Special Issue: EU health data governance and the proposed European Health Data Space

Technology and Regulation

Scientific Research Regime 2.0?

How the proposed EHDS Regulation may change the GDPR Research Regime

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health data, genetic data, scientific research, GDPR scientific research regime, secondary use

The proposed European Health Data Space regulation (the proposed EHDS regulation) intends to facilitate the secondary use of electronic health data for scientific research purposes. The mechanism that the proposal contains will co-exist with the scientific research regime that has been established under the General Data Protection Regulation. This article examines how the proposed EHDS regulation promises to transform the EU scientific research regime and protection of a data subject in scientific research. This paper shows that a scientific research regime 2.0 is put forward, where sharing is enhanced at the cost of self-determination of the individual and without resolving many of the challenges that emerged under the GDPR.

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1. Introduction

On the 3rd of May, 2022, a proposal for the European Health Data Space regulation (the proposed EHDS regulation) was launched.[1] It is a tool to further the EU's ambitions in the health field for realizing such objectives as the EU Social Pillar and the building of the European Health Union. Moreover, it is part of the collection of actions scheduled for the coming years to realize the ambition of creating a single European data space and furthering digital transformation and data usage within different sectors and across the European Union.[2] The European Commission has envisaged that the single European data space shall become "a genuine single market for data" that will further the development of the data economy within the EU.[3] Health data, in that regard, have a considerable role to play.

The proposed EHDS regulation can also be seen as a relatively prompt regulatory response to the uncertainties and challenges relating to the General Data Protection Regulation (GDPR) and scientific research involving health and genetic data.[4] One of the central novelties that the GDPR brought along was an EU-wide scientific regime for personal data.[5] The regime provoked diverse views, including critique pointing in different directions. Some have criticized the enhanced protection that the instrument creates for data subjects in scientific research. For example, Peloquin et al. have argued that the GDPR has disrupted the secondary use of data for scientific research purposes. One of the central arguments raised in support of this claim is capturing enhanced data protection within the EU and treating coded data as pseudonymized data instead of anonymized data as was commonly customary pre-GDPR era.[6]

Others have taken a different point of departure and criticized the low level of protection that the GDPR offers to data subjects as research participants. For example, Pormeister has specifically focused on the protection of data subjects in biomedical research and questioned whether the GDPR is not going too far in the attempts to further data use in scientific research.[7] After all, one of the striking features of the GDPR is the detailed and extensive set of rights afforded to a data subject, except for when it comes to a few areas, including scien-

1 European Commission, Proposal for a regulation of the European Parliament and the Council on the European Health Data Space (COM (2022)197 final) p. 1

2 Proposed EHDS regulation (n 1)

3 See the vision outlined in European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic, and Social Committee, and The Committee of the Regions COM (2020) 66 final p. 4

4 For an overview, see Panel for the Future of Science and Technology, How the General Data Protection Regulation changes the rules for scientific research European Parliamentary Research Service (2019) https://www.europarl.europa.eu/RegData/etudes/STUD/2019/634447/EPRS_STU(2019)634447_EN.pdf accessed 20 October 2022. For challenges in regard to the scientific research regime from a biobanking perspective, see, e.g., Santa Slokenberga, Jane Reichel, and Olga Tzortzatou (eds), GDPR, and Biobanking. Individual Rights, Public Interest and Research Regulation across Europe (Springer International Publishing 2021)

5 Cf with Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data where the regulation of research was left to the Member States.

6 David Peloquin and others, 'Disruptive and Avoidable: GDPR Challenges to Secondary Research Uses of Data' (2020) 28 European Journal of Human Genetics 697

7 Kärt Pormeister, 'Genetic Data and the Research Exemption: Is the GDPR Going Too Far?' (2017) 7 International Data Privacy Law 137

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tific research.[8] The enhanced role of the EU in data-driven research, coupled with the weak protection offered to the data subject in the GDPR in comparison with the ethico-legal standards for scientific research,[9]resulted in a call for an integrated bioethics approach to data protection regulation.[10]

In light of the challenges and discussions illustrated above, the proposed EHDS regulation is a much-awaited legal framework. It has been hoped that it would offer solutions to the different challenges attributed to scientific research under the GDPR.[11] After all, the European Union was not ignorant of the emerging discussions and critiques and launched initiatives, including targeted thorough analysis of the national legal frameworks regarding health and genetic data to gain an accurate picture of the field.[12] However, thus far, it does not seem that high hopes for a shift in regard to the protection of the data subject and alignment to the bioethics standards in the field have been made.

This article seeks to inquire how the proposed EHDS regulation promises to transform the EU scientific research regime created under the GDPR and explore whether an integrated approach to bioethics is taken to safeguard individuals' rights and interests in data-driven scientific research. It begins by exploring the status of an individual in scientific research more generally, which later on serves as a platform to reflect on the EU scientific regime for personal data and the transformations that the proposed EHDS brings along. Thereafter, it moves on to mapping out central features of the GDPR scientific research regime, with a particular focus on those aspects that have a bearing on the protection of the data subject. Subsequently, it examines the proposed EHDS regulation and discusses the transformations that it is set to offer. Finally, it takes up a contextual discussion regarding the transformations and the EU's approach to regulating data-driven scientific research in comparison with key medico-legal standards in the field. It shows that a scientific research regime 2.0 in the EU legal order is about to be created, where an individual has become an object to achieve the EU's public health and market aspirations and where the EU continues to be reluctant to assume responsibility for ensuring that data-driven scientific research conforms to the basic ethico-legal standards widely accepted for scientific research.

2. Ethico-Legal Standards for Scientific Research: Some Historical and Principal Starting Points

Much of the reported history that relates to involving human beings in scientific research focuses on biomedical interventions.[13] A trigger point for the most significant evolution of scientific research regulation has been the atrocities committed during World War II. As a result of the "Doctor's Trial," where 23 doctors were prosecuted for the horrific scientific experiments in Nazi concentration camps,[14] the Nuremberg Code – a key early document on medical ethics – was drafted. This code sets forth 10 key principles that shall be observed in scientific experimentation to protect human subjects. The first principle that was set in this document addresses the individual's self-determination and stipulates that"[t]he voluntary consent of the human subject is absolutely essential."[15] It is framed as an absolute rule; therefore, no exceptions are provided. Other principles include a requirement for the appropriate research design, avoidance of all unnecessary injury, as well as risk and benefit balance, and the requirement for appropriate qualifications of the person conducting an experiment.

The Nuremberg Code, as a key early document in medical ethics, has served as a point of reference for the subsequent instruments in the field of medical research, including, for example, the World Medical Association (WMA) Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.[16] There are, however, noticeable differences between these two instruments because, as rightly pointed out by scholars, initially, physicians did not see the code applicable to them due to the war crime context in which it was created.[17] Thus, the Helsinki declaration enabled not only non-therapeutic clinical research and requested that a participant is informed and consents to it, but it also envisaged a possibility of involving in such research the "legally incompetent" on the condition that consent from a guardian is procured.[18] The principle set out in the Nuremberg Code is reflected in the protections prescribed in the legal frameworks, such as the ban on human experimentation set forth in Article 7 of the International Covenant on Civil and Political Rights.[19]

8 See Ciara Staunton, 'Individual Rights in Biobank Research Under the GDPR' in Santa Slokenberga, Olga Tzortzatou and Jane Reichel (eds), GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe (Springer International Publishing 2021)

9 Ciara Staunton, Santa Slokenberga and Deborah Mascalzoni, 'The GDPR and the Research Exemption: Considerations on the Necessary Safeguards for Research Biobanks' (2019) 27 European Journal of Human Genetics 1159.

10 Ciara Staunton and others, 'Appropriate Safeguards and Article 89 of the GDPR: Considerations for Biobank, Databank and Genetic Research' (2022) 13 Frontiers in Genetics.

11 Fruzsina Molnár-Gábor and others, 'Harmonization after the GDPR? Divergences in the Rules for Genetic and Health Data Sharing in the Four Member States and Ways to Overcome Them by EU Measures: Insights from Germany, Greece, Latvia and Sweden' [2021] Seminars in Cancer Biology.

12 E.g., Johan Hansen, Petra Wilson, Eline Verhoeven, M. Kroneman, Mary Kirwan, Robert Verheij, E-B. van Veen Assessment of the EU Member States' rules on health data in the light of GDPR. European Union (2021) https://doi.org/10.2818/546193

13 David B. Resnik, Bioethicist 'Research Ethics Timeline, NIEHS/NIH' (National Institute of Environmental Health Sciences) https://www.niehs.nih.gov/research/resources/bioethics/timeline/index.cfm accessed 5 July 2022.

