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

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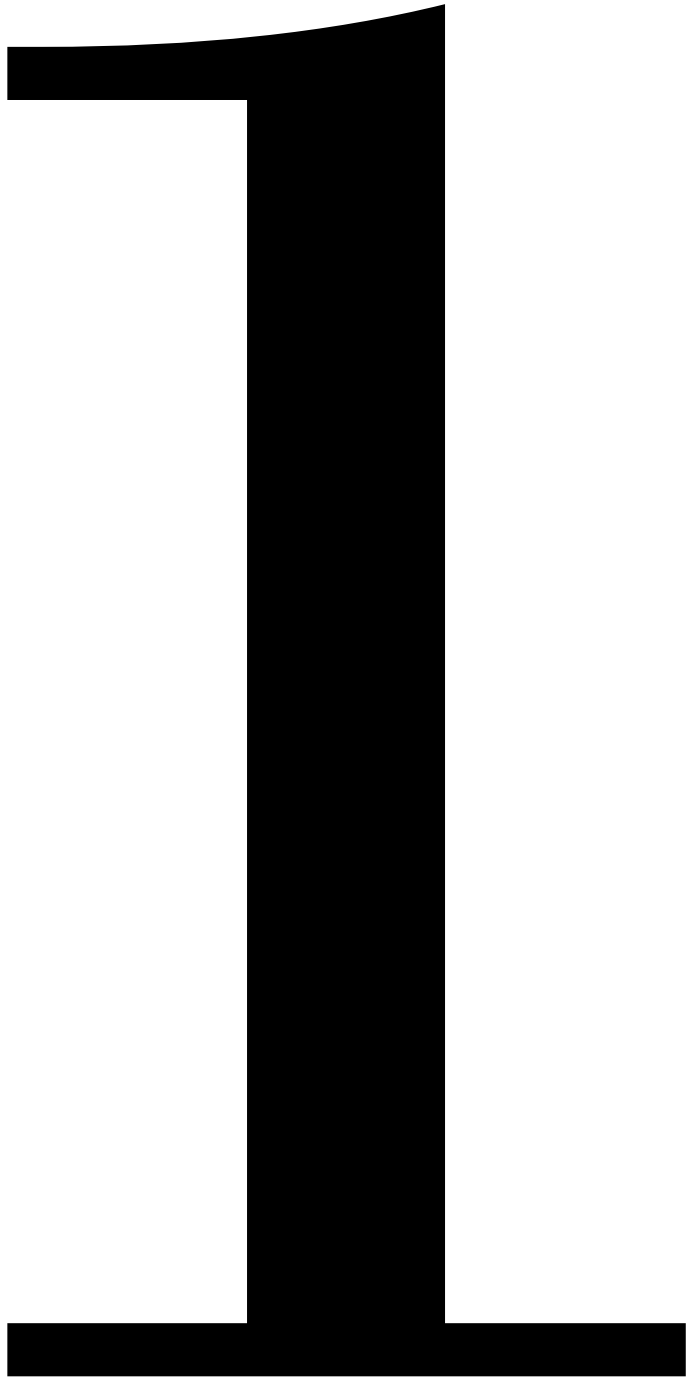

Introduction

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.