Cancer Core Europe Annual Meeting in Barcelona. Member of the Data Access Committee (DAC).

• July: submission of a conference paper for the sixth International Workshop on Genome Privacy and Security (GenoPri'19) on 20 and 21 October 2019 in Boston, Massachusetts. Title of the paper: "GDPR consent requirements and other legal bases for processing." [544]

• 25 November 2019: Data Access Committee (DAC) of Cancer Core Europe at the Netherlands Cancer Institute, Amsterdam.

• 2 September 2019: panelist at the Work forum about Artificial Intelligence at the Netherlands Cancer Institute, Amsterdam.

• 6 November 2019: moderator at the Congress on Internet Accountability in the Digital Age at the Peace Palace in The Hague.

2020:

• 4 and 5 February 2020: guest speaker at the Data Protection World Forum in London. Topic: international data transfers in health research.

• 24 February 2020: guest speaker at the ELSI (Ethical, Legal and Social Issues) workshop on the GDPR and observational health research, organized by the ELSI Servicedesk of Health-RI (Research Infrastructure).[545]

• 11 March 2020: participant at the round table, organized by the Dutch Data Protection Authority.

• 1 June 2020: publication of my GDPR brief for the Global Alliance for Genomics and Health (GA4GH) on "The interplay between the Clinical Trials Regulation and the GDPR."[546]

[543] The list includes professional activities from 2018 until January 2024.
[544] For the full program, see https://broadinstitute.swoogo.com/ga4gh7thplenary/388434. Accessed 30 October 2023.
[545] https://elsi.health-ri.nl/nieuws/meld-u-nu-aan-voor-workshops-over-verantwoord-nader-gebruik-van-lichaamsmateriaal-en-data. Accessed 30 October 2023.
[546] https://www.ga4gh.org/news_item/ga4gh-gdpr-brief-the-interplay-between-the-clinical-trials-regulation-and-the-gdpr-june-2020/. Accessed 30 October 2023.

• 10 June 2020: guest speaker at the virtual AI Symposium, organized by the Elisabeth Twee Steden hospital.[547]
• 16 June 2020: member of the advisory group on the Revision of the Code of Conduct in Health Research (*Herziening Gedragscode Gezondheidsonderzoek*)
• February – July 2020: member of the task group on the digitalization of consent, organized by the Cooperation Organization for digital services in higher education and research *(Samenwerkingsorganisatie voor Computerdienstverlening in Hoger Onderwijs en Onderzoek (SURF)*
• 25 August 2020: participant at the Roundtable of data protection officers, organized by the Dutch Data Protection Authority on the topic of "De-regulate science" (*Ontregel de wetenschap*).

2021:
• From 2020 – 2021: member of the expert group of the model authorization of the Dutch Basic Registration of Persons (*Basis Registratie Personen*). Result: revision of the Dutch Authorization Decree (*Autorisatiebesluit*).
• 26 May 2021: completion of the course Scientific Conduct for PhD candidates in Law.
• Fall: Completion of the Course Philosophy of Science for PhD candidates by Leiden University (5 ECTS).
• Fall: co-author of a case study, a dilemma with legal, ethical and medical components. This case study was published in the Dutch Journal of Health care and Ethics (*Tijdschrift voor Gezondheidszorg en Ethiek*).[548]
• 17 – 19 November 2021: IAPP Conference in Brussels.

2022:
• 19 May 2022: presentation at the General Membership meeting of the Dutch Association of data protection officers (*Nederlands Genootschap voor Functionarissen Gegevensbescherming, NGFG*).
• 8 and 9 June 2022: guest speaker at the IAPP Dutch Intensive.
• August 2022: interview as 'Captain of Privacy', organized by the Dutch Center for Information Security and Privacy (*Centrum voor Informatiebeveiling en privacybescherming, CIP)*.[549]
• August 2022 – present: member of the Data Protection Advisory Committee at the Municipality of Amsterdam *(Commissie Persoonsgegevens Amsterdam*).

[547] https://www.etz.nl/Over-ETZ/Nieuws/2020/06/Veel-belangstelling-online-Ai-symposium. Accessed 30 October 2023.
[548] T. Smorenburg et al., Casus: altijd transparant over medische informatie? Tijdschrift voor Gezondheidszorg en Ethiek, 3(2021)31. https://www.tijdschrifttge.nl/art/50-6663_Casus-Altijd-transparant-over-medische-informatie. Accessed 30 October 2023.
[549] https://www.it-academieoverheid.nl/actueel/nieuws/2022/10/27/captains-of-privacy. Accessed 30 October 2023.

• 24 November 2022: guest lecture at the Free University of Amsterdam (*Vrije Universiteit Amsterdam)*.

2023:
• 2022 – 2023: member of the Health-RI expert group on legislative developments in the Obstacles Removal Trajectory (*Obstakel Verwijder Traject, OVT)*.
• 15 – 16 March 2023: Guest speaker at the Dutch Hospital Association (*Nederlandse Vereniging van Ziekenhuizen, NVZ*).
• 16 May 2023: guest lecture for clinicians and researchers at the Academic Medical Center in Leiden on data sharing in health care and research.
• 23 May 2023: master class on data protection in health care and research, hosted at Erasmus University, together with the data protection officer at the Erasmus Academic Medical Center in Rotterdam.
• 6 June 2023: guest lecture at the Center of expertise for standardization and Ehealth (Nederlandse kennisorganisatie voor digitale informatievoorziening in de zorg, Nictiz).
• 1 June – present: chair of the privacy committee at the Netherlands Institute for Health Services Research (*Nivel, Nederlands Instituut voor Onderzoek van de Gezondheidszorg*).
• 15 June 2023: guest speaker at the International Association of Privacy Professionals (IAPP) Dutch Intensive.
• 4 September 2023: guest speaker at the International Litigation Forum in Amsterdam. Topic: international data sharing in health & legal foundations.
• 21 – 22 September 2023: guest speaker based on a conference paper at the symposium on Privacy in Context in Toronto, with author and organizer prof. Helen Nissenbaum.[550]
• 27 September 2023: guest speaker at the World Litigation Forum in Amsterdam. Topic: preventive actions in international data sharing.
• 12 October 2023: panelist at the Health-RI (Research Infrastructure) conference.
• 9 November 2023: guest speaker at the National Biobanking and Collections Day.
• 14 November 2023: guest speaker at the Center for Post-graduate Legal Education (*Centrum voor Postacademisch Juridisch Onderwijs, CPO*).
• 15 November 2023: guest speaker at the NedMec Congress (the Medical Research Ethics Committee (MREC) NedMec is the medical research ethics committee to which the Antoni van Leeuwenhoek, the Princess Máxima Center for pediatric oncology and the UMC Utrecht are affiliated).