14 Evelyne Shuster, 'Fifty Years Later: The Significance of the Nuremberg Code' (1997) 337 The New England Journal of Medicine 1436.

15 The first principle of the Code set forth a fundamental requirement that in the scientific experiment, "[t]he voluntary consent of the human subject is absolutely essential." 'Nuremberg Code' (United States Holocaust Memorial Museum) https://www.ushmm.org/information/exhibitions/online-exhibitions/special-focus/doctors-trial/nuremberg-code accessed 5 July 2022.

16 For an insight into the historical parallels of the Nuremberg Code and the Declaration of Helsinki, see Urban Wiesing, 'The Declaration of Helsinki—Its History and Its Future' (2014) 11 World Medical Association, November https://www.wma.net/wp-content/uploads/2017/01/Wiesing-DoH-Helsinki-20141111.pdf accessed 20 October 2022. Substantively, the Declaration of Helsinki took a softened approach to respect for a person more than that in the Nuremberg Code. William E Seidelman, 'Nuremberg Lamentation: For the Forgotten Victims of Medical Science' (1996) 313 BMJ 1463.

17 See, e.g., George J Annas, 'Beyond Nazi War Crimes Experiments: The Voluntary Consent Requirement of the Nuremberg Code at 70' (2018) 108 American Journal of Public Health 42

18 WMA historical version https://www.wma.net/wp-content/uploads/2018/07/DoH-Jun1964.pdf accessed 20 October 2022.

19 UN General Assembly, International Covenant on Civil and Political Rights (16 December 1966, United Nations, Treaty Series, vol. 999) p. 171. See Annas (n 17).

This provision equals non-consensual scientific experimentation to torture, cruel, inhuman, or degrading treatment and prohibits medical or scientific experimentation without the free consent of the person concerned.

The protection of an individual – though focusing *expressis verbis* on scientific research as opposed to scientific experimentation and containing an opening also for non-consensual research –, to date, is reflected in different research regulatory instruments, such as 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 (Biomedicine Convention),[20] its Additional Protocol on Scientific Research[21]as well as UNESCO Universal Declaration on Bioethics and Human Rights.[22] As opposed to the original approach of taking self-determination as an absolute value in the context of experimentation, these later instruments acknowledge the potential benefits of involving people in scientific research who cannot consent to the participation and envisage participation, subject to particular safeguards. Key to those is the scientific soundness of the intended study as well as its ethical acceptability.[23] More recently, the EU Clinical Trials Regulation has opened up for clinical trials in emergency situations, where involvement is expected to be directly beneficial to the subject and subject to several safeguards.[24] In regard to research that cannot benefit the ones unable to consent, the lowest involvement threshold includes a requirement that the research should benefit the group the person belongs to and the person concerned does not object.[25]

Despite the exponential evolution of the field, scientific research involving personal data has not specifically been regulated in international human rights law or addressed by global policy-makers.[26] However, personal data in different sectors have been of regulatory and policy attention. One such sector is genetic data and biobanking. For example, Principle 5 of the WMA Declaration of Taipei sets out that health research represents a common good that is in the interest of individual patients as well as the population and society. Consequently, research and other activities relating to health databases and biobanks should contribute to the benefit of society, in particular, in the public health context.[27] Respect for the dignity, autonomy, privacy, and confidentiality of the individual is one of the cornerstones of the declaration.[28] Principle 11 emphasizes the importance of voluntariness. It stipulates that "[t]he collection, storage and use of data and biological material from individuals capable of giving consent must be voluntary."[29] However, simultaneously, it does not preclude collecting samples and data from individuals incapable of giving consent subject to informed consent from a legally authorised representative of that person.[30] For those situations, Principle 13 sets forth an obligation to invest reasonable efforts to seek consent when these persons regain consenting capacity. This principle relates to the WMA Helsinki Declaration, which emphasizes the need for at least a group-related benefit when a person unable to consent is involved in research.[31] To research organization and requirements regarding those conducting research, principles set out in the Helsinki Declaration apply, such as the necessity to comply with generally accepted scientific principles, approval of a research ethics protocol by a research ethics committee, as well as a requirement for appropriate ethics and scientific education for those conducting research.[32]

The approach taken by the WMA in the two mentioned documents regarding the protection of the individual and the necessity for an examination of the scientific merit and verification of the ethical acceptability of a research project is also reflected in the recent Council of Europe recommendation concerning research on biological materials of human origin.[33] UNESCO International Declaration on Human Genetic Data also emphasizes voluntary consent, but when a person is not capable of consenting, the intervention needs to be in the best interests of the person concerned.[34] Likewise, it urges consultation with an ethics committee in regard to specific research projects.[35]

As this brief insight demonstrates, it is rather obvious that the research regulation has evolved. The initial focus on experimentation has shifted towards scientific research regulation, even though there are overlaps, and the interplay between the two is still somewhat ambiguous. However, even in data-intense research such as biobanking, where the physical risk and harm related to the individual are rather minimal, and arguably the most significant risks are attributable to data privacy rather than the removal of a cellular sample, the protection threshold is quite high. The individual, for the interests of society, may be involved in scientific research if she is incapable of consenting, provided that particular conditions are met and subject to other safeguards, such as a review of scientific quality and ethical acceptability of the intended research activity. Thus far, the research regulatory and policy instruments do not envisage the non-consen-

20 Council of Europe, Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997, ETS No. 164)
21 Council of Europe, Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (2005, ETS No. 195).
22 UNESCO Universal Declaration on Bioethics and Human Rights 2005.
23 See, for example, 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 (1997, ETS 164) art 16 iii.
24 See Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC Text with EEA relevance OJ L 158, 27.5.2014, p. 1–76, art 35. Annas (n 17).
25 See, for example, Biomedicine Convention (n 23) art 17.2.
26 However, calls in that regard have been made. See Konrad Siemaszko et al.D5.6: Recommendations for the enhancement of the existing legal frameworks for genomics, human enhancement, and AI and robotics (SIENNA v2.0 2020), p. 23 https://www.sienna-project.eu/digitalAssets/894/c_894270-l_1-k_sienna_d5.6_recommendations-for-the-enhancement-of-the-existing-legal-frameworks-for-genomics--human-enhancement--and-ai-and-robotics_www.pdf accessed 5 July 2022.
27 WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks, adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016, principle 8.
28 Declaration of Taipei (n 27) principle 9.
29 Declaration of Taipei (n 27).
30 See, e.g., WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the: 64th WMA General Assembly, Fortaleza, Brazil, October 2013, principle 28 and 30.
31 WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, last revised 64th WMA General Assembly, Fortaleza, Brazil, October 2013, principle 28.
32 Declaration of Helsinki (n 30), in particular, principles 12, 21, and 23.
33 Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin, arts. 12 and 22.
34 UNESCO International Declaration on Human Genetic Data 2003, art 8.
35 International Declaration on Human Genetic Data (n 34) art 6.

sual and non-beneficial participation of an individual capable of consenting to scientific research. Likewise, they do not depart from the requirements prescribed for the research, such as quality and approval, and the requirements prescribed to those carrying out research.

3. GDPR Scientific Research Regime and the Data Subject

3.1 Context of the Research Regime

Much ink has already been spilled over the GDPR scientific research regime. Nonetheless, without an account of the central pillars that the scientific research regime rests upon and its take on the data subject, it is rather difficult to appreciate the transformation that the proposed EHDS regulation is about to bring along. Hence, this section will briefly recap the contextual and conceptual foundations and the central features of the regime, along with highlighting the protection of the data subject in scientific research under the GDPR.

