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

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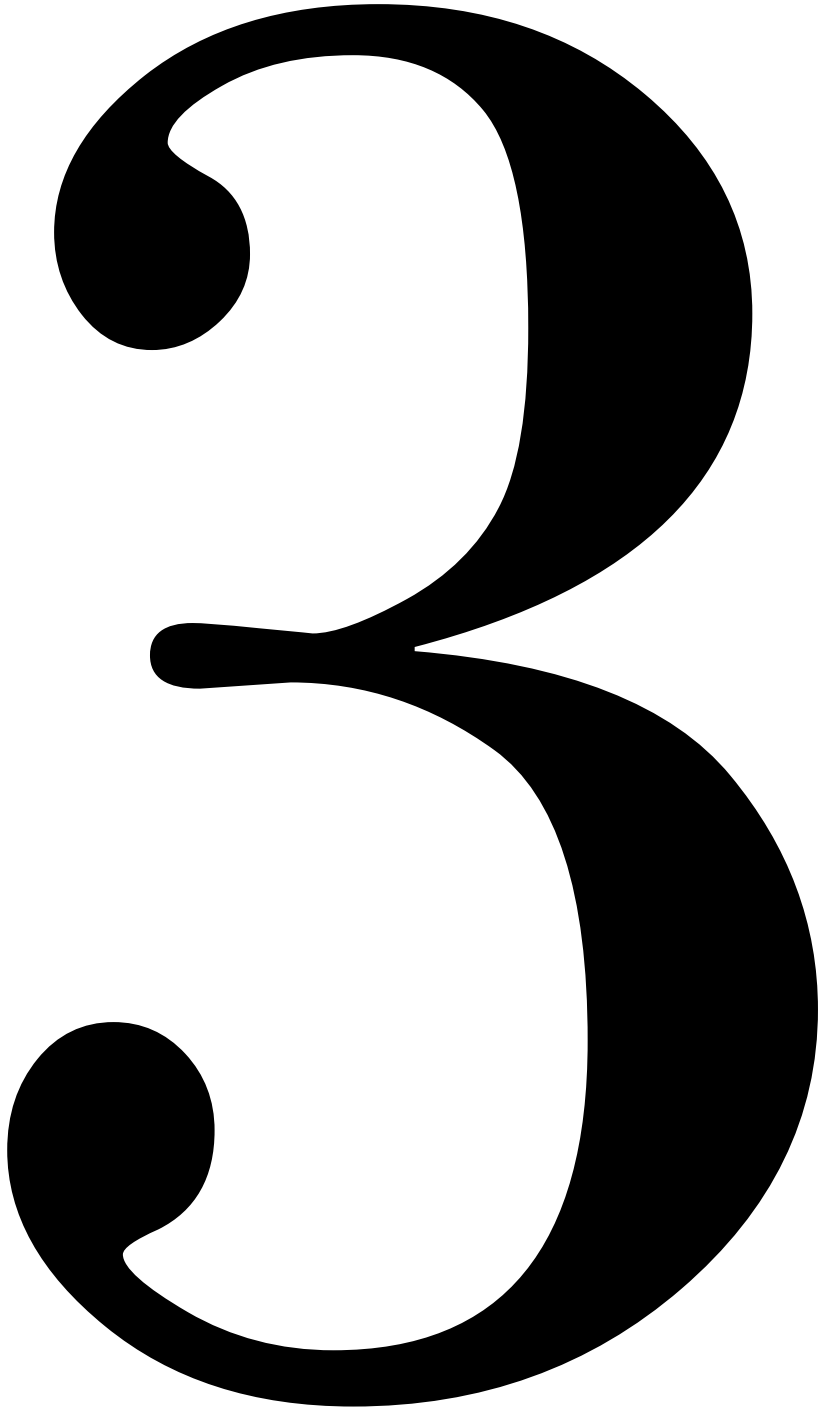

# Assessment of the Dutch rules on health data in the light of the GDPR

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

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

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

## Abstract

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

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

## 3.1. Introduction

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

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

### *3.1.1. Scope*

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

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

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

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

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

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

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

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

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

### *3.1.2. Aim*

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

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

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

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

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

## 3.2. EU legal framework

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

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

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

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

[238] Recital 7 GDPR.

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

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

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

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

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

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

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

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

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

### *3.2.1. GDPR consent*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[265] Recitals 33, 157 and 159 GDPR.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### *3.3.1. Consent in Dutch law*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## 3.5. Avenues for further exploration

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## 3.6. Conclusion

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

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

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

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

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

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

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

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

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

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

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

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

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