[550] Based on her conceptual framework of privacy. See, inter alia: Nissenbaum, H. (2020). *Privacy in context: Technology, policy, and the integrity of social life*. Stanford University Press.

2024:
• 22 and 23 January 2024: guest speaker at the World Litigation Forum in Dubai. Topic: emerging trends in data privacy and litigation.

Professional affiliations and memberships
• Member of CIP; member of the group of legal experts for CIP.
• Member of Collaborating Intramural Health Institutions in the Amsterdam Region (*Samenwerkende Intramurale Gezondheidszorgvoorzieningen Regio Amsterdam, SIGRA*).
• Member of the Regulatory Ethics Working Group of the Global Alliance for Genomics and Health (GA4GH).
• Member of the expert group of data protection officers at the Dutch Hospital Association (*Nederlandse Vereniging van Ziekenhuizen, NVZ*).
• Member of the Dutch Association of data protection officers (*Nederlands Genootschap voor Functionarissen Gegevensbescherming, NGFG*).
• Member of the International Association of Privacy Professionals (IAPP).
• Member of two expert groups at Health-RI (Research Infrastructure).
• Member of the Data Protection Advisory Committee at the Municipality of Amsterdam *(Commissie Persoonsgegevens Amsterdam*).
• Chair of the privacy committee at the Netherlands Institute for Health Services Research (*Nivel, Nederlands Instituut voor Onderzoek van de Gezondheidszorg*).

12. Curriculum Vitae

Irith Rolinka Kist (Broek in Waterland, 1972) completed her secondary education at the Gymnasium in Apeldoorn in 1990. She pursued her education in the United States during a one-year exchange program. She began a bachelor's program at the College of Translation and Interpretation in Maastricht, specializing in legal translation in English and Spanish. She obtained a bachelor's degree in 1996 and continued her studies at the University of Amsterdam. She completed a master's degree in Political Science in 1997 and a law degree in 1999. She obtained a second law degree in Tax Law at the University of Amsterdam in 2009.

Irith began her career abroad with the OSCE mission to Bosnia and Herzegovina in 1996. Upon returning to the Netherlands, she combined her studies with a position in the banking sector and as a legal translator from 1997 to 1999. In 1999, she continued her career as a lecturer in law at the Royal Netherlands Naval College. Subsequently, she represented the Netherlands as a diplomat with the Ministry of Foreign Affairs until 2003. She pursued her career at the University of Applied Sciences in Amsterdam and the Law Faculty at the University of Amsterdam, where she assumed several posts, among them lecturer and program manager, from 2003 to 2016.

Since 2016, she has specialized in privacy law as data protection officer with the Amsterdam Institute for Secondary Vocational Education, the municipality of The Hague, and the Netherlands Cancer Institute. She has been working at the Netherlands Cancer Institute since 2018 and has been an external Ph.D. researcher at Leiden University from 2020 to 2024.

Irith is married and has two children.

13. Summary

A fair balance: health data protection and the promotion of health data use for clinical and research purposes

Introduction

This thesis was largely conducted during the COVID-19 pandemic, in a world surrounded by technological innovations, where the individual has become an active player in monitoring his own health. This thesis has found a balance between individual data protection rights and the free flow of data. On the one hand, this balance serves to protect the individual and his data. He is entitled to be informed about the use of his data and to invoke his rights as a data subject. On the other hand, health care must be given and health research must be carried out using personal data within and beyond national borders.

The main research question reads as follows:

> *In what way can a balanced approach be found for the exchange of health data that serves the data protection of the individual on one hand, and the furtherance of health care and health research in the interest of society, on the other?*

Approach

The legal research methodology applied in this thesis consists of doctrinal legal research. Both primary and secondary sources of the law were scrutinized and case law was included. Proposals for European and Dutch legislation were analyzed as well, such as the European Health Data Space (EHDS). Furthermore, publications and academic research carried out in previous studies were analyzed. This thesis also comprises elements of co-production of knowledge, in close cooperation with the Netherlands Cancer Institute – Antoni van Leeuwenhoek hospital.

Results

This thesis has yielded the following results. Firstly, as regards health care, the lawful basis of consent is not the optimal lawful basis if the individual is not or no longer capable of expressing his will. The strength lies in the triangle of care where both the individual, the care provider and the formal or informal representative play a role to give the individual the best care possible.

Secondly, in today's world with technological innovations, the traditional relationship between the care provider and care receiver may be absent. In existing health law, the care provider acts pursuant to the professional medical secrecy and the health

system is based on the patient's informed consent of shared decision-making. In the new health context, the individual gives his consent to the processing of health data outside the realm of traditional health care. The traditional legal system does not protect him and his personal health data in this new health context. A legislative gap exists in the protection of health data where the individual interacts with organizations that process his data beyond the traditional relationship between care provider and receiver.

Thirdly, as regards secondary health research, Dutch legislation provides for explicit consent as the primary lawful basis. However, the focus solely on consent obstructs scientific health research. The GDPR provides for other lawful bases, such as the public interest and legitimate interests, used in other countries in the European Union. Additionally, the EHDS provides for a legal ground for the primary and secondary use of data. The secondary use also includes secondary health research.

