DISSERTATIONES
IURIDICAE
UNIVERSITATIS
TARTUENSIS
97

MARET KRUUS

Balancing the Freedom of Scientific Research and Privacy in Health Data Research: Public Interest, Legal Bases, and Objection and Opt-Out Rights

DISSERTATIONES IURIDICAE UNIVERSITATIS TARTUENSIS
97

DISSERTATIONES IURIDICAE UNIVERSITATIS TARTUENSIS
97

MARET KRUUS

Balancing the Freedom of Scientific Research and Privacy in Health Data Research: Public Interest, Legal Bases, and Objection and Opt-Out Rights

UNIVERSITY OF TARTU
Press
1632

School of Law, University of Tartu, Estonia

The dissertation has been accepted for the commencement of the Doctor of Philosophy (PhD) degree in law on 21 April 2026, by the resolution of the Council of the School of Law.

Supervisor: Professor, Dr. iur. Karin Sein (University of Tartu)

Opponent: Associate Professor, LLD Santa Slokenberga (Uppsala University)

Commencement will take place on 18 June 2026 at 14.00 in the School of Law, Tartu, Näituse 20, room 203, and via video bridge.

The publication of this dissertation is supported by the School of Law of the University of Tartu.

ISSN 1406-6394 (print)
ISBN 978-9908-57-217-8 (print)
ISSN 2806-2353 (pdf)
ISBN 978-9908-57-218-5 (pdf)

University of Tartu Press
www.tyk.ee

ACKNOWLEDGEMENTS

I wish to express my deepest gratitude to Professor Karin Sein for her exemplary supervision throughout the preparation of this doctoral thesis. Her guidance, constructive feedback, and consistent support have been essential to the completion of this work. I also thank all other members of the School of Law of the University of Tartu for their valuable feedback on my thesis. Sincere thanks go to Paloma Krõõt Tupay for leading the discussion during the thesis pre-defence.

I extend my sincere thanks to Professor Päivi Korpisaari and Juli Mansnérus from the University of Helsinki for hosting me as a visiting researcher in April–May in 2023. Their academic engagement has significantly contributed to the direction and advancement of this dissertation.

I am also indebted to my friends and colleagues for their encouragement and support during this process. I would like to express particular appreciation to Heili Püümann and Kristiina Koll, who have made this journey fun.

My gratitude further extends to Kärt Pormeister and Triin Siil for the numerous discussions that informed and enriched my understanding of the subject matter.

Finally, I express my profound appreciation to my family. Their patience, understanding, and support have enabled me to dedicate the necessary time and attention to completing this thesis.

TABLE OF CONTENTS

LIST OF ORIGINAL PUBLICATIONS

This dissertation is based on the following publications:

1. Kruus M, 'The Public Interest Requirement in the Secondary Use of Health Data in Scientific Research: The Examples of Estonia and Finland' 2023 Juridica International 64 (**Publication I**);
2. Kruus M, 'Development and Innovation Activities with Health Data: On What Legal Basis? Examples of Estonia, Finland, and the EHDS Proposal' (2023) 7 European Health & Pharmaceutical Law Review 97 **(Publication II)**;
3. Kruus M, 'Opting Out of Scientific Research with Health Data: The Limits of the EHDS and the GDPR' (2025) 32 European Journal of Health Law 165 **(Publication III)**.

ABBREVIATIONS

Charter	Charter of Fundamental Rights of the European Union OJ C 326 [2012]
CJEU	The Court of Justice of the European Union
DGA	Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) [2022] OJ L152/1
HDAB	Health data access body in the meaning of the EHDS
EDPA	Estonian Data Protection Act *(Isikuandmete kaitse seadus)* adopted on 12 December 2018 (RT I, 04.01.2019, 11)
EDPB	European Data Protection Board
EDPS	European Data Protection Supervisor
EHDS	Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 [2025] OJ L 2025/327
EU/ Union	The European Union
FDPA	Finnish Data Protection Act *(Tietosuojalaki)*1050/2018
GDPR	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) [2016] OJ L 119/1

ANALYTICAL COMPENDIUM TO A CUMULATIVE DISSERTATION

1. INTRODUCTION

1.1. Setting the scene

The reuse of health data for scientific research purposes enables the application of existing data to accelerate the generation of new knowledge in healthcare. Such reuse supports, for example, faster drug discovery and improved understanding of disease progression.[1] Based on scientific knowledge, new products and services can be developed and policy decisions made. Often, scientific research is not only academic but also driven by commercial interests. The volume of health data that could benefit scientific research is increasing rapidly. The technology and scientific methods for processing health data are continuously improving.[2] This combination raises high hopes for breakthroughs in health care while also raising deep concerns about the privacy of data subjects.