The GDPR attempts to strike a balance between the right to data protection and the free flow of personal data.[36] It builds on the premise that the protection of personal data, as set out in Article 8 of the Charter of Fundamental Rights of the European Union (Charter), is not an absolute right. As stipulated in recital 4 of the GDPR, this right "must be considered in relation to its function in society and be balanced against other fundamental rights, in accordance with the principle of proportionality." Scientific research falls within the protection scope of the Charter.[37] For some specific research objectives, also other Charter protections are of relevance. For example, some health-related research could potentially relate to the aspiration to ensure a high level of human health protection in the definition and implementation of all EU policies and activities and thus trigger the application of Article 35 of the Charter.[38]

Striking a balance between the right to data protection and other rights and principles as safeguarded by the Charter is not a straightforward task. After all, there is neither a mathematical calculation as to how the different rights and interests should be balanced against each other nor guidance on how this balancing needs to be weighted in the aspiration for free movement of personal data.[39] One way to look at the issue is through Article 52(1) of the Charter, the so-called "respect-for-the-essence test,"[40] coupled with the proportionality assessment required under the very same provision. Under this test, as a rule, any limitation that is not depriving this right of its essence could be measured against proportionality and is permitted only if necessary and genuinely meet objectives of general interest recognized by the EU or the need to protect the rights and freedoms of others. As has been in doctrine emphasized, the essence of the fundamental right is narrowly defined for good reasons – the strong protection it aspires to provide.[41] This enables extensive room for balancing various competing rights and interests at stake in the pursuit of particular objectives.

The Court of Justice of the European Union (CJEU) has had a chance to reflect on the essence of the right in cases that concern private life and data protection,[42] but not yet in the context of the scientific research regime set out in the GDPR. However, even where the CJEU has considered the essence of the right to data protection, what this essence is more closely, remains undefined.[43] For example, from *Schrems II* can be inferred that departure from the mechanism set up by the EU legislature to safeguard an individual from the state's intervention and a mechanism to ensure the effectiveness and enforceability of a data subject's rights favouring enhanced data access by the authorities and infringing on the effective judicial protection is not compatible with the essence of the right.[44] However, this case in itself does not guide in how to reason regarding setting the threshold for limits of public interference. As derived from *Tele 2 Sverige* case regarding data retention, even far-reaching interference, such as causing persons to feel that their private lives are the subject of constant surveillance,[45] can be in line with the respect for the essence of the rights test if the interference can be deemed proportional.[46]

Thus, what can be briefly noted is that the fundamental rights of the EU do not give a concrete answer regarding how a data subject should be protected within the scientific research and how much privacy and data protection the data subject should retain. The minimum threshold is what falls within the core of the right to data protection, which is something that has not been exhaustively defined by the CJEU. The implications are that there is a room of manoeuvre for the EU legislator regarding how the right to data protection in the context of scientific research should be regulated, and what is the minimum level of protection that a data subject could rely on is difficult to define.

3.2 Building Blocks of the GDPR Scientific Research Regime

The scientific research regime that has been built in the GDPR rests on several building blocks.[47] They include the notion of scientific

36 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), OJ 2016 L 119/1, art 1.

37 Charter of Fundamental Rights of the European Union OJ C 326[2012] p. 391–407, art 13.

38 Charter (n 37) art 35.

39 For a requirement for balancing, see recital 4 of the GDPR. For the interplay between the protection of natural persons and free the movement of personal data, see GDPR (n 36) art 1.

40 Koen Lenaerts, 'Limits on Limitations: The Essence of Fundamental Rights in the EU' (2019) 20 German Law Journal 779. Earlier in the case law, respect for "the very essence" has been used. However, it has been suggested that they may be used interchangeably. This approach is supported by the explanations relating to the Charter, see Explanation on Article 52 — Scope and interpretation of rights and principles in Explanations relating to the Charter of Fundamental Rights [2007] OJ C 303, p. 17–35.

41 Lenaerts (n 40).

42 See, e.g., C-293/12 Digital Rights Ireland Ltd v Minister for Communications, Marine and Natural Resources and Others and Kärntner Landesregierung and Others, ECLI:EU:C:2014:238, C-203/15 Tele2 Sverige AB v Post- och telestyrelsen and Secretary of State for the Home Department v Tom Watson and Others, ECLI:EU:C:2016:970 and C-311/18 Maximilian Schrems v Facebook Ireland Limited, ECLI:EU:C:2020:559.

43 See Mark Dawson, Orla Lynskey, and Elise Muir, 'What Is the Added Value of the Concept of the "Essence" of EU Fundamental Rights?' (2019) 20 German Law Journal 763. For a more thorough insight, please consult the special issue on the question of the essence of rights. (2022) 23 German Law Journal, 7 https://germanlawjournal.com/volume-23-issue-7/ accessed 20 October 2022.

44 Schrems II (n 42), paras. 168-187 in particular paras. 184 and 187.

45 Tele2 Sverige AB (n 42) paras. 100-107.

46 Tele2 Sverige AB (n 42) paras. 100, on the one hand, paras. 101-112, on the other hand.

47 For a thorough insight, see Santa Slokenberga, 'Setting the Foundations: Individual Rights, Public Interest, Scientific Research and Biobanking' in Santa Slokenberga, Olga Tzortzatou and Jane Reichel (eds), GDPR and

research, lawfulness and legal basis for data processing in scientific research, and individual rights, as well as a need for adequate safeguards.

Scientific research is a particular interest that the research regime upholds without setting forth clear and unambiguous delimitations of what scientific research is.[48] This has provoked earlier discussions, and even policy stands, for example, from the European Data Protection Supervisor.[49] However, to this day, clarity regarding the exact content of the concept is lacking. Therefore, borders of the scientific research regime – and consequently, possibilities to take advantage of the rules set forth therein – remain undefined.

At its very basic meaning, the principle of lawfulness requires that a legal basis for data processing needs to be met. For special categories of data, such as health and genetic data, this entails that lawful processing would require that one of the legal bases in Article 6(1) GDPR coupled with one of the provisions lied down in Article 9(2) GDPR that entails lifting the ban to process these data need to be fulfilled. The principle of purpose compatibility set out in Article 5(1)(b) *expressis verbis* indicates that scientific research is always compatible with the original purpose for which personal data were collected. However, when it comes to the legal basis of Article 6(1), and in contrast to Article 9(2)(j), a specific legal basis for scientific research is not prescribed. Thus, a cautious interpretation is that in the case of further processing of personal data for scientific research purposes, a legal basis set out in Article 6(1) must be met nonetheless. A more extensive interpretation is that the original legal basis may be relied upon even for data processing in scientific research.[50]

As opposed to Article 6(1) GDPR, Article 9(2) sets forth a provision that addresses scientific research in greater detail. Article 9(2)(j) expressly enables scientific research if envisaged in EU law or national law. It is required that Article 89(1) is followed and the processing for scientific research "shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject." However, at the same time, Article 9(2)(j) is not the only legal basis that may be used in scientific research. Other options, such as consent of the data subject under Article 9(2)(a), can also be invoked in scientific research. Moreover, Member States retain under Article 9(4) freedom in envisaging a higher level of protection or setting limitations to processing health and genetic data. Precisely as under Article 6(1), also under Article 9(2), consent and thereby respect for self-determination of the data subject and control of the personal information is one of several avenues that enable the processing of personal data. However, there are situations when consent cannot be deemed an acceptable legal basis due to, for example, the balance of power.[51]

Finally, the third element of the research regime is individual rights. Chapter III of the GDPR sets forth a number of rights that the data subject enjoys. However, at the same time, it sets out a multilevel mechanism to enable derogations. Firstly, these derogations can be applied directly by the researcher in the capacity of the controller.[52] Secondly, these derogations may be enabled through the Member State's national law or EU law in a particular field.[53] Additionally, under specific circumstances, the rights can be further curbed through the general derogation clause in Article 23 of GDPR. As Staunton and others have rightfully pointed out, at the most extreme, the data subject is left without almost any of the individual rights that the GDPR offers.[54]

In regard to the secondary use of previously collected data, one of the most significant curtailments is set out in Article 14 of the GDPR. Generally, the right to information is an essential element of ensuring transparency vis-à-vis the subject of the data. It also enables the data subject to exercise its other rights and interests, including bottom-up-oversight through requests regarding processing to the respective research institution acting as a controller, and also enables to submission of complaints to the competent authority. Put differently; if the data subject is not informed about processing, it is very difficult to request further details and explore whether any violation could have occurred. The avenue that the data subject may have is to approach the controller and, through processing record activities, seek access to relevant information. If disproportionally applied, it risks putting at stake other rights, such as a right to an effective remedy.