The Dutch Code of Conduct for Health Research provides for a layered structure of consent: explicit, specific consent, general (broad) consent and the exceptions to the lawful basis of consent as included in article 7:458 WGBO and article 24 UAVG. The latter exceptions include a no-objection system and can be used when the conditions of these articles are fulfilled. Revised sectoral health legislation in the Netherlands may eventually solve the issue of the lawful basis for secondary health research.

Fourthly, as regards monitoring by supervisory authorities, risk-based regulatory compliance could facilitate international data sharing. Moreover, risk-based regulatory compliance requires a proactive approach from the organizations to demonstrate accountability and transparency while the burden of demonstrating compliance is reduced at the same time. At the same time, risk-based regulatory compliance also requires a different approach from the data protection authorities that monitor compliance.

Analysis

Though the objective of the GDPR was to provide a set of harmonized data protection laws across all member states, this aim has not yielded full effects in terms of data sharing for health care and research purposes. The GDPR has created a fragmented legal landscape due to legal incongruities in national (implementation and sectoral) legislation, as a result of which cross-border collaboration is obstructed. Several lawful bases are used throughout the European Union for the secondary use of health data for scientific research. Furthermore, provisions in the GDPR leave room for different interpretations and cause delays in collaboration agreements. For instance, there is

some ambiguity in defining concepts such as consent, research, purpose (limitation), and the further processing of personal data.

Specifically, the ambiguity surrounding consent in terms of both its wording and its use as a lawful basis for data processing obstructs data sharing in health care and research. The individual runs a risk when his data are not shared if he has not given his consent, while the data sharing is required for information about his health. He may also run a risk when he shares his data beyond the traditional care provider–care receiver relationship. When this occurs, he lacks the protection granted to him by the health provider who is bound by medical professional secrecy. When health data are not shared for research purposes, not only the individual's health but also public health may be jeopardized.

Ambiguity surrounding legal terminology not only exists in the interpretation by the member states, but also within Union legislation itself. For instance, terminology used in the GDPR varies from that used in the EHDS or AI Act. The EDPB and EDPS issue guidelines, opinions and recommendations, but these have not prevented ambiguities in interpreting concepts or delays, or even the absence of cross-border research. The GDPR has not established a uniform framework in the European Union. Member states may still maintain national exceptions to the general rules in the GDPR. Since the EDPB has indicated that this lack of homogeneity cannot be resolved in EDPB guidelines or by means of codes of conduct, the health institutions are challenged to take up the gauntlet themselves.

These observations lead to yet another issue. Though the GDPR provides for a general, risk-based and technology-neutral framework, the data protection authorities pursue this objective differently. The number of fines imposed by the data protection authorities varies throughout the European Union and data protection authorities merely follow a regulatory, rule-based approach based on compliance rather than a risk-based approach. Furthermore, several supervisory mechanisms, both general and sector-specific authorities, monitor compliance in the health sector. Moreover, the EHDS and AI Act create additional supervisory mechanisms, both at a European level and within the member states. Questions arise regarding the division of tasks among these authorities.

Conclusions

A balanced approach for the exchange of health data can be found in the following four ways. Firstly, a broad(-er) interpretation of the lawful basis of consent can facilitate secondary health research in the Netherlands and the European Union. To

this end, the granularity of consent included in recital 33 needs further clarification as regards the scope for secondary research purposes.

Secondly, the use of other lawful bases, such as the public interest and legitimate interests can be a solution for the legitimation of secondary health research in the Netherlands and the European Union. Furthermore, a separate legal ground for secondary research purposes can be a solution to resolve the issue of a proper lawful basis for health research. A separate legal ground for this research has neither been included in the GDPR nor in Dutch law yet. The EHDS contains provisions about the primary and secondary use of data. However, the concept of secondary use is not completely similar to the concept of further processing in the GDPR. With the developments in the EHDS, amendments in the Dutch legislation, in particular article 24 UAVG, as well as articles 7:457 and 7:458 WGBO, and the draft Wzl, would be needed as well.

Thirdly, a balance can be found in the individual's autonomy and (informational) self-determination vis-à-vis the accountability of the health institution that processes his data, and the attention drawn to the free flow of data. In health care and research, the individual exercises the control over his data with the expression of his consent. However, he may not be able to oversee the consequences of the expression of his will. In health care, the balance can be found in the triangle of care where the formal or informal representative and the care provider assist the individual in his decision-making. In health research, the balance can be found in the objective of the GDPR that individual rights are protected whilst the free flow of data is not hampered. The focus is shifted from the individual's control over his data towards the data controller with the use of other lawful bases than consent and with a fair balance between data protection rights on one hand, and the free flow of data, on the other.

Fourthly, a risk-based approach to monitoring compliance, performed by the Data Protection Authority and sectoral supervisory mechanisms, contributes to balancing the rights and interests of individuals with data sharing for health care and research purposes. Furthermore, this approach will encourage health institutions to focus on compliance on the one hand and to balance the individual's data protection with health research on the other. At the same time, clarity is needed as to the roles and responsibilities of the various supervisory mechanisms in data protection and health. With the advent of new supervisory bodies under the EHDS and the AI Act, legal certainty is required about the boundaries of their different and perhaps overlapping roles and responsibilities.

Recommendations

In the context of this thesis, I offer the following seven recommendations to the European and Dutch legislature, as well as to the supervisory authorities in data protection and health law.

Recommendation 1: Emphasize the burden of control by the data controller

Firstly, I recommend that the data controller acknowledges its burden of control as regards data processing. The individual is neither able to control the processing of the data himself, nor is he able to implement the technical and organizational measures. Regardless of which lawful basis is used for data processing in health care and research, the controller must take the necessary technical and organizational measures. Furthermore, the data controller must inform the individual in a clear, transparent manner about the data processing. In sum, the focus must be on the data controller's transparency and accountability, which, in turn, will also garner the individual's trust in the health or research institution.