Scientific research involving personal health data inevitably raises tensions between the fundamental freedom of scientific research and the fundamental rights to privacy and data protection, all of which are protected by the Charter of Fundamental Rights of the European Union (Charter).[3] Scientific freedom is primarily deduced from the freedoms of thought and expression and interacts with the rights to privacy and data protection.[4] The right to privacy and the right to data protection are closely linked.[5] For the freedom of scientific research, having access to detailed, representative datasets is advantageous, with no strict restrictions on the types of research activities that can be undertaken. To support privacy and data protection rights, it is essential to maintain the data subject's control over their data and establish clear boundaries on permissible research

---

1 Fidelia Cascini, *Secondary Use of Electronic Health Data: Public Health Perspectives, Use Cases and Challenges* (Springer Cham 2025) 83 <https://doi.org/10.1007/978-3-031-88497-9>.

2 ibid 3, 58, 83.

3 Charter of Fundamental Rights of the European Union OJ C 326 [2012] (Charter), arts 7, 8, 13.

4 Debbie Sayers, 'Article 13 – Freedom of the Arts and Sciences' 406–408 in Steve Peers and others (eds), *The EU Charter of Fundamental Rights. A Commentary* (Bloomsbury Publishing 2021).

5 As explained by Kranenborg, the inclusion of the separate right to data protection in the Charter confirms and reflects the system of checks and balances which ensures lawful processing of personal data. The CJEU does not apply a consistent approach to the distinction between Articles 7 and 8 of the Charter and, often, the two rights are assimilated. See: Herke Kranenborg, 'Article 8 – Protection of Personal Data' 239, 242 in Steve Peers and others (eds), *The EU Charter of Fundamental Rights. A Commentary* (Bloomsbury Publishing 2021).

activities. However, data subjects also have a shared interest in benefiting from health-data-driven research, including the development of new medicines, treatments, and personalised feedback.

Limitations to the rights of the Charter may be made if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.[6] However, relying on the case law by the Court of Justice of the European Union (CJEU), Slokenberga has concluded that the fundamental rights of the Union do not give a concrete answer regarding how a data subject should be protected within scientific research and how much privacy and data protection the data subject should retain.[7]

At an overarching level, the data-protection aspects of processing health data for scientific research are regulated by the General Data Protection Regulation (GDPR).[8] In the GDPR, scientific research holds a special place, offering more flexible rules for controllers than the GDPR's general standard.[9] The data subject's consent is not necessarily required, even when health data is involved.[10] However, Member States may require the data subject's consent as a further condition.[11] This thesis focuses on scientific research conducted without the data subject's consent. In practice, reliance on consent is often considered unsuitable for database research, given the unpredictability of future research uses and the requirement that consent be specific and withdrawable at any time.[12] Under the legal basis for scientific research, the GDPR enables extensive limitations to data subjects' rights.[13] A justification suggested for such an approach is that research is of public interest,

---

6 Charter (n 3), art 52(1).

7 Santa Slokenberga, 'Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject That the Proposed EHDS Regulation Promises to Bring Along' [2022] Technology and Regulation 135, 138 <https://doi.org/10.26116/TECHREG.2022.014>.

8 Regulation (EU) 2016/679 of the European Parliament and 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) [2016] OJ L119/1 (GDPR).

9 Kärt Pormeister, 'Genetic Data and the Research Exemption: Is the GDPR Going Too Far?' (2017) 7 International Data Privacy Law 137, 138–141 <https://doi.org/10.1093/idpl/ipx006>.

10 GDPR, art 9(2)(j).

11 ibid, art 9(4). However, please note that in the EHDS data access mechanism, the Member States' discretion is significantly limited (Recital 52 EHDS).

12 Mette Hartlev, 'Health Data-Driven Research – Time for a Stronger Human Rights Governance Structure?' (2025) 32 European Journal of Health Law 559, 566 <https://doi.org/10.1163/15718093-12423580>; European Data Protection Board, 'Guidelines 05/2020 on Consent under Regulation 2016/679 Version 1.1', para 163.

13 GDPR, arts 5(1)(e), 14(5)(b), 17(3)(d), 89(2); Evert-Ben van Veen, 'Observational Health Research in Europe: Understanding the General Data Protection Regulation and Underlying Debate' (2018) 104 European Journal of Cancer 70, 72–73 <https://doi.org/10.1016/j.ejca.2018.09.032>.

poses fewer direct risks to data subjects than processing for other purposes, and that relevant harms can be mitigated through technical safeguards.[14] Flexible rules also enhance the efficiency of data processing in scientific research.

The GDPR's legal basis for scientific research, i.e., Article 9(2)(j), requires that additional national or Union law apply.[15] For that reason, Member States have established rules governing the processing of health data for scientific research purposes in their national laws. Data governance and access mechanisms vary across Member States.[16] In the thesis, the national legislations and practices of two neighbouring Member States, Estonia and Finland, are analysed. Finland is widely regarded as a true leader in enhancing the secondary use of health data through a central national Findata data access mechanism established in 2019. The Findata mechanism has also served as a reference for the European Health Data Space Regulation[17] in developing a future data access mechanism applicable throughout the European Union (EU).[18] While in Estonia, there is no similar central data access mechanism, the Estonian National Health Information System, which contains medical data from the entire population across all healthcare providers, is widely used for scientific research.[19] Similar to each other, Estonia and Finland both enable the processing of health data for scientific research purposes without the data subject's consent.[20] More detailed reasons for including these two Member States in the study are provided in Section 1.5 of the analytical compendium, which explains the research methods.