Precisely to Article 9(2)(j) GDPR, also the first two categories of derogations mentioned above – through direct applicability of the GDPR and through the EU or Member State law – are *expressis verbis* subjected to Article 89(1), which requires the existence of appropriate safeguards. What these safeguards are, however, is not generously elaborated in the GDPR. It merely states that "[t]hose safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation." As indicated in Article 89(1), they may include pseudonymization, but if possible, anonymisation. However, what other measures can serve as safeguards is rather ambiguous. In scholarship, two ways to approach them have been put forward.[55] According to Staunton *and others*, one way is that only the GDPR's safeguards shall be permitted. Another way is that the notion of adequate safeguards should be interpreted broadly to encompass even those research sector-specific safeguards that are set out in research regulatory instruments. While such an approach is generous towards the plurality of the different co-existing regulations for a particular type of research,

Biobanking: Individual Rights, Public Interest and Research Regulation across Europe (Springer International Publishing 2021).

48 The closest guidance GDPR provides can be found in recital 159 GDPR, which emphasises that "the processing of personal data for scientific research purposes should be interpreted in a broad manner including, for example, technological development and demonstration, fundamental research, applied research and privately funded research."

49 European Data Protection Supervisor, A Preliminary Opinion on data protection and scientific research, 6 January 2020. For critique, see Slokenberga (n 47).

50 The EDPB had committed to providing some guidance in its Guidelines on processing personal data for scientific research purposes. See EDPB Document in response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, paras.20-21. However, to date, these guidelines have not been released. See EDPB, https://edpb.europa.eu/our-work-tools/general-guidance/guidelines-recommendations-best-practices_en accessed 21 October 2022.

51 See EDPB 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, para 20. https://edpb.europa.eu/sites/default/files/files/file1/edpb_opinionctrq_a_final_en.pdf accessed 21 October 2022.

52 See GDPR (n 36) arts. 14(5)(b), 17(3)(d), 21(6).

53 See GDPR (n 36) art 89(2).

54 Staunton, Slokenberga and Mascalzoni (n 9).

55 Staunton and others (n 10).

it simultaneously opens up difficult – and thus far unresolved – questions, such as to what extent these safeguards could hinder the objectives that the GDPR aims to further, such as free movement of personal data.[56]

Under Article 9(4) GDPR, Member States retain the freedom to maintain or introduce further conditions, including limitations, for the processing of health, genetic as well as biometric data. It is not precluded that there can be an overlap between the prescribed further conditions, including limitations for processing personal data under this provision and safeguards under Article 89(1) GDPR. For example, the common requirement of ethical approval in biomedical research could be seen equally as a condition under Article 9(4) and as an appropriate safeguard under Article 89(1). One of the central features of measures adopted under Article 9(4) GDPR is that they should not hamper the free flow of personal data within the EU when those conditions apply to the cross-border processing of such data.[57] This suggests that the measures could apply when the research situation is constrained to one state or even when comparable requirements apply in several states. However, it might be difficult to uphold them under Article 9(4) when they pose hindrances to free movement. The rationale inbuilt for this provision in the GDPR goes back to the old Cassis-doctrine establishing the principle of mutual recognition in the internal market, specifically, the free movement of goods.[58] However, the application of this doctrine is not problem-free. While the GDPR itself aspires to further also free movement of personal data,[59] it is worth recalling that its legal basis is solely Article 16 TFEU and that there is a substantive difference in regulating alcoholic beverages, such as the case of *Cassis de Dijon* and regulating fundamental rights.

Ethical approval is one prime example of a measure that could equally be regarded as a safeguard that is required by Article 89(1), and that could also be a condition under Article 9(4) GDPR. While ethical approval has long been an essential feature in biomedical research,[60] not necessarily all countries have adopted that as a requirement for purely data-driven research. Here, a case in point is the contrast that Sweden and Latvia offer. In Sweden, research that involves special categories of personal data falls within the scope of the Ethics Review Act. Hence, unless ethical approval is obtained, the intended research shall not be carried out.[61] Latvia, on the other hand, does not set out any general requirement for ethical approval of research involving special categories of data.[62] If, for the purposes of a research project, a Latvian researcher wishes to access personal data for scientific research purposes from Sweden, a question is whether such a requirement for ethical approval can be upheld under the GDPR. While the GDPR aspiration is that national measures adopted under Article 9(4) GDPR shall not hinder free movement, it has to be recalled that the GDPR in itself does not create an obligation to provide access to data. Thus, one could argue that such a measure shall be compatible with the GDPR.

56 Staunton and others (n 10).
57 GDPR (n 36) recital 53.
58 See Case 120/78 Rewe v Bundesmonopolverwaltung für Branntwein ECLI:EU:C:1979:42.
59 See GDPR (n 36) art 1.
60 E.g., Biomedicine Convention (n 23) art 16(iii) .
61 See Act Concerning the Ethical Review of Research Involving Humans (Lag (2003:460) om etikprövning av forskning som avser människor), secs. 3.1 and 6.
62 It establishes a different data access mechanism, Cabinet Regulation No. 446 of 4 August 2015, Procedures for Using the Patient Data in a Specific Research, Latvijas Vēstnesis, 152, 06.08.2015.

While this ambiguity could be of equal relevance to any other national measure in the field of research regulation,[63] it should also be noted that ethics is a somewhat special case. Questions that concern moral values have obtained a particular role in the EU legal order. For example, the case of *Omega*, which dealt with a clash between free movement and the protection of fundamental rights, demonstrated an openness to a generous interpretation of the principle of human dignity, thereby also a generous possibility to restrain free movement.[64] Subsequent cases show that the CJEU is open to accounting for ethics as a restriction to free movement, even in cases where the EU legislature has chosen not to do so.[65] This creates an additional – treaty-based – avenue to claim lawfulness even if the measure hinders the free movement of personal data.

3.3 Status of the Data Subject

The GDPR research regime puts data subjects, in many ways, in a unique position. In regard to research on the residual material samples from healthcare, under the Biomedicine Convention, an opt-out regime has long been regarded as an acceptable solution for meeting information and consent requirements.[66] That requires, however, that the individual has received adequate information and has had the possibility to opt out of the research. In research ethics, various approaches to loosen the requirement for consent have been put forward, including broad consent.[67] As has been briefly illustrated in section 2 above, non-consensual research has been seen as an exception rather than the rule, coupled with a number of safeguards.[68] One central feature of the non-consensual involvement has been either direct benefit to the person concerned or, at least, benefit to the group the person belongs.

The GDPR takes a departure from the self-determination approach to participation in scientific research. Consent is one of the possibilities to satisfy the requirement of lawfulness attributable to processing health and genetic data in scientific research. However, as was previously discussed, not the only one; for example, secondary research is possible without the consent of the data subject under other clauses under both, Article 6(1) and Article 9(2) GDPR and without putting any requirements for benefits to the data subject or a group the subject belongs to in relation to the intended research. The Member States could, nonetheless, in accordance with Article 9(4) GDPR, choose to enable research only if the consent requirement is met, provided that it is compatible with the GDPR, or require consent as a safeguard.

63 Another such example is scientific approval and national requirements prescribed to the researcher in line with the reviewed ethical standards in section 2 above.
64 C-36/02 Omega Spielhallen- und Automatenaufstellungs-GmbH v Oberbürgermeisterin der Bundesstadt Bonn, ECLI:EU:C:2004:614.
65 See Case C-165/08 Commission of the European Communities v Republic of Poland ECLI:EU:C:2009:473
66 See Biomedicine Convention (n 23) art 22. Explanatory Report to 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, para 137.
67 Mats G Hansson and others, 'Should Donors Be Allowed to Give Broad Consent to Future Biobank Research?' (2006) 7 The Lancet Oncology 266.
68 See Council of Europe, Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (2005, ETS No. 195) ch V. See also Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin, art 12 https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=0900001680064e8ff accessed 21 October 2022.

In a more general way, elsewhere, I have argued that informational privacy protection in the era of data protection is not about the individual's seclusion or secrecy.[69] As the GDPR creates a data processing mechanism, the nature of the right to data protection that is offered to the data subject is a controlled access mechanism. This entails that the one who meets prescribed requirements in the GDPR – coupled with EU law or national law based on the GDPR, as relevant – is entitled to access even deeply private information such as health or genetic data, and the GDPR itself does not create any room for the data subject to object.[70] The Member States, nonetheless, retain a discretion to envisage higher protection for the data subject's right to self-determination. However, as this discretion should not hamper free movement – i.e., constrained to wholly internal research situations –,[71] its impact is difficult to assess. Privacy, generally, as a right, allows for limitations, including establishing a mechanism for accessing one's zone of seclusion without the consent of the individual. In this light, the GDPR places a number of other interests, including scientific research, higher than the data subject's interest in being secluded in some respects without investing adequate efforts in prescribing limits to what can be regarded as scientific research within the meaning of the GDPR, or what are the compensatory measures that are supposed to uphold the protection in the absence of the individual's control.