Recommendation 2: Mutually agree on the use of various lawful bases for secondary research purposes

Secondly, I recommend that a further analysis be carried out when other lawful bases, in addition to consent, serve as a proper legitimation for the secondary use of health data in research, and under which conditions these lawful bases can be applied. For instance, the lawful bases of the public interest and legitimate interests are used in the European Union. Additionally, I recommend that member states acknowledge the use of different legal grounds based on which the data exchange for health research takes place. This requires mutual trust between the research institutions that the rights and interests of the individual are safeguarded, while the controller undertakes the necessary technical and organizational measures, regardless of which lawful basis is applied. It also requires mutual trust between the member states as regards the choice of a lawful basis and specific Member State laws. Furthermore, the developments in the EHDS must be aligned with the current legal framework of the GDPR, AI Act, Data Act and Data Governance Act.

Recommendation 3: Aim for a comprehensive interpretation of the lawful basis of consent

Thirdly, I recommend that the lawful basis of consent be interpreted in a comprehensive manner. Suffice it to say that the elements of consent, i.e., the freely given,

explicit, informed, and unambiguous consent, require an interpretation that coincides with reality and cultural differences.

In health care, I recommend that careful attention be given to the capacity of the individual and, therefore, the expression of his consent. With his consent, the individual expresses his free choice and self-management in the care given to him. However, he may withhold himself from required care when he expresses his will, for instance in the case of individuals developing dementia. In these situations, the triangle of the individual, health provider, and representative deserves further attention. In health research, the element "informed" may not be completely achieved when the research was initiated. The researcher may not be aware of findings that become known at a later stage and that may form the basis for new research. Asking repetitive consent may place a burden on the individual, particularly in the case of longitudinal studies, which can last up to several decades.

Recommendation 4: Separate the lawful basis of consent from the assumption of the individual's full control over his data

Fourthly, I recommend that a fair balance be achieved in practice between data protection rights and the free flow of data. To this end, I recommend that the lawful basis of consent be separated from the assumption that the individual has full control over his personal data. The individual, in his role as patient or client who receives medical care and whose data could be of value for health research, may very well not read all the privacy statements or balance the pros and cons of his consent. The GDPR (articles 12 – 22) grants the individual a number of rights as regards his personal data, rights that he can exercise towards the data controller. However, this does not mean that he actually owns or fully controls the data himself. The GDPR does not grant the individual full control over his data either.

Recommendation 5: Explain concepts in European legislation

Fifthly, I recommend that the concepts of secondary use, further processing, public interest and research in the GDPR and EHDS be further detailed, preferably by the EDPB. The interpretation of the GDPR framework substantially differs among member states. This has resulted in fragmentation rather than a common approach to the interpretation and use of health data. Additionally, I recommend that similar concepts used in the GDPR, the EHDS, and the AI Act be explained.

Recommendation 6: Aim for a risk-based approach in monitoring and supervision

Sixthly, I recommend that the risk-based approach, which has been included in the GDPR, be given new impetus by the supervisory authorities. In practice, data controllers are involved in showing compliance with records of data processing activities (article 30 GDPR), Data Protection Impact Assessments (article 35 GDPR), records of data breaches (article 33 (5) GDPR), and the presence of a data protection officer (articles 37 – 39 GDPR). Although the activities have proved useful, these documents alone do not ensure that the individual rights or interests are guaranteed. I recommend that the data controller focus more on the balance between the individual rights or interests and the free flow of data, while fulfilling the obligations enunciated in article 5 GDPR. The return to a risk-based approach by the data controller also requires a shift by the data protection authorities.

Recommendation 7: Aim for a closer cooperation between Data Protection Authorities and sectoral supervisory mechanisms

Seventhly, I recommend that the Data Protection Authorities in the Union and the Netherlands cooperate more closely with sectoral supervisory bodies. This way, the individual is protected from both the data protection and health law perspectives. Since the individual plays an active role in monitoring his own health and sharing data beyond the traditional care provider–care receiver context, I recommend that the governance structure be broadened to safeguard his position in both contexts. The governance structure offered by the EHDS can be a starting point to closing the gaps in the individual's data protection rights regarding health beyond his role as a patient in the traditional setting. In addition, the EHDS can also provide a framework to close the gap between the supervisory mechanisms in health and the general data protection authorities.

Final considerations for future research

This research did not touch upon many related topics that merit future research. Firstly, future research is recommended on the principles of solidarity and reciprocity in health research. Secondly, future research is recommended on the elements of informed (ethical) consent (in the Clinical Trial Regulation) and the elements of consent in the GDPR, especially in relation to new legislative developments in the Netherlands (which incorporate the requirements of the GDPR consent).

Thirdly, future research is recommended on the interaction between the European legislation (EHDS, AI Act, Data Act, and Data Governance Act) and Dutch legislative developments (inter alia, the draft Dutch Authority over Human tissue Act, *Wet zeggenschap lichaamsmateriaal, Wzl*). Additionally, future research is recommended on

the interaction between the GDPR, the UAVG and, more specifically, sectoral health legislation.

Fourthly, future research is recommended on the compliance mechanisms by the European and national data protection authorities, as well as sectoral supervisory mechanisms. This research could include the interaction between the different supervisory mechanisms, both at a European and national level, and both by general and sectoral authorities.

Fifthly, future research is recommended regarding the individual's own role in monitoring his health. Self-tracking devices in monitoring one's health could benefit individual decision-making. However, the very same innovative technologies could compromise the individual's autonomy and informational self-determination. Further research could further unravel the individual autonomy, self-determination and informational privacy amidst the use of new technologies.

Lastly, further research is recommended on the proper communication strategy for informing a patient population, a nation's population, or any other population in the EU, about the use of his data for clinical and research purposes. A tailor-made communication strategy for different target groups contributes to the individual's feeling of trust and willingness to share health data.