In 2025, the European Health Data Space Regulation (EHDS), as the relevant Union law linking to the GDPR's legal basis for scientific research, was adopted. As a novelty, the EHDS will establish a largely harmonised data access mechanism that enables access to electronic health data across the Member States.[21] The EHDS aims to enhance scientific research involving electronic health data by providing a data access mechanism with common rules.[22] Under the EHDS, the

---

[14] Hartlev (n 12) 567.

[15] GDPR, art 9(2)(j).

[16] Commission, 'Assessment of the EU Member States' Rules on Health Data in the Light of GDPR' 97–111 <https://data.europa.eu/doi/10.2818/546193> accessed 26 March 2026.

[17] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 [2025] OJ L 2025/327 (EHDS).

[18] Commission, 'Commission Staff Working Document Impact Assessment Report Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space' SWD (2022) 131 final, paras 2.2, 2.3, 6.1.1, and 6.1.3.2.

[19] TEHIK, 'Data Requests' <www.tehik.ee/en/data-requests> accessed 26 March 2026.

[20] Estonian Data Protection Act (*Isikuandmete kaitse seadus)* adopted on 12 December 2018 (RT I, 04.01.2019, 11) (EDPA), § 6; The Act on the Secondary Use of Social and Health Data (*Laki sosiaali- ja terveystietojen toissijaisesta käytöstä*) 552/2019 (The Secondary Use Act), § 38.

[21] EHDS, art 1(2)(c).

[22] ibid, art 53(1)(e), recitals 53, 61.

data subject's consent will not be sought for the use of health data via this mechanism, except where required by national law for certain data categories.[23] In the EHDS, the provisions governing the secondary use of data, relevant for scientific research, will apply gradually, with most operational obligations becoming applicable from March 2029.[24] In the following years, the new data access mechanism introduced by the EHDS needs to find its place in practice, while the existing national mechanisms remain in place until that and possibly even later.[25]

In this thesis, the term 'health data' is used in the sense of 'data concerning health' as defined in Article 4(15) of the GDPR. This covers 'personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status'.[26] It should be noted that in the EHDS, the notion 'personal electronic health data' is broader in the sense that it means both data concerning health and genetic data in the meaning of Article 4(13) GDPR.[27] This thesis does not address the specifics of the genetic data, which are often regulated more precisely in national legislation.[28] It should also be noted that the EHDS regulates the processing of both personal and non-personal health data.[29] This thesis is limited to analysing the processing of personal health data only.

As another repeatedly used term, by 'scientific research', scientific research in the meaning of Article 9(2)(j) GDPR has been meant. This has been explained in Recital 159 GDPR as: '[...] 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.' According to the Commission's explanations, the notion of 'scientific research' used in the EHDS is the same as that in the GDPR.[30]

---

[23] ibid, art 51(4), recital 52.

[24] ibid, art 105.

[25] For the explanation of the interactions between the data access mechanisms, see Section 2.2. of this analytical compendium.

[26] According to the case-law by the CJEU, the concept of 'data concerning health' must be interpreted broadly. See C-21/23, *Lindenapotheke* (Grand Chamber, 4 October 2024), paras 81, 83.

[27] EHDS, art 2(2)(a).

[28] For example, in Estonia, the specific law is the Human Genes Research Act (*Inimgeeniuuringute seadus*) adopted on 13.12.2000 (RT I 2000, 104, 685).

[29] EHDS, art 2(2)(c).

[30] Commission, 'Frequently Asked Questions on the European Health Data Space' 31 <https://health.ec.europa.eu/latest-updates/frequently-asked-questions-european-health-data-space-2025-03-05_en> accessed 30 December 2025.

Other terms, such as 'personal data', 'processing', 'controller', and 'processor', are used in the meaning of the GDPR as an overarching regulation governing the legal aspects of personal data processing. Terms specific to the EHDS, such as 'health data holder' (abbreviated also as 'data holder'), 'health data user' (abbreviated also as 'data user'), 'health data access body' (abbreviated also as 'HDAB') are used in the meaning of the EHDS.