4. The Proposed EHDS Regulation, Scientific Research, and the Data Subject

4.1 On the Proposed EHDS Regulation

The proposed EHDS regulation is designed in order to achieve several ambitious tasks, including supporting health research and innovation, as well as policy-making, regulatory and personalized medicine purposes.[72] It makes a distinction between the primary and secondary use of electronic health data.[73] Whereas healthcare and health administration belong to the primary use, such purposes as scientific research are part of the secondary use, even though data are collected in order to carry out a particular research project. This approach roots in the idea that primarily electronic health data have a medical purpose, and thus their primary use is healthcare. However, simultaneously, it is not only confusing from the regulatory research perspective as research could be the purpose for which data are collected but also has been argued to sit uneasily with the terminology of the GDPR that makes a distinction between the processing of data and further processing of the previously collected data.[74]

The use of electronic health data for scientific research is regulated in Chapter IV of the proposed EHDS regulation. It addresses several aspects of relevance to the secondary use of electronic health data, such as purposes for which data may be used, and lists some prohibited uses. It designs a framework for accessing the data, where a key role is assigned to a data access body (or bodys) at the national level. Moreover, building on the Data Governance Act, it prescribes rules regarding data altruism in health, the duties and obligations of the data holders and the data users, and the responsibilities of the health data access bodies and data users as joint controllers. It also prescribes rules regarding costs associated with the secondary use of electronic health data, an infrastructure and a process for cross-border data exchange, as well as dataset quality and utility standards.

Nowhere in this framework *expressis verbis* attention is given to the data subject's rights.[75] Moreover, the term data subject has not been used in Chapter IV of the proposed regulation. Understandably so in so far as the mechanism regulates non-personal data. Instead, the proposal refers to natural persons, which may and may not be data subjects. Hence, how the proposed EHDS regulation impacts the status of the data subject needs to be examined through insight into the designed mechanism for facilitating the secondary use of electronic health data and examined in correlation with the GDPR.

4.2 On Electronic Health Data and Secondary Use

The proposed EHDS regulation applies to the use of electronic health data in scientific research that have been previously collected in the context of the primary use and electronic health data collected for the intended secondary use.[76]

Electronic health data capture personal as well as non-personal electronic health data.[77] Personal electronic health data cover data concerning health and genetic data as defined in GDPR. Additionally, it also captures data referring to determinants of health or data processed in relation to the provision of healthcare services if processed in an electronic form.[78] To what extent this can be seen as an expansion of the definition is not easy to ascertain as the health data definition under the GDPR is open-ended, and the assessment thus needs to be case-by-case based. However, the attempt to deviate from the definition set out in the GDPR has been subject to critique by the EDBP and the EDPS.[79] Non-personal electronic health data, however, means health and genetic data in electronic format if the respective data cannot be regarded as personal data within the meaning of Article 4(1) of the GDPR.[80] Consequently, whereas for the personal electronic health data, both legal instruments will co-exist, non-personal electronic health data will be subject to the proposed EHDS regulation only.

Article 33 sets out the minimum categories of electronic health data that shall be made available for secondary use, including scientific research. These categories cover, for example, electronic health records, data that have an impact on health (e.g., social, environmental, behavioral determinants); human genetic, genomic, and proteomic data; person-generated electronic health data, including medical devices, wellness applications or other digital health applications; as well as electronic health data from biobanks and dedicated databases. Overall, these categories cover a broad range of data coming from different environments, including those where trust and

69 Santa Slokenberga, 'You can't put the genie back in the bottle: on the legal and conceptual understanding of genetic privacy in the era of personal data protection in Europe' [2021] BioLaw Journal - Rivista di BioDiritto 223. On different facets of privacy, see Daniel J Solove, 'A Taxonomy of Privacy' (2006) 154 University of Pennsylvania Law Review 477.
70 Slokenberga (n 69).
71 GDPR (n 36) recital 53.
72 See proposed EHDS regulation (n 1) p. 2.
73 See proposed EHDS regulation (n 1) arts 2(2)(d) and 2(2)(e).
74 In regard to the latter, the EDPB and the EDPS, in their joint opinion, have called for reconsideration of the use of terminology. EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, Adopted on 12 July 2022, https://edpb.europa.eu/system/files/2022-07/edpb_edps_jointopinion_202203_europeanhealthdataspace_en.pdf, accessed 21 October 2022, para 42.
75 See proposed EHDS regulation (n 1) ch IV.
76 Proposed EHDS regulation (n 1) art 2(2)(e).
77 Proposed EHDS regulation (n 1) art 2(2)(c).
78 Proposed EHDS regulation (n 1) art 2(2)(a).
79 EDPB-EDPS Joint Opinion 03/2022 (n 74) para 40.
80 Proposed EHDS regulation (n 1) art 2(2)(b).

confidentiality are of paramount importance, such as health care and scientific research, as well as that relates to other personal – even deeply personal – spheres, such as those generated as a result of choice to use wellness applications. Generally, these data stem from such sources as healthcare and public health administration, scientific research, where trust has traditionally been a vital component, as well as cover data resulting from personal choices of the individuals, such as the use of wearables.

As derived from Article 34(1)(e) of the proposed EHDS regulation, scientific research is among the purposes for which electronic health data can be processed for secondary use when relating to health or care sectors, provided that the intended use does not fall under prohibited uses of electronic health data listed in Article 35. In a way, the proposed EHDS regulation follows the ambiguous approach taken by the GDPR. It creates a framework for data use that is dependent on several concepts, but at the same time, it does not pin down their content exhaustively. For example, neither scientific research nor health or the care sectors are defined in the proposed EHDS regulation. This allows posing questions regarding the scope of application of the respective secondary use purpose.

Some guidance regarding scientific research is set out in recital 41 of the proposed EHDS regulation. It makes a split between scientific research, on the one hand, and development and innovation, on the other hand. Development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or medical devices, are supposed to be different from scientific research.[81] This, however, does not seem to be well aligned with the approach taken under the GDPR that was discussed above in section 3, under which the GDPR urges to interpret the notion in a broad manner "including for example technological development and demonstration, fundamental research, applied research and privately funded research."[82] The split that the proposed EHDS offer between research, on the one hand, and development and innovation, on the other hand, in itself, however, does not resolve the discussion under the GDPR regarding the scope of application of a scientific regime therein.[83] What it does, however, is that it creates possibly far-reaching implications for the protection of data subjects, as discussed below in section 4.4.

What concerns the health and care sectors, these two notions are mentioned at times in recitals of the proposed EHDS regulation.[84] However, it fails to elaborate on the modalities of this concept and, therefore, provides only some pointers regarding the scope of the intended uses.[85] These ambiguities risk rendering the scope of the duty to share data rather difficult to ascertain, which risks resulting in ambiguities regarding the scope of interference with the right to data protection that data subjects have.[86]

4.3 Roles, Obligations, and Tools

The proposed EHDS regulation creates a new framework for accessing electronic health data for secondary use. In that regard, it designs three essential roles and puts forward three administrative tools. First, regarding the roles, those are the data holder, the data user, and the data access body. Secondly, regarding the administrative tools to further the secondary use of electronic health data, it defines a data permit, data access application, and data request.

To begin with, a data holder is a natural or legal person holding the right or obligation to make available certain data[87] according to the rules set out in Chapter IV of the proposed EHDS.[88] A different approach is taken regarding non-personal data – there, it is enough if the data holder has the ability, through the control of the technical design of a product and related services, to make available certain data.[89] As a general rule, micro-enterprises are exempted from the obligation to make the specified categories of electronic data available for secondary use.[90] However, at the same time, the proposed EHDS regulation intends that public and private entities receiving public EU or a Member State's funding are subjected to the duty to release the data.[91] It remains to be clarified how this will relate to the micro-enterprises.