14. Summary in Dutch (Samenvatting)

Een billijk evenwicht: bescherming van gezondheidsgegevens hand in hand met de bevordering van het gebruik van gezondheidsgegevens voor zorg en wetenschappelijk onderzoek

Inleiding

Dit proefschrift is grotendeels tot stand gekomen tijdens de coronapandemie, in een wereld die het speelveld is van technologische innovaties en waarin de mens een actieve deelnemer is in het bewaken van zijn gezondheid. In dit proefschrift is het evenwicht gevonden tussen het individuele recht op gegevensbescherming en het vrij verkeer van persoonsgegevens. Dit evenwicht ziet enerzijds op de bescherming van de natuurlijke persoon en zijn gegevens: hij heeft recht op informatie over het gebruik van zijn persoonsgegevens en de uitoefening van zijn rechten als betrokkene. Anderzijds moeten gezondheidszorg en gezondheidsonderzoek plaatsvinden waarbij persoonsgegevens binnen en buiten de landsgrenzen worden verwerkt.

De hoofdvraag van dit proefschrift luidt als volgt:

> *Hoe kan een evenwichtige benadering worden gevonden voor de uitwisseling van gezondheidsgegevens die enerzijds de individuele gegevensbescherming dient, terwijl anderzijds de gezondheidszorg en het wetenschappelijk gezondheidsonderzoek in het algemeen belang worden bevorderd?*

Aanpak

Als juridische onderzoeksmethode is in dit proefschrift juridisch-doctrinair onderzoek uitgevoerd. Zowel primaire als secundaire rechtsbronnen zijn onderzocht en jurisprudentie is opgenomen. Ook voorstellen van Europese en Nederlandse wetgeving zijn geanalyseerd, zoals de Europese Ruimte voor Gezondheidsgegevens (*European Health Data Space, EHDS*). Tevens zijn eerder verschenen publicaties en eerder uitgevoerd academisch onderzoek geanalyseerd. Dit proefschrift omvat ook elementen van co-creatie van kennis, in nauwe samenwerking met het Nederlands Kanker Instituut – Antoni van Leeuwenhoekziekenhuis.

Resultaten

Dit proefschrift heeft de volgende resultaten opgeleverd. Ten eerste is de toestemmingsgrond niet de meest passende rechtsgrond als het individu niet of niet meer in staat is om zijn wil te uiten. De kracht ligt in het drieluik van zorg waarin zowel het individu zelf, alsook de zorgverlener en de formele of informele vertegenwoordiger een rol spelen om aan het individu de best mogelijke zorg te verlenen.

Ten tweede kan het zijn dat er geen sprake is van een traditionele behandelrelatie tussen de zorgverlener en -ontvanger in de huidige tijdgeest waarin we worden omringd door technologische innovaties. In het geldende recht werkt de zorgverlener met inachtneming van het beroepsgeheim en het gezondheidsstelsel is gebaseerd op de instemming van de patiënt en *shared decision-making*. In de nieuwe gezondheidsomgeving geeft het individu toestemming voor de verwerking van gezondheidsgegevens buiten het bereik van de traditionele gezondheidszorg. Het traditionele gezondheidsstelsel beschermt noch hemzelf noch zijn gezondheidsgegevens in deze nieuwe gezondheidsomgeving. Er bestaat een wetgevingsleemte inzake de bescherming van gezondheidsgegevens op het moment dat het individu contact heeft met organisaties die zijn gegevens verwerken buiten de traditionele behandelrelatie tussen zorgverlener en –ontvanger.

Ten derde schrijft de Nederlandse wetgeving expliciete toestemming voor als de primaire rechtsgrondslag voor nader wetenschappelijk onderzoek. De eenzijdige nadruk op toestemming belemmert echter het wetenschappelijk gezondheidsonderzoek. In de AVG zijn andere rechtsgrondslagen opgenomen, zoals het algemeen belang en de gerechtvaardigde belangen. Deze grondslagen worden in andere lidstaten van de Europese Unie toegepast. Daarnaast voorziet de EHDS in een rechtsgrond voor het primair en secundair gebruik van data. Nader wetenschappelijk onderzoek valt ook binnen het secundair gebruik.

In de Nederlandse Gedragscode Gezondheidsonderzoek is een gelaagde toestemmingsstructuur opgenomen: nadrukkelijke, specifieke toestemming, algemene toestemming en de uitzonderingen op het uitgangspunt van toestemming in artikel 7:458 WGBO en artikel 24 UAVG. Een geen-bezwaar-systeem valt binnen deze laatste twee uitzonderingen. Dit systeem kan worden gebruikt als aan de voorwaarden in deze artikelen is voldaan. Herziening van de sectorale gezondheidswetgeving in Nederland kan op den duur een oplossing vormen voor het vraagstuk van de rechtsbasis voor nader wetenschappelijk onderzoek.

Ten vierde kan het risicogericht toezicht van de toezichthoudende autoriteiten bijdragen aan internationale gegevensdeling. Daarbij draagt risicogericht toezicht bij aan proactief handelen door de organisaties waarin zij verantwoordelijkheid en transparantie tonen terwijl de druk van de aantoonbaarheid van compliance tegelijkertijd afneemt. Dit risicogerichte toezicht vergt ook een andere aanpak van de autoriteiten persoonsgegevens die de naleving monitoren.

Analyse

Hoewel de AVG een geharmoniseerde gegevensbeschermingswetgeving in alle lidstaten heeft beoogd, is deze doelstelling niet volledig behaald voor de gegevensdeling ten

behoeve van zorg en onderzoek. De AVG heeft een versnipperd wettelijk landschap tot gevolg gehad vanwege verschillen in nationale (uitvoerings- en sectorale) wetgeving. Hierdoor wordt de internationale samenwerking belemmerd. In de Europese Unie worden diverse rechtsgronden gebruikt voor het nader gebruik van gezondheidsgegevens voor wetenschappelijk onderzoek. Daarbij laten de bepalingen in de AVG ruimte voor velerlei uitleg als gevolg waarvan samenwerkingsovereenkomsten met vertraging worden afgesloten. Zo worden begrippen als toestemming, onderzoek, doel (-beperking) en het nader gebruik van persoonsgegevens verschillend uitgelegd.