1.2. The research problem

In health data research, where the freedom of scientific research is in tension with the rights to privacy and data protection, an appropriate balance between these fundamental rights must be struck. This balance is not established in the GDPR, as it leaves a wide margin of discretion to Member States. The GDPR does not specify whether scientific research involving health data, conducted without the data subject's consent, must serve the public interest. Furthermore, it does not define 'scientific research', a notion that is central to the legal basis for processing the data (Article 9(2)(j) GDPR). Although 'scientific research' is an autonomous concept under EU law and must be interpreted uniformly across the EU, the absence of a definition and established CJEU case law means that, in practice, Member States interpret the term as they see fit. Furthermore, the GDPR does not establish a right to opt-out or a strong right to object, and it leaves Member States a margin of discretion to further derogate from the right to object.[31]

At the same time, the public interest requirement, the scope of the notion of 'scientific research' in the legal basis, and the data subject's objection and opt-out rights play an important role in balancing the freedom of scientific research with the rights to privacy and data protection, as explained further in this section. Therefore, in national laws and practices, these legal limitations must be specified and applied carefully to find an appropriate balance. This is especially relevant in Estonia at the time of finalising the analytical compendium, as amendments have been proposed to the rules governing the processing of health data in scientific research.[32]

While the EHDS is more specific about its limitations on the processing of health data for scientific research than the GDPR, it still leaves Member States a significant margin of discretion. For example, it enables Member States to require ethics review under national law to facilitate access to health data for scientific research.[33] The ethics review can shape, and potentially raise, the standard by which the research project's contribution to the public interest is evaluated.

---

[31] GDPR, arts 21, 89(2).

[32] These amendments do not concern the implementation of the EHDS yet, but the national data access mechanism only. See: Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) <https://eelnoud.valitsus.ee/main/mount/docList/1461fdb4-9e8b-4860-a015-92a741384a90> accessed 5 February 2026.

[33] EHDS, arts 55(2), 67(2)(j), recital 69.

Furthermore, 'scientific research' as an allowed processing purpose and legal basis under the EHDS will, in practice, be interpreted by national health data access bodies (HDABs).[34] Additionally, the EHDS enables Member States to foresee exceptions from the opt-out right, which significantly shape data subjects' autonomy.[35] Therefore, although the EHDS imposes more concrete limitations on processing health data for scientific research, Member States still play an important role in balancing the freedom of scientific research with the rights to privacy and data protection. Guidance on balancing these rights is therefore also needed in the context of the EHDS.

The public interest requirement is among the main concerns to consider when justifying the use of health data without the data subject's consent. It may be argued that processing health data without the data subject's consent, when there is no potential societal value, unjustifiably limits individual autonomy and privacy. At the same time, overly strict requirements for the contribution to the public interest may unjustifiably limit the freedom of scientific research. To understand the role of the public interest requirement in balancing these rights, it is necessary to examine whether, why, and how data access mechanisms require that health data processing serve the public interest. If there is no explicit public interest requirement in the legislation, it needs to be examined whether such a requirement can still be embedded in the procedures for accessing health data. The thesis examines the public interest requirements embedded in data access procedures, on the examples of ethics review in Estonia and the data permit procedures in Finland, and under the EHDS. The thesis continues with an evaluation of which approach to the public interest requirement best balances the freedom of scientific research with the rights to privacy and data protection.

The requirement of a legal basis limits the processing of health data to the purposes and conditions set out in the legislation, thereby ensuring the lawfulness and foreseeability of data processing. At the same time, the constraints imposed by the legal basis should not unduly restrict the freedom of scientific research. While processing health data for fundamental (basic) scientific research usually does not raise questions about compliance with the notion of 'scientific research' in the legal basis, the case with development and innovation activities, which may also be sometimes regarded as scientific research, is more complicated. The boundaries of development and innovation activities that qualify as scientific research provide a good understanding of how far scientific research, as a legal basis (Article 9(2)(j) GDPR), extends. For that reason, the thesis examines these boundaries of 'scientific research' within the GDPR as an overarching framework, as well as in the national laws of Estonia and Finland, and the EHDS. It also offers suggestions on how to limit the scope of the notion 'scientific research', a central component of the legal basis, to balance the freedom of scientific research with the rights to privacy and data protection.

---

[34] ibid, art 68(1)(a).

[35] ibid, art 71(4).

Data subjects' objection and opt-out rights directly affect their self-determination and autonomy, as well as the researcher's ability to conduct scientific research using unbiased data. According to Article 21 GDPR, the data subject has the right, under certain conditions, to object to the processing of their personal data for scientific research purposes. National laws and practices may shape the application of this right.[36] The EHDS introduces a new opt-out right for secondary use of data within the EHDS framework, enabling data subjects to opt out at any time without providing a reason.[37] Although the opt-out right under the EHDS is not the same as the objection right under the GDPR, nor is it an explicit extension of it, in practice, it serves the same purpose: enabling data subjects to prohibit the use of their data in scientific research. For this reason, these rights are examined together. The scope and limitations of these rights are not evident solely from reading the GDPR, the EHDS, or Estonian or Finnish national laws, without critically analysing the interactions between the EU and national law provisions and practices. Therefore, the EHDS' opt-out right, as well as the GDPR's objection right, require closer examination to understand the rights they provide to data subjects and the limits they place on the use of health data for scientific research. Based on the evaluation, this thesis offers Member States guidance on how to shape these rights to balance the fundamental rights at stake.