In regard to personal electronic health data, it is intended that the proposed EHDS regulation constitutes a legal basis under Article 6(1)(c) GDPR, enabling the data holder to process data for sharing purposes. Simultaneously, the regulation also intends to meet the requirements of Article 9(2)(j) along with 9(2)(h) and (i) so that the ban on processing special categories of data can be lifted and data holders can fulfil the duty of sharing. While, on the surface, the mechanism is rather straightforward, a closer look reveals some challenges. In particular, under the GDPR, some data could be subject to consent requirements, for example, either as a legal basis for the processing to be lawful in accordance with 9(2)(a) or a condition or restriction in accordance with Article 9(4) GDPR or as a safeguard under Article 89(1) GDPR. Whilst the proposed EHDS regulation acknowledges that some data could be covered under the consent requirement in accordance with national law, the effect of this consent vis-à-vis the sharing duty is unclear, as Article 34(5) requires reliance on Chapter IV in order to provide access to electronic health data.[92]

The list of minimum categories of electronic health data that are subject to secondary use seems to be constructed in an exhaustive way but, simultaneously, subject to amendments from the European Commission.[93] The requirement of sharing applies even if the data entails protected intellectual property and private enterprise trade secrets. In such a case, all measures necessary to preserve the confidentiality

81 Cf art 34(1)(e) and 34(1)(f) of the proposed EHDS regulation.
82 GDPR (n 37) recital 159.
83 Overall, there is a rather ambiguous alignment between Article 9(2) GDPR and Article 34(1) of the proposed EHDS regulation, making it difficult to assess whether what could qualify as scientific research under the GDPR would become as an innovation and development activity under the EHDS. See in that regard also EDPB-EDPS Joint Opinion 03/2022 (n 74) para 86.
84 e.g., recital 40 mentions the health sector.
85 It includes the definition of healthcare under Directive 2011/24/EU. However, the "health and care sector" is presumably broader than healthcare as defined in Article 3(a) of the directive, namely, as "health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation, and provision of medicinal products and medical devices."
86 See in this regard EDPB-EDPS Joint Opinion 03/2022 (n 74) para 85.
87 Proposed EHDS regulation (n 1) art 2(2)(y). Overall, art 2(2)(y) sets out a broad definition and consequently could make it ambiguous as to who can be regarded as a data holder. See EDPB-EDPS Joint Opinion 03/2022 (n 74) para 44.
88 Proposed EHDS regulation (n 1) art 33.
89 Proposed EHDS regulation (n 1) art 2(2)(y).
90 Proposed EHDS regulation (n 1) art 33(2).
91 Proposed EHDS regulation (n 1) recital 40.
92 See in this regard also a critique of the EDPB-EDPS Joint Opinion 03/2022 (n 74) paras 91-92.
93 Proposed EHDS regulation (n 1) art 33(7).

of intellectual property rights and trade secrets shall be taken.[94] However, notwithstanding the fact that the data categories are enlisted in the proposed EHDS regulation, "health data access bodies may provide access to additional categories of electronic health data that they have been entrusted with pursuant to national law or based on voluntary cooperation with the relevant data holders at the national level, in particular to electronic health data held by private entities in the health sector."[95] This is in line with the task that the bodies will have in expanding the data categories subject to secondary use.

A data user is a natural or legal person who gains lawful access to personal or non-personal electronic health data for secondary use as prescribed in Chapter IV of the proposed EHDS regulation.[96] The notions of natural or legal persons capture public and private actors, not-for-profit entities, and individual researchers.[97] In order to gain access to electronic health data, the data user is obliged to show that the legal basis for accessing personal data, as well as other requirements, such as the purpose specification under the proposed EHDS regulation, are met.[98] However, unlike for the data holder, for the data user, the proposed EHDS regulation is intended to meet Article 9(2) GDPR requirements only. For lawfulness under Article 6(1), the prescribed GDPR requirements must be met differently. The proposed EHDS regulation does not prescribe any further requirements, such as qualification of the data user vis-à-vis the intended purposes of data use. However, a potential data user needs to assume responsibility to make sure that the intended use does not fall under the prohibited uses listed in Article 35 of the proposed EHDS regulation.

An essential component in promoting the secondary use of electronic health data is the already mentioned data access body. Unlike data holders and users, the notion of a data access body is nowhere defined in the proposed EHDS regulation. Its status and role can be inferred from the status and obligations prescribed within Chapter IV and recitals 42-44, and from other EU instruments. In short, an actor under the national laws will need to be established to fulfil the obligations in the proposed EHDS regulation in regard to ensuring that the data access system is duly functioning and each data user has the possibility to access the necessary data.[99]

Of the three novel administrative tools that are proposed for the purposes of furthering the secondary use of electronic health data, only data permit is defined in Article 2 of the proposed EHDS regulation.[100] The essence of the data request and access application needs to be inferred from the substantive provisions and recitals of the proposed EHDS regulation.

Data request provides for the possibility to access information in an anonymized statistical format for the purposes that are listed in Article 34[101] without providing access to the data that have been used to provide the answer to the request. The data request may be applied for by any natural or legal person.[102] This tool could be of use in order to obtain a better picture of a data holder's data. In comparison with the requirements for data access applications, data requests shall include much less information that motivates the request, namely, a detailed explanation of the intended use of the electronic health data as well as a description of the requested electronic health data.[103] This mandatory data request requirement is somewhat confusing as under Article 47(1), the data requests result in an answer in an anonymised statistical format without providing access to the electronic health data used to provide the answer.

For any natural or legal person to gain access to electronic health data covered under the proposed EHDS regulation, a data access application needs to be submitted to the data access body, or where the data relating to a single country and single holder, the application may be submitted directly to the data holder.[104] The application shall include but is not limited to, a detailed explanation of the intended use of the electronic health data, a description of the requested electronic health data, their format and data source, and a specification of whether the data should be provided in an anonymized format or a pseudonymized format. If data are sought in a pseudonymized format, a relevant explanation must be provided. A description of safeguards that are intended to prevent any other use of the requested data needs to be specified. Likewise, a description of safeguards planned to protect the rights and interests of the data holder and of the natural persons concerned. Furthermore, an estimation of the period for which the data are needed shall be provided, as well as a description of the tools and computing resources needed for a secure environment.[105] The content of the application, however, is not limited to the listed elements. Simultaneously, it is unclear how much additional information could be required. For example, Article 35 lists prohibited secondary uses of electronic health data and are constructed to target the actions of a data user. However, the data holder might have an interest in verifying that the intended use is not prohibited under EU law.

Additionally, in cases where personal electronic health data are sought, the proposed EHDS regulation mandates two additional considerations. Firstly, a description of how the processing would comply with Article 6(1) of GDPR. It does not request reflections under Article 9(2) GDPR, presumably because the proposed EHDS regulation needs to be regarded as EU law under Article 9(2)(j) GDPR.[106] This, however, can make it difficult to assess compliance with the requirements set out in the GDPR unless compliance is presumed. As derived from the joint opinion of the EDPB and EDPS, it does not seem that a presumption would be a possible solution.[107] Secondly, information on the assessment of ethical aspects of the processing needs to be provided, where applicable and in line with national law.[108] This means, for example, that for the researchers in Sweden, compliance with the Ethics Review Act would need to be ensured, whereas, for the researchers in Latvia, the ethics requirement would be irrelevant as the law does not mandate it.

Finally, should the natural or legal person who has applied for access-

94 Proposed EHDS regulation (n 1) art 33(4).
95 Proposed EHDS regulation (n 1) art 33(8).
96 Proposed EHDS regulation (n 1) art 2(2)(z).
97 Proposed EHDS regulation (n 1) recital 41.
98 Proposed EHDS regulation (n 1) recital 37 and art 34.
99 Proposed EHDS regulation (n 1) ch V sec 2.
100 See Proposed EHDS regulation (n 1) Article 2(2)(aa).
101 See Proposed EHDS regulation (n 1) art 47(1).
102 See proposed EHDS regulation (n 1) art 47(1).
103 Article 47(2) with reference to Article 45(2)(a) and (b). Moreover, the requester is also enabled to specify, for example, a description of the result expected from the health data access body and a description of the statistic's content.
104 Proposed EHDS regulation (n 1) art 45(1) and 49(1).
105 Proposed EHDS regulation (n 1) art 45(2).
106 Proposed EHDS regulation (n 1) recital 37.
107 See EDPB-EDPS Joint Opinion 03/2022 (n 74) paras 83-90.
108 Proposed EHDS regulation (n 1) art 45(4).

ing electronic health data meet the requirements set out in Chapter IV of the proposed EHDS regulation, data permit shall be issued.[109] It is an administrative decision issued to a data user by a health data access body or data holder to process the electronic health data specified in the data permit for the secondary purposes specified in the data permit.[110] This means that if the formal conditions for data access are met, nothing hinders accessing the data for the intended purpose. No particular professional qualification requirements, such as a demonstration of appropriate expertise, are requested.