Met name de velerlei uitleg van het begrip toestemming belemmert de gegevensdeling in zorg en onderzoek. Dit is het geval voor de zowel uitleg van het begrip toestemming alsook de toepassing van de rechtsbasis toestemming voor de verwerking van persoonsgegevens. Het individu loopt risico als zijn gegevens niet worden gedeeld wanneer hij geen toestemming heeft gegeven, terwijl de gegevensdeling nodig is voor informatieverstrekking over zijn gezondheid. Het individu loopt ook risico als hij zijn data buiten de traditionele behandelrelatie van zorgverlener – zorgontvanger deelt. In dat geval geniet hij niet de bescherming die de zorgverlener, die gebonden is aan het beroepsgeheim, hem kan bieden. Indien gezondheidsdata niet worden gedeeld voor onderzoeksdoeleinden, dan kan dit niet alleen zijn gezondheid maar ook de volksgezondheid in gevaar brengen.

Het vraagstuk van de velerlei uitleg over juridische begrippen speelt niet alleen bij de uitleg door de lidstaten maar ook binnen de Uniewetgeving zelf. Zo loopt de terminologie in de AVG uiteen in vergelijking met het begrippenkader in de EHDS en de AI Act. Het Europees Comité voor Gegevensbescherming (*European Data Protection Board, EDPB*) en de Europese Toezichthouder voor Gegevensbescherming (*European Data Protection Supervisor, EDPS*) vaardigen richtsnoeren, opinies en aanbevelingen uit, maar deze instanties zijn er niet in geslaagd om de velerlei uitleg in de interpretatie van begrippen te voorkomen. Ook komt niet zelden voor dat internationaal wetenschappelijk onderzoek vertraging oploopt of zelfs niet meer wordt uitgevoerd. De AVG heeft niet een uniform kader in de Europese Unie tot stand gebracht. Lidstaten kunnen nog steeds nationale uitzonderingen op het algemeen kader van de AVG laten bestaan. En aangezien de EDPB heeft aangegeven dat dit gebrek aan homogeniteit niet in richtsnoeren van de EDPB of met gedragscodes kan worden verholpen, staan de gezondheidsinstellingen voor de schone taak om de handschoen zelf op te pakken.

Deze observaties brengen mij tot het volgende vraagstuk. Hoewel de AVG voorziet in een algemeen, risico gebaseerd en technologieneutraal kader, vullen de autoriteiten persoonsgegevens dit doel verschillend in. Het aantal boetes dat door de

nationale gegevensbeschermingsautoriteiten wordt opgelegd wisselt in de Europese Unie. Autoriteiten persoonsgegevens voeren doorgaans toezicht uit dat gericht is op compliance in plaats van een inschatting van de risico's. Daarnaast voeren verschillende toezichthouders, zowel algemene alsook sectorspecifieke, toezicht uit op de gezondheidssector. Bovendien worden door de EHDS en AI Act opnieuw toezichthoudende organen in het leven geroepen, zowel op Europees niveau alsook binnen de lidstaten. De vraag luidt hoe de taakverdeling tussen deze toezichthoudende organen zal zijn.

Conclusies

Een billijk evenwicht voor de uitwisseling van gezondheidsgegevens kan op de volgende vier wijzen worden gevonden. Ten eerste kan een brede uitleg van de rechtsgrond toestemming het nader wetenschappelijk onderzoek in Nederland en de Europese Unie bevorderen. Daartoe is meer duidelijkheid nodig over de zogeheten granulariteit van toestemming uit overweging 33 AVG voor het nader wetenschappelijk onderzoek.

Ten tweede kan het gebruik van andere rechtsgronden, zoals het algemeen belang en de gerechtvaardigde belangen, een oplossing bieden voor de legitimering van nader wetenschappelijk onderzoek in Nederland en de Europese Unie. Daarnaast kan een aparte rechtsgrond voor nader wetenschappelijk onderzoek een oplossing bieden voor het vraagstuk van de juiste rechtsgrond voor gezondheidsonderzoek. Op dit moment voorzien de AVG en de Nederlandse wetgeving nog niet in een aparte rechtsbasis voor dit onderzoek. In de EHDS is het primair en secundair gebruik van data opgenomen. Het begrip *secundair gebruik* is evenwel niet volledig gelijk aan het begrip *verdere verwerking* in de AVG. Met de ontwikkelingen rond de EHDS zal tevens een aanpassing in de Nederlandse wetgeving benodigd zijn, in het bijzonder artikel 24 UAVG alsmede artikelen 7:457 en 7:458 WGBO en de concept Wet zeggenschap lichaamsmateriaal (Wzl).

Ten derde kan een balans worden gevonden in de autonomie en (informationele) zelfbeschikking van het individu ten opzichte van de verantwoordelijkheid van de gezondheidsinstelling die zijn gegevens verwerkt en het belang van het vrij verkeer van persoonsgegevens. Het individu oefent met de wilsuiting in de vorm van toestemming controle uit over zijn persoonsgegevens ten behoeve van de gezondheidszorg en het wetenschappelijk onderzoek. Wellicht overziet hij echter de gevolgen van zijn wilsuiting niet. In de zorg kan het evenwicht worden gevonden in het drieluik van zorg waarin de formele of informele vertegenwoordiger en de zorgverlener het individu ondersteunen bij zijn besluitvorming. In gezondheidsonderzoek kan het evenwicht worden gevonden in de doelstelling van de AVG dat individuele rechten worden beschermd zonder dat het vrij verkeer van persoonsgegevens wordt belemmerd. Met het gebruik van andere

grondslagen dan toestemming wordt de nadruk niet langer gelegd op de individuele controle over persoonsgegevens, maar op de verwerkingsverantwoordelijke. Zo wordt een billijk evenwicht gevonden tussen gegevensbescherming enerzijds en het vrij verkeer van persoonsgegevens anderzijds.