Finally, the way these limitations are foreseen and applied in combination affects the overall balance between the fundamental freedom of scientific research and the rights to privacy and data protection. For example, limitations on data subjects' rights to object or opt out may be justified by a strong public interest. Thus, the interactions between the legal limitations need to be analysed. By examining and evaluating the limitations together, this thesis shows where the current balance in the analysed data access mechanisms may either fail to protect data subjects adequately or unnecessarily restrict scientific research. The thesis proposes a model for Member States to shape the public interest requirement and the notion of 'scientific research' in the legal basis, together with the data subject's rights to object and opt out, to properly balance the freedom of scientific research with the rights to privacy and data protection.

1.3. Research objectives and research questions

This doctoral thesis aims to critically analyse and evaluate how the public interest and legal basis requirements, with a focus on the notion 'scientific research', as well as data subjects' objection and opt-out rights, limit the processing of health data for scientific research purposes and balance the fundamental freedom of scientific research with the fundamental rights to privacy and data protection. Based on the synthesis of these evaluations, the thesis proposes a model that balances the freedom of scientific research with the rights to privacy and data

[36] GDPR, art 89(2).

[37] EHDS, art 71.

protection through the public interest and legal basis requirements, as well as data subjects' objection and opt-out rights. The model will be designed with consideration of two situations: 1) separately from the EHDS as a national mechanism – especially relevant where the EHDS mechanism is not yet available; 2) the specification of the EHDS mechanism under national law. This model is proposed within the borders of the GDPR and the EHDS, as they stand. The thesis does not propose amendments to the GDPR and the EHDS, as achieving more specific political consensus on these legal limitations at the EU level was considered unlikely at the time of writing. This is exemplified by the negotiations on the EHDS, where best efforts were made to balance the freedom of scientific research with the rights to privacy and data protection at the EU level. However, the outcome still left a margin of discretion to Member States.

Considering this, the thesis asks which model optimally balances the fundamental freedom of scientific research with the fundamental rights to privacy and data protection through the public interest and legal basis requirements, as well as data subjects' objection and opt-out rights, relying on the assessment of the existing national data access mechanisms of Estonia and Finland as well as the EU one established by the EHDS. To answer the central research question, the thesis addresses the following sub-questions.

1) Concerning the public interest requirement for processing health data for scientific research:
   - How do the GDPR, the Estonian and Finnish national legislations and the EHDS balance the freedom of scientific research with the rights to privacy and data protection through the public interest requirement?
   - What is the optimal approach to balancing the freedom of scientific research with the rights to privacy and data protection in regard to the public interest requirement?

2) Concerning the scope of 'scientific research' in the legal basis:
   - How do the GDPR, the Estonian and Finnish national legislations and the EHDS balance the freedom of scientific research with the rights to privacy and data protection through the scope of 'scientific research' in the legal basis?
   - What is the optimal approach to balancing the freedom of scientific research with the rights to privacy and data protection in regard to the notion of 'scientific research' in the legal basis?

3) Concerning the data subject's rights to object to and opt out of the data processing for scientific research purposes:
   - How do the GDPR and the Estonian and Finnish national legislations balance the freedom of scientific research with the rights to privacy and data protection through the right to object?
   - How does the EHDS balance the freedom of scientific research with the rights to privacy and data protection through the right to opt out?

– What is the optimal approach to balancing the freedom of scientific research with the rights to privacy and data protection in regard to the rights to object and opt-out?

4) Concerning the interactions between the legal limitations analysed in this thesis:
   – How does the combined application of these limitations in the Estonian, Finnish, and EHDS data access mechanisms shape the overall balance between the freedom of scientific research and the rights to privacy and data protection?
   – What model design, combining the legal limitations analysed in this thesis, optimally balances the freedom of scientific research and the rights to privacy and data protection?

Answering the research questions does not offer an exhaustive list of limitations for processing health data for scientific research. For example, other significant legal limitations not covered in this thesis include security and transparency requirements. Consequently, the evaluation of the balance between the freedom of scientific research and the rights to privacy and data protection is also limited, as other factors also affect this balance. However, as explained, the limitations analysed in this thesis are among the most important, aiming to balance the freedom of scientific research with the rights to privacy and data protection. Thus, these legal limitations have a powerful impact on the overall balance between these fundamental rights.

1.4. State-of-the-art in the area

1.4.1. The state-of-the-art in the area in general

There is no unified analysis that links public interest, the scope of 'scientific research' in the legal basis, and objection and opt-out rights into a single balancing framework. As its main original contribution, this dissertation offers such a model based on the synthesis of national data access mechanisms in Estonia[38] and Finland[39], as well as the EU data access mechanism established by the EHDS. However, earlier academic works on the legal frameworks in general or on specific legal limitations have informed the thesis, as explained below.

At the time of writing this dissertation, a substantial body of legal literature has been available on the GDPR's scientific research regime.[40] One valuable

[38] EDPA, § 6.

[39] The Secondary Use Act.