4.4 Data Subject and the Proposed EHDS Regulation

The only place in Chapter IV of the proposed EHDS that expressly relates to individuals is Article 38 – obligations of the health data access bodies – and it addresses natural persons generally and not data subjects specifically. In Article 38(2), it is stated that the health data access bodies shall not be obliged to provide the specific information under Article 14(5)(b) of the GDPR to each natural person concerning the use of their data for projects subject to a data permit. Instead, it shall provide the general public information on all the data permits issued.

Regarding the GDPR, one of the critical aspects highlighted was that Article 14 enables a derogation for scientific research purposes.[111] This means that when data are accessed through the data access body, in the case of sharing pseudonymized data, the data subject might have rather limited options in finding out the data flow and exercising rights that the GDPR affords. The duty to inform remains with the data holder, but that then requires an active interest from the data subject in attempting to get information regarding the use of the data from the data controller. While cumbersome on the data subject, it is rather difficult to claim that a derogation *per se* affects the core of the right to data protection if one presumes that the GDPR did not do so. To quote Kokott regarding the peculiarities of the EU law, "[t]he devil is, however, as so often, in the detail."[112] As a general rule under the EU law, all exceptions need to be interpreted narrowly. A broad exemption, whilst the data access body holds the status of a joint controller, could risk undermining the data subject's rights.[113] Moreover, the impact on the core of the right can also not be precluded, as transparency is one of the data protection principles set out in Article 5(1)(a) GDPR and strongly relates to the effective judicial remedy.

There are a number of potential indirect influences on the status and protections of the data subject that derive from the secondary use framework in scientific research as set out in Chapter IV of the proposed EHDS regulation. To begin with, secondary use entails scientific research. However, as previously noted, the proposed EHDS regulation fails to define what scientific research is. Furthermore, in addition to scientific research, it explicitly opens up data access for other uses, including the already mentioned development and innovation. This might seem on the surface to solve the problem scrutinized under the GDPR regarding what exactly constitutes scientific research. In particular, whether generating the knowledge alone is or should be covered, or technological development – activities to apply the scientific knowledge to deliver new products and services – as well. However, if an obligation to demonstrate that the prohibition to process special categories of data under Article 9(2) GDPR is taken seriously and not presumed merely because a purpose under Article 34 of the proposed EHDS regulation is identified, then the problem vis-à-vis personal electronic health data is not resolved. Moreover, this split could have far-reaching implications if one considers the national laws and the fact that ethical approval may potentially be required for scientific research at the national level, but not necessarily development and innovation. The implications risk is that scientific research is then subject to higher accountability standards than development and innovation.

The proposed EHDS regulation as a legal basis for processing data in scientific research builds on the opening that the GDPR created under Article 9(2)(j) for adopting EU law in the field. Simultaneously for data users, it is not a legal basis within the meaning of Article 6(1) GDPR, where one of these bases is consent. Furthermore, as was discussed, a Member State may have opted for particular conditions, including restrictions for scientific research under Article 9(4) GDPR, such as an informed consent requirement, or at least enabled an opt-out from the health or genetic data processing in scientific research. The proposed EHDS regulation acknowledges that consent could be required under national law. In particular, Article 33(5) of the proposed EHDS regulation states that "[w]here the consent of the natural person is required by national law, health data access bodies shall rely on the obligations laid down in this Chapter [Chapter IV] to provide access to electronic health data." However, the implications of this provision are unclear vis-a-vis data subject to the consent requirements, but also, as pointed out by the EDPB and EDPS in their joint opinion, also implications vis-a-vis the data permit are unclear.[114]

In line with Article 9(4) GDPR, under the national law, data subjects could also be enabled to choose in what research to participate in. As the exact role of Article 9(4) GDPR and national measures in regard to electronic health data is ambiguous, there is a risk that the choice of opting out of some research could be deprived. If that is the case, one can be subjected to research that the data subject finds unacceptable, e.g., because of moral objections.

The proposed EHDS regulation intends to put in place "[s]trong safeguards and security measures will be implemented to ensure that the fundamental rights of data protection are fully protected, in accordance with Article 8 of the EU Charter of Fundamental Rights."[115] Already the GDPR emphasized the need for data minimization.[116] If possible, as a rule, anonymized data have to be preferred, thereby rendering the GDPR inapplicable.[117] However, if not, pseudonymised.[118] The proposed EHDS regulation reiterates this approach under Article 44 and subjects the data minimization principle to external control in the data access procedure depending on the access situation, either exercised by the data access body or the data holder. This can be regarded as a positive step from the data subject's perspective. However, simultaneously, it presumes that an individual whose data are subject to the data sharing mechanism in anonymised form should not be concerned about the data use. Ironically, this presumption is steering the secondary use framework, whilst it is also acknowledged that some data are particularly sensitive, and there is a

109 Proposed EHDS regulation (n 1) art 46(1).
110 Proposed EHDS regulation (n 1) art 2(2)(aa).
111 Slokenberga (n 47).
112 View of Advocate General Kokott delivered on 13 June 2014 (1) Opinion procedure 2/13, ECLI:EU:C:2014:2475, para 4.
113 See in that regard EDPB-EDPS Joint Opinion 03/2022 (n 74) paras 95-96.
114 See proposed EHDS regulation art 46(6)(f) and EDPB-EDPS Joint Opinion 03/2022 (n 74) para 92.
115 Proposed EHDS regulation (n 1) sec 3.
116 GDPR (n 36) art 5(1)(c).
117 GDPR (n 36) recital 26.
118 See, e.g., GDPR (n 36) art 89(1).

risk of identification that exceeds the *Breyer* threshold of the reasonable likelihood.[119] As regards sharing of the pseudonymised data, a safeguard in terms of respect for the pseudonymisation measures is required, accompanied by a requirement of appropriate penalties.[120] The effective legal remedy for a data subject concerned in such a case is not envisaged in the proposed EHDS regulation. The requirement of respect and penalties, however, under the current wording of Article 44(3) of the proposed EHDS regulation does not extend to anonymous data. This is ignorant to the concerns that are acknowledged in the proposal regarding risks of identification that go beyond reasonable likelihood. To ensure the effective functioning of anonymisation as a safeguard, the requirements set out in Article 44(3) should be extended to anonymous data.

The question of ethical approval also has a bearing on the protections that the data subject has in the context of the secondary use of electronic health data. As was discussed in section 2 above, ethical approval is a common feature in different research areas to ensure not only that the research is ethical but also that the rights and interests of the persons concerned are safeguarded. As the proposed EHDS regulation demonstrates, the European Commission opts for coordinating in case of a Member State requires approval and is reluctant to raise the requirement at the EU level as a uniform standard throughout the EU Member States.[121] This approach can be criticized in particular as the EU is adopting measures to facilitate the secondary use of personal data. While this approach might be easier to justify if cross-border healthcare and free movement of persons did not exist, at a time when it is rather straightforward to access care in another country or even become socially ensured and have health and the genetic data part of another county's electronic health records, it seems rather difficult to justify this reluctance. More so, if one considers that the EU is founded on a number of values, including human rights and bioethical principles anchored in human rights.[122] Ultimately, in the aspiration to safeguard the subsidiarity of the Member States, the European Commission implicitly proposes that the data subject should keep track of the diverse national rules instead of the EU assuming responsibility for ensuring that the secondary data use is ethical and instead of offering uniform and unambiguous protection throughout the EU.

5. Connecting the Dots: Scientific Research Regime 2.0?

The previous section outlined the central features of scientific research as part of the secondary use under the proposed EHDS regulation and highlighted some of the transformations that the proposal suggests bringing along to the scientific research regime and the data subject. By way of conclusion, some general reflections regarding the scientific research regime under the GDPR, the proposed EHDS regulation, and the protection that has been afforded to a data subject being involved in scientific research should be made.

The proposed EHDS regulation builds on the foundations that the GDPR has set for health, genetic data, and scientific research. It has far-reaching aspirations in the area of public health, expressed through the objective to further the common good. However, at the same time, the foundations of the proposed regulation rest on the data protection and internal market legal grounds, Article 16 (data protection) and 114 (internal market) TFEU, respectively, without relying on Article 168 (public health) TFEU.[123] The choice not to include public health as a legal basis sits rather unwell with the objectives of Chapter IV of the proposed EHDS regulation, including strengthening data access for scientific research purposes related to health or care sectors.

