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

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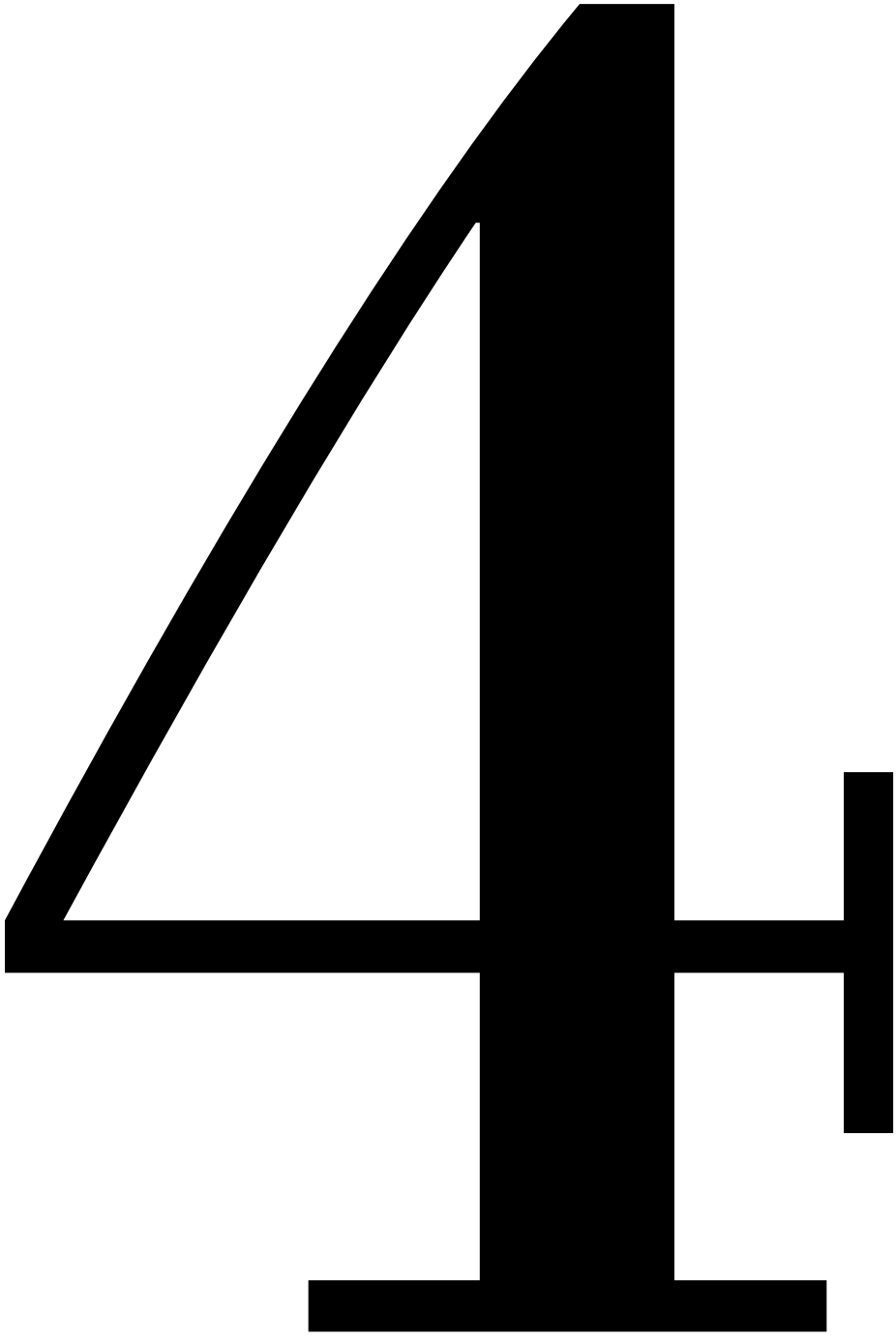

The Dutch Code of Conduct for Health Research and the implementation of the lawful basis of consent

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

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

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

Abstract

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

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

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

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

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

4.1. Introduction

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4.1.1. Case study

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

4.1.2. The legal framework

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

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

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

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

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

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

4.1.3 The lawfulness of processing

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

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

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

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

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

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

[340] Dutch Code of Conduct, chapter 5.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4.6. Conclusion

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

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

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

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

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

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

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

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