[40] To mention some, Pormeister, 'Genetic Data and the Research Exemption' (n 9); Edward S Dove, 'The EU General Data Protection Regulation: Implications for International Scientific Research in the Digital Era' (2018) 46 Journal of Law, Medicine & Ethics 1013 <https://doi.org/10.1177/1073110518822003>; van Veen (n 13); Mary Donnelly and Maeve

source is the book 'GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe', edited by Slokenberga, Tzortzatou, and Reichel.[41] Although it focuses on biobanking, it is also relevant more broadly for scientific research involving health data. The book also includes chapters on the law and practice of Estonia and Finland, the Member States analysed in this thesis.[42] In addition to academic writings, reports are available that explain the GDPR and national rules governing the processing of health data for scientific research.[43]

The EHDS was proposed by the Commission in 2022 and was adopted in 2025. The final text of the EHDS became publicly available at the end of 2024. At the time of writing Publications I-III, only a few academic writings were available on the legal issues of the EHDS. These include articles by Slokenberga, Shabani, Yilmaz, and Terzis.[44] Later, more publications on EHDS have become available. Several of them have already examined the final version of the EHDS. For example, in 2025, a book on the European Health Data Space containing many analytical chapters, edited by Slokenberga, Cathaoir, and Shabani, was published.[45] Regarding research articles, Vera Lúcia Raposo provided a critical assessment of why the EHDS might not operate effectively in practice.[46] As another example, Afra published an article questioning the innovator's ability for

McDonagh, 'Health Research, Consent and the GDPR Exemption' (2019) 26 European Journal of Health Law 97 <https://doi.org/10.1163/15718093-12262427>; Paul Quinn, 'Research under the GDPR – a Level Playing Field for Public and Private Sector Research?' (2021) 17 Life Sciences, Society and Policy 4 <https://doi.org/10.1186/s40504-021-00111-z>.

41 Santa Slokenberga, Olga Tzortzatou and Jane Reichel (eds), *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe* (Springer Cham 2021).

42 Kärt Pormeister, 'Regulatory Environment for Biobanking in Estonia'; Tom Southerington, 'Access to Biomedical Research Material and the Right to Data Protection in Finland' in Santa Slokenberga, Olga Tzortzatou and Jane Reichel (eds), *GDPR and Biobanking* (Springer Cham 2021).

43 Teodora Lalova, 'Study on the Secondary Use of Personal Data in the Context of Scientific Research. Final Report EDPS/2019/02-04' (2020) <www.edpb.europa.eu/system/files/2025-04/20250401_study_on_the_secondary_use_of_personal_data_in_the_context_of_scientific_research_23102020_en.pdf> accessed 5 February 2026; Commission, 'Assessment of the EU Member States' Rules on Health Data in the Light of GDPR' (n 16).

44 Slokenberga (n 7); Mahsa Shabani and Sami Yilmaz, 'Lawfulness in Secondary Use of Health Data: Interplay between Three Regulatory Frameworks of GDPR, DGA & EHDS' (2022) 2022 Technology and Regulation 128 <https://doi.org/10.26116/techreg.2022.013>; Petros Terzis, 'Compromises and Asymmetries in the European Health Data Space' (2022) 30 European Journal of Health Law 345 <https://doi.org/10.1163/15718093-bja10099>.

45 Santa Slokenberga, Katharina Ó Cathaoir and Mahsa Shabani (eds), *The European Health Data Space: Examining A New Era in Data Protection* (Routledge 2025) <https://doi.org/10.4324/9781003544111>.

46 Vera Lúcia Raposo, 'Can Personal Data Be Recycled? The Reuse and Repurposing of Data under the EHDS' (2025) 33 International Journal of Law and Information Technology eaae016 <https://doi.org/10.1093/ijlit/eaae016>.

consent-free health data reuse in the context of the GDPR and the EHDS.[47] It should be noted, however, that many earlier publications do not analyse the final version of the EHDS, but either the Commission's proposal for the EHDS or the earlier draft versions, which differ significantly from the final version.[48] These publications still contribute to understanding the current debate on the EHDS, and some of them may have influenced the drafting of the final version of the EHDS.

Regarding Estonian national law, Pormeister has published valuable academic works on the processing of health data in scientific research. Regarding both EU and Estonian law, in 2019, she published a doctoral thesis on the processing of genetic data and transparency requirements.[49] In the articles 'Genetic data and the research exemption: is the GDPR going too far'[50] and 'New personal data protection law and personal data in science: three examples of problematic legislation'[51], as well as in the book chapter 'Regulatory Environment for Biobanking in Estonia'[52] she has analysed the problems of data processing in research both in the context of the GDPR and Estonia. Although most of Pormeister's work focused on genetic data, a significant portion is also relevant to health data processing in scientific research in general. Her previous work has been relied upon in this dissertation to further develop the discussion of specific research questions.

Regarding Finland, Southerington has provided an overview of the Finnish national law regulating the secondary use of health data for research purposes in a book chapter titled 'Access to Biomedical Research Material and the Right to

---

47 Maryam Afra, 'An Assessment on Innovator's Ability for Consent-Free Health Data Reuse, In the Context of the GDPR and EHDS: The Netherlands Case Study' (2024) 31 European Journal of Health Law 475 <https://doi.org/10.1163/15718093-bja10136>.