Overall, the proposed EHDS regulation has considerable ambitions in the area of secondary use of electronic health data, and scientific research is only one dimension that it addresses. Data-driven research is not specifically regulated under international human rights law. At most, soft law instruments, such as the UNESCO Declaration on Genetic Data and the Council of Europe Recommendation regarding biobanking, exist. The EU scientific research regime consisting of the GDPR and the proposed EHDS regulation could become a data research standard within the EU and potentially, judging by the GDPR extraterritorial effects,[124] and envisaged sharing with the third countries under the proposed EHDS regulation, even beyond. Although some national laws still could exist in the field and even co-exist with both of the EU frameworks, the cumulated effect of the GDPR and the proposed EHDS regulation could be easily expected to dominate in data-intensive scientific research due to such reasons as unwillingness or lack of prioritization to regulate the matter at the national level, or acceptance of the standard set by the EU. This places considerable responsibility in the hands of the EU legislature and requires careful consideration regarding different rights and interests at stake in the pursuit of the common good and finding a fair balance to reconcile them.

The proposed EHDS regulation will co-exist with the GDPR in regard to personal electronic health data. This means that the scientific research requirements under both instruments will complement each other in regard to such research that involves electronic health data. In a way, in so far as they will co-exist, the cumulated effect could be said to be a scientific research regime 2.0. However, the proposed EHDS regulation goes further than the GDPR and also covers non-personal electronic health data. It is well in line with the structure of the EU's data protection regime that the proposed EHDS regulation builds on the principles set out in the GDPR. As a primary objective in regard to scientific research, it seems to set its focus on data sharing and data access – two issues heavily discussed under the GDPR and in light of the fragmentation of the scientific research regime. However, as has become apparent, it fails to give due regard to the matters that are of importance to the data subject's protection in scientific research and that should be remedied during the legislative process.

The central starting point of the proposed EHDS regulation seems to be an assumption that electronic health records are part of the common good, and the individuals – as a starting point – do not have a legitimate interest in enjoying seclusion regarding their

119 C-582/14 Patrick Breyer v Bundesrepublik Deutschland, ECLI:EU:C:2016:779, para 45. GDPR (n 37) recital 26.
120 Proposed EHDS regulation (n 1) art 44(3). However, see the wording of recital 49 that suggests some discretion. Moreover, compare this approach vis-à-vis situations where data are directly acquired from a data holder.
121 Proposed EHDS regulation (n 1) recital 50 and art 45(4)(b).
122 See Consolidated version of the Treaty on European Union OJ C 326, 26.10.2012, p. 13–390, art 2.
123 See Proposed EHDS regulation (n 1).
124 See, e.g., Anu Bradford, The Brussels Effect: How the European Union Rules the World (Oxford University Press 2020).

health or genetic data and restraining access to them. Whereas scientific research in the area of health has long been regarded as part of the public interest, under the proposed EHDS regulation, scientific research is only one of the many interests that the mechanism upholds. A number of other purposes, including development and innovation, carried out by market actors, are placed on equal footing, disregarding the empirical data that for individuals, not all users and not all purposes are equal.[125] At the core, this is about finding a balance between respect for self-determination and interest in accessing the data for a presumed common good. One could argue that the proposed EHDS regulation, by default, takes the balance to the extreme. One can question the foundations of this approach and how that relates to the core of the right to data protection safeguarded under Article 8 of the Charter.

A starting point in early scientific research regulation was the status of an individual as a subject and not that of an object. This anchors in the principle of human dignity, among others, set out in Article 1 of the Charter. At its core, it requires that individuals are not treated as means for furthering particular interests. In the case of the proposed EHDS regulation, those are personal data that are treated as an object and, by extension, the rights and interests of the individual. For example, the question of the importance of self-determination – or lack of it thereof – in data research is a significant issue in the context of the scientific research regulatory and governance requirements. It must, nonetheless, be acknowledged that there is a fundamental difference between scientific research on a human being and scientific research involving one's data. This could potentially be a key argument in arguing that the EU's approach is compatible with the principle of human dignity nonetheless.[126] Its weakness, however, is the fact there are other important interests than bodily harm at stake that the principle of self-determination could seek to protect, including a wish to preserve a meaningful choice regarding the types of common good furthered through one's data. Moreover, this approach goes directly against the ambition of the proposed EHDS regulation expressed in Article 1(2)(a) to strengthen "the rights of natural persons in relation to the availability and control of their electronic health data." Either the mechanism set out in Chapter IV needs to be amended so that some control to the individuals is given, which would be the preferred approach considering ethico-legal standards of scientific research, or the scope of Article 1(2)(a) needs to be tamed to the primary use of electronic health data only.

In regard to ensuring the protection of self-determination, both for mandating consent as well as enabling opt-out from some research, the central question will be regarding the freedom that the Member States retain under Article 9(4) GDPR. While the GDPR emphasises that any measure under Article 9(4) should not hamper the free movement of personal data, there is one important aspect regarding the GDPR. It does not in itself create a duty to share data. This is a key novelty of the proposed EHDS regulation. If consent and opt-out mechanisms are the subjects of national law, then even more so, the implications of these rules under the new mandatory data-sharing mechanism need to be clear and transparent so that the trialogue in the legislative process can make a deliberate decision regarding the intended interplay between the two legal frameworks.

The approach that the proposed EHDS regulation takes in regard to the protection of the data subject could rather be said to be an evolution of the GDPR and, thus, in principle, is nothing that could not be expected given the key pillars of the GDPR. However, what the EU can be criticized for is taking these opportunities to the extreme without paying due regard to the sensitive nature of where the electronic health data stem from – including healthcare and research environments and risks that push to the extreme could pose to trust healthcare and research. Moreover, it can be criticised for choosing not to take full responsibility regarding the area that it is harmonizing, imposing obligations without setting up a mechanism to ensure that fundamental pillars of scientific research are upheld, arguably in an attempt to uphold some degree of subsidiarity and self-determination for the Member States.

Recital 4 of the GDPR notes that all personal data should be designed to serve mankind. It provides a valuable tool for rethinking the existing balance under the GDPR and the prescribed balance under the proposed EHDS regulation between individual rights and other aspirations, such as scientific research. Whether particular research, a particular derogation, or limitations are necessary to serve mankind is a question of assessment. The GDPR, at least as far as individual rights are concerned, left this to the case-by-case assessment. However, the proposed EHDS regulation seems to presume that research in health or care sectors is serving mankind. Such a broad take could be argued to require some qualifications for scientific research, some delimitations of the sectors concerned, and some requirements to verify that the intended research is serving mankind. Moreover, in light of the discussed ethico-legal standards in section 2, it could also require some scientific quality standards for the intended research, including those carrying out the research, in order to ensure that the objective to serve mankind can be met. At this point, the proposal does not provide a mechanism that allows verifying whether the intended research activity is indeed such that it is capable of contributing to the common good.[127] This should be remedied during the legislative process.

As the proposed EHDS regulation is advancing in the legislative process, it is of utmost importance to reconsider the EU's approach to taking greater steps in data-driven scientific research regulation. If the EU is claiming an enhanced role in the area, it needs to be ready to assume the responsibility that follows it. As a minimum, in addition to setting up a clear mechanism to verify the intended data use, also requiring ethical approval to the research involving personal data, and ensuring that appropriate respect to

125 Karen Spencer and others, Patient Perspectives on Sharing Anonymized Personal Health Data Using a Digital System for Dynamic Consent and Research Feedback: A Qualitative Study, J Med Internet Res 2016;18(4):e66.

126 See in this regard the EDPB Document in response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, Adopted on 2 February 2021, para 6.

127 This can be contrasted with limitations permissible on the right to science under the International Covenant on Social, Economic, and Cultural Rights. See UN General Assembly, International Covenant on Economic, Social and Cultural Rights, 16 December 1966, United Nations, Treaty Series, vol. 993, p. 3, art 15 (1) (b) and Committee on Economic, Social and Cultural Rights, General Comment No. 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights), E/C.12/GC/25.

the individual and their interest in making choices is given, should be ensured, along with a mechanism to ensure full transparency vis-à-vis the individual. After all, stakes are high, as the data, to a large degree, will stem from medical care and scientific research – two areas where the trust is key – and the loss of it could risk bringing along unwelcomed consequences for the health of individuals and the public health objectives.

Acknowledgements

The author would like to thank the two anonymous reviewers and dr. Mahsa Shabani and David Fåhraeus for the insightful comments on the earlier drafts of the article.