Ten vierde draagt een risicogerichte benadering van toezicht door de Autoriteit Persoonsgegevens en sectorspecifieke toezichthouders bij aan het evenwicht tussen de rechten en belangen van het individu ten opzichte van de datadeling voor zorg en wetenschappelijk onderzoek. Deze benadering zal ook een stimulans vormen voor gezondheidsinstellingen om zich aan de ene kant te richten op compliance maar aan de andere kant de balans te vinden tussen de individuele gegevensbescherming en het onderzoek. Daarbij is tegelijkertijd helderheid nodig over de rollen en verantwoordelijkheden van de verschillende toezichthoudende organen in gegevensbescherming en zorg. Met de komst van nieuwe toezichthoudende organen in de EHDS en de AI Act is rechtszekerheid nodig over de reikwijdte van de verschillende en misschien overlappende rollen en verantwoordelijkheden.

Aanbevelingen

In dit proefschrift geef ik zeven aanbevelingen aan de Europese en Nederlandse wetgever alsmede de toezichthouders in gegevensbescherming en zorg.

Aanbeveling 1: Leg de controlelast bij de verwerkingsverantwoordelijke

Ten eerste beveel ik aan dat de verwerkingsverantwoordelijke de last op zijn schouders neemt voor de controle over de gegevensverwerking. Het individu is noch in staat om de gegevensverwerking zelf te beheersen, noch is hij in staat om technische en organisatorische maatregelen te treffen. Ongeacht welke rechtsbasis wordt gebruikt voor de gegevensverwerking in zorg en onderzoek moet de verwerkingsverantwoordelijke de benodigde technische en organisatorische maatregelen treffen. Daarnaast moet de verwerkingsverantwoordelijke het individu op heldere, transparante wijze over de gegevensverwerking inlichten. Kortom, de focus dient op de transparantie en verantwoordelijkheid van de verwerkingsverantwoordelijke te liggen. Hiermee groeit het vertrouwen van het individu in de zorg- of onderzoeksinstelling.

Aanbeveling 2: Erken het gebruik van verschillende rechtsgronden voor nader wetenschappelijk onderzoek

Ten tweede beveel ik aan dat een nadere analyse wordt uitgevoerd wanneer andere grondslagen naast toestemming als een passende legitimering kunnen dienen voor het nader gebruik van gezondheidsgegevens in onderzoek, en aan welke voorwaarden voor

deze rechtsgrondslagen moet worden voldaan. In de Europese Unie worden bijvoorbeeld de grondslagen algemeen belang en gerechtvaardigde belangen gebruikt. Ook beveel ik aan dat de lidstaten het gebruik van verschillende rechtsgrondslagen wederzijds erkennen op grond waarvan de gegevensuitwisseling voor gezondheidsonderzoek plaatsvindt. Wederzijds vertrouwen tussen de onderzoeksinstellingen is hierin een basisvoorwaarde, waarbij de rechten en belangen van het individu worden behartigd terwijl de verwerkingsverantwoordelijke passende technische en organisatorische maatregelen treft: ongeacht welke rechtsbasis wordt gebruikt. Ook is wederzijds vertrouwen tussen de lidstaten nodig over de keuze van een rechtsgrond en specifieke nationale uitvoeringswetgeving. Voorts moeten de ontwikkelingen in de EHDS in lijn worden gebracht met het huidig juridische kader van de AVG, AI Act, de Data Act en de Data Governance Act.

Aanbeveling 3: Streef naar een integrale uitleg van de rechtsgrond toestemming

Ten derde beveel ik aan dat de rechtsgrond toestemming op een integrale wijze wordt geïnterpreteerd. De componenten van de AVG-toestemming, namelijk de vrijwillig gegeven, expliciete, geïnformeerde en ondubbelzinnige toestemming, vereisen een uitleg die aansluit bij een realiteit en culturele verschillen. Ik beveel voor de gezondheidszorg aan dat aandacht wordt besteed aan de bekwaamheid van het individu en daarmee aan de wilsuiting van toestemming. Het individu geeft met zijn toestemming uiting aan zijn vrije keuze en zelfbeschikking in de zorg die aan hem wordt verleend. Hij kan zich hiermee echter ook benodigde zorg onthouden als hij zijn wil uit, bijvoorbeeld wanneer hij het ziektebeeld van dementie heeft. In deze situaties vraagt het drieluik van het individu, de zorgverlener en de vertegenwoordiger nadere aandacht. In gezondheidsonderzoek kan niet altijd volledig aan de component 'geïnformeerd' worden voldaan bij de start van het onderzoek. De onderzoeker is bijvoorbeeld nog niet op de hoogte van bevindingen die later naar boven komen en die de start kunnen zijn van nieuw onderzoek. Telkens opnieuw toestemming vragen kan een last vormen voor het individu, vooral bij longitudinale studies die decennialang kunnen duren.

Aanbeveling 4: Week de rechtsbasis toestemming los van de aanname dat het individu volledige controle heeft over zijn persoonsgegevens

Ten vierde beveel ik aan dat een billijk evenwicht wordt in de praktijk tot stand wordt gebracht tussen gegevensbeschermingsrechten en het vrij verkeer van data. In dit licht beveel ik aan dat de rechtsgrond toestemming wordt losgeweekt van de aanname dat het individu volledige controle heeft over zijn persoonsgegevens. Het kan zeer goed zijn dat het individu, als patiënt of cliënt en ontvanger van medische

zorg wiens data waardevol kunnen zijn voor wetenschappelijk onderzoek, niet alle privacy-verklaringen leest of de voor- en nadelen van toestemming op een weegschaal legt. De AVG (artikelen 12 - 22) kent het individu een aantal rechten toe inzake zijn persoonsgegevens. Hij kan deze rechten jegens de verwerkingsverantwoordelijke uitoefenen. Dit betekent evenwel niet dat hij daadwerkelijk eigenaar van de gegevens is of dat hij volledige controle heeft over deze gegevens. Het betekent ook niet dat de AVG hem de volledige individuele controle over zijn gegevens geeft.