48 For example, Luca Marelli and others, 'The European Health Data Space: Too Big to Succeed?' (2023) 135 Health Policy 104861 <https://doi.org/10.1016/j.healthpol.2023.104861>; David Fåhraeus, Jane Reichel and Santa Slokenberga, 'The European Health Data Space: Challenges and Opportunities' (2024) <https://sieps.se/media/qgkapq2t/2024_2epa.pdf> accessed 5 February 2026; Fanni Kertesz, 'Collaboration in Healthcare: Implications of Data Sharing for Secondary Use in the European Union' (2024) 31 European Journal of Health Law 497 <https://doi.org/10.1163/15718093-bja10133>; Paul Quinn, Erika Ellyne and Cong Yao, 'Will the GDPR Restrain Health Data Access Bodies Under the European Health Data Space (EHDS)?' (2024) 54 Computer Law & Security Review 105993 <https://doi.org/10.1016/j.clsr.2024.105993>; Ciara Staunton and others, 'Ethical and Social Reflections on the Proposed European Health Data Space' (2024) 32 European Journal of Human Genetics 498 <https://doi.org/10.1038/s41431-024-01543-9>; Edward S Dove (ed), *Confidentiality, Privacy, and Data Protection in Biomedicine: International Concepts and Issues* (Routledge 2025).

49 Kärt Pormeister, *Transparency in Relation to the Data Subject in Genetic Research – an Analysis on the Example of Estonia* (2019) <http://hdl.handle.net/10062/66697> accessed 26 March 2026.

50 Pormeister, 'Genetic Data and the Research Exemption' (n 9).

51 Kärt Pormeister, 'Uus isikuandmete kaitse seadus ja isikuandmed teaduses: kolm näidet probleemsest õigusloomest' 2019/4 Juridica 239.

52 Pormeister, 'Regulatory Environment for Biobanking in Estonia' (n 42).

Data Protection in Finland'.[53] There are also academic articles analysing Finnish national law on the secondary use of health data. For example, Doetsch and others have included Finland in their study as one comparative Member State, explaining the regulation and practical setting for health data processing in scientific research in Finland, with a focus on record-linkage options.[54] Brück and others have critically demonstrated, using the example of the Finnish Secondary Use Act[55], how increased data privacy regulations might reduce registry-based health research.[56] Similarly, Åm and others have highlighted the shortcomings of the Finnish system in their comparative analysis.[57] The existing literature on Finnish national law and practice provides a good background for analysing the research questions posed in this thesis.

In the following sections, the current state of the art in the field will be explained in more detail, with consideration of each legal limitation analysed in the thesis.

1.4.2. Publications on the public interest requirement

Regarding the GDPR, there is no consensus on whether the GDPR requires the processing of health data without the data subject's consent to be in the public interest. Georgieva and Kuner have explained that the GDPR does not require the health data processing for scientific research to be in the public interest.[58] Schneider has explored the link between the legal grounds of processing for research purposes and for public interest in the GDPR. She explained that, under the GDPR, scientific research is not a specification of the public interest.[59] Verhenneman is of the view that even though legal uncertainty remains, scientific research does not necessarily have to serve the public interest, but it must have

---

53 Southerington (n 42).

54 JN Doetsch and others, 'Record Linkage of Population-Based Cohort Data from Minors with National Register Data: A Scoping Review and Comparative Legal Analysis of Four European Countries' (2021) 1 Open Research Europe 15–16; 20–26 <https://doi.org/10.12688/openreseurope.13689.2>.

55 The Secondary Use Act.

56 Oscar Brück and others, 'European Health Regulations Reduce Registry-Based Research' (2024) 22 Health Research Policy and Systems 135 <https://doi.org/10.1186/s12961-024-01228-1>.

57 Heidrun Åm and others, 'The Politics of Constructing Health Data Spaces: Border Work and the Stickiness of Fragmentation' (2025) 12 Big Data & Society 20539517251320012 <https://doi.org/10.1177/20539517251320012>.

58 Ludmila Georgieva and Christopher Kuner, 'Article 9 Processing of Special Categories of Personal Data' in Christopher Kuner and others (eds), *The EU general data protection regulation (GDPR): a commentary* (Oxford University Press 2020) 381.

59 Giulia Schneider, 'Health Data Pools under European Policy and Data Protection Law: Research as a New Efficiency Defence?' (2020) 11 JIPITEC – Journal of Intellectual Property, Information Technology and E-Commerce Law 49, 62 <https://nbn-resolving.de/urn:nbn:de:0009-29-50827>.

value to society.[60] In the context of fundamental rights, Slokenberga has explained that balancing the rights at stake should not result in depriving the data subject of their rights without a return.[61] Van Veen has suggested that, for processing health data without the data subject's consent, there should be justification that the research will contribute to the public interest.[62] Meszaros and Ho believe that only scientific research serving the public interest fits under the scientific research exemption of the GDPR.[63] In this thesis, prior analyses by other authors are considered in reaching the conclusion that the GDPR falls short of protecting data subjects' interests because it does not explicitly require that scientific research be in the public interest.

Some authors have explained their understanding of whether the public interest requirement exists in Estonian national law. However, there is no consensus on this question between the legal literature and the supervisory authority. Kuuskmaa is of the view that while scientific research itself need not necessarily serve the aim of public interest, the pseudonymisation or anonymisation of directly identifiable data must, unjustifiably, be in the overriding public interest.[64] Pormeister, as well as Denga and Hoffmann are also of the view that the requirement of overriding public interest only applies to the processing of directly identifiable data.[65] In contrast, the Data Protection Inspectorate of Estonia has found that the overriding public interest requirement also applies to the processing of pseudonymised data.[66] In addition, Keppi has mentioned overriding public

---

[60] Griet Verhenneman, *The Patient, Data Protection and Changing Healthcare Models: The Impact of e-Health on Informed Consent, Anonymisation and Purpose Limitation* (Intersentia 2021) 297.

[61] Santa Slokenberga, 'Setting the Foundations: Individual Rights, Public Interest, Scientific Research and Biobanking' in Santa Slokenberga, Olga Tzortzatou and Jane Reichel (eds), *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe* (Springer Cham 2021) 22 <https://doi.org/10.1007/978-3-030-49388-2_2>.

[62] van Veen (n 13) 75–76.

[63] János Mészáros and Chih-hsing Ho, 'Big Data and Scientific Research: The Secondary Use of Personal Data under the Research Exemption in the GDPR' (2018) 59 Hungarian Journal of Legal Studies 403, 409 <https://doi.org/10.1556/2052.2018.59.4.5>; Janos Meszaros and Chih-hsing Ho, 'AI Research and Data Protection: Can the Same Rules Apply for Commercial and Academic Research under the GDPR?' (2021) 41 Computer Law & Security Review 105532, 10 <https://doi.org/10.1016/j.clsr.2021.105532>.

[64] Liisa Maria Kuuskmaa, 'Isikuandmete töötlemise õiguslik alus ning andmesubjekti õiguste kaitse tervise infosüsteemi kogutud terviseandmete kasutamisel kliiniliste otsuste tugisüsteemide arendamiseks ja rakendamiseks' (Tartu Ülikool 2020) 39, 63 <http://hdl.handle.net/10062/68545> accessed 25 August 2025.

[65] Pormeister, *Transparency in Relation to the Data Subject in Genetic Research – an Analysis on the Example of Estonia* (n 49) 59; Michael Denga and Thomas Hoffmann, 'The Estonian Electronic Health Record – a Prototype for Data Governance in the European Health Data Space?' (2023) 7 European Health & Pharmaceutical Law Review 5, 12 <https://doi.org/10.21552/ehpl/2023/1/4>.

[66] Response from the Data Protection Inspectorate of Estonia to the Author's request for clarification (26 January 2023).

interest as a general condition for scientific research, while also acknowledging Kuuskmaa's interpretation.[67] However, in the legal literature, before writing this thesis, it was not discussed to what extent the ethics review requirement itself functions as a public interest assessment, regardless of whether the law explicitly sets the public interest requirement. This gap was filled in Publication I, where it was concluded that, in principle, the mandatory ethics review requirement can appropriately ensure that health data is processed only for justified research projects.

Regarding Finland, Southerington has addressed the public interest, with particular focus on biobanking.[68] However, the publication does not delve into the details of the Findata data permit procedure. This gap was addressed in Publication I, which argued that the Findata data-permit procedure, to some extent, involves assessing what constitutes public interest in the context of scientific research.

In Publication I, the requirements set out in the EHDS proposal for assessing the public interest were examined, with consideration of the national contexts of Estonia and Finland. As a result, it was found that at the national level, the ethics review requirement may serve as the standard-setter within the EHDS mechanism. This finding also remains relevant to the final version of the EHDS, as explained in Section 3.3.1 of the analytical compendium.

At the time of writing the analytical compendium, some publications have already explored the public interest requirement in the EHDS. The author of the thesis takes these publications into account when developing her evaluation on whether the EHDS adequately balances the rights through the limitations on allowed processing purposes, the openness requirements, and the requirement to inform natural persons of significant findings. Some earlier publications by other authors rely on the Commission's proposal, whereas others rely on the final version of the EHDS. The question of whether the EHDS provides a mechanism for assessing the public-interest and ethical aspects has been analysed by some authors.[69] Also linked to public interest, it has been analysed whether the processing purposes possible under the EHDS are justified.[70] Some authors have assessed whether the EHDS requires offering public value in return for using the data access mechanism. Petročnik has observed that the EHDS' approach seems to be that merely opening up the health data market for data users will in itself result in certain benefits that will then reach patients and healthcare systems in