Aanbeveling 5: Leg begrippen in Europese wetgeving uit

Ten vijfde beveel ik aan dat de begrippen van nader gebruik, verdere verwerking, algemeen belang en onderzoek in de AVG en EHDS nader worden uitgelegd, bij voorkeur door de EDPB. De lidstaten leggen het AVG-kader zeer verschillend uit. Hierdoor is eerder fragmentatie dan een gezamenlijke benadering in de interpretatie over het gebruik van gezondheidsdata ontstaan. Ik beveel ook aan dat verwante begrippen in de AVG, EHDS en de AI Act worden toegelicht.

Aanbeveling 6: Streef naar risicogerichte benadering bij monitoring en toezicht

Ten zesde beveel ik aan dat de toezichthoudende autoriteiten een nieuwe impuls geven aan de risico gebaseerde benadering zoals deze in de AVG is verwoord. In de praktijk leggen verwerkingsverantwoordelijken zich toe op de aantoonbaarheid van compliance met een verwerkingsregister (artikel 30 AVG), gegevensbeschermingseffectbeoordelingen (artikel 35 AVG), een register van datalekken (artikel 33 (5) AVG) en de aanwezigheid van een functionaris gegevensbescherming (artikelen 37 – 39 AVG). Hoewel deze inspanningen nuttig zijn gebleken, wordt met de aantoonbaarheid van documenten alleen niet de garantie gegeven dat de individuele rechten or belangen worden geborgd. Ik beveel aan dat de verwerkingsverantwoordelijke zich meer richt op het evenwicht tussen de individuele rechten of belangen en het vrij verkeer van gegevens, terwijl de verplichtingen uit artikel 5 AVG worden nageleefd. De terugkeer naar een risico gebaseerde benadering door de verwerkingsverantwoordelijke vereist ook een wijziging in het toezicht door de gegevensbeschermingsautoriteiten.

Aanbeveling 7: Streef naar een nauwere samenwerking tussen de gegevensbeschermingsautoriteiten en sectorale toezichthouders

Ten zevende beveel ik aan dat de gegevensbeschermingsautoriteiten in de EU en Nederland nauwer gaan samenwerken met de sectorale toezichthouders. Dan geniet het individu bescherming zowel vanuit het oogpunt van gegevensbescherming als het gezondheidsrecht. Aangezien het individu een actieve rol speelt in de monitoring van

zijn eigen gezondheid en data deelt buiten de traditionele context van de zorgverlener en –ontvanger, beveel ik aan dat de governance-structuur wordt uitgebreid opdat de positie van het individu in beide contexten wordt beschermd. De governance-structuur die de EHDS biedt kan een startpunt zijn voor het dichten van de lacunes die zijn ontstaan in de individuele bescherming van gezondheidsgegevens van het individu buiten zijn rol als patiënt in de traditionele context. Daarbij kan de EHDS ook voorzien in een kader om het gat te dichten tussen de toezichthouders in de zorg en de gegevensbeschermingsautoriteiten.

Enkele overwegingen tot slot voor toekomstig onderzoek

In dit onderzoek ben ik niet ingegaan op talrijke verwante onderwerpen die voorwerp kunnen zijn van nader onderzoek. Ten eerste raad ik nader onderzoek aan over de beginselen van solidariteit en reciprociteit in gezondheidsonderzoek. Ten tweede raad ik nader onderzoek aan inzake de onderdelen van geïnformeerde (ethische) toestemming (in de Europese verordening klinische proeven) en de onderdelen van toestemming in de AVG, in het bijzonder met betrekking tot de nieuwe wetsontwikkelingen in Nederland (waarin de vereisten van de AVG-toestemming zijn opgenomen).

Ten derde raad ik toekomstig onderzoek aan over het samenspel tussen de Europese wetsontwikkelingen (EHDS, AI Act, Data Act en Data Governance Act), en de Nederlandse wetsontwikkelingen (onder andere het wetsvoorstel zeggenschap lichaamsmateriaal). Voorts raad ik nader onderzoek aan inzake de interactie tussen de AVG, de UAVG en meer in het bijzonder sectorale gezondheidswetgeving.

Ten vierde raad ik nader onderzoek aan inzake de handhavingsinstrumenten van de Europese en nationale gegevensbeschermingsautoriteiten, alsook het sectorale gezondheidstoezicht. Dit onderzoek zou ook de interactie tussen de verschillende toezichthoudende autoriteiten kunnen omvatten, zowel op Europees alsook nationaal niveau, en zowel door de algemene als de sectorale toezichthouders.

Ten vijfde raad ik nader onderzoek aan over de zelfstandige rol die het individu speelt in de monitoring van zijn gezondheid. *Self-tracking devices* voor gezondheidsmonitoring hebben wellicht een positieve invloed op de individuele besluitvorming. Maar deze innovatieve technologieën kunnen ook afbreuk doen aan de autonomie en informationele zelfbeschikking. De individuele autonomie, zelfbeschikking en informationele privacy te midden van het gebruik van nieuwe technologieën zouden voorwerp kunnen zijn van nader onderzoek.

Ten slotte raad ik nader onderzoek aan over de juiste communicatiestrategie voor een patiëntpopulatie, de bevolking van een staat, of welke andere bevolkingsgroep

dan ook in de EU, over het gebruik van zijn persoonsgegevens voor zorg- en onderzoeksdoeleinden. Een passende communicatiestrategie voor de verschillende doelgroepen draagt bij aan het vertrouwen en de bereidheid tot datadeling van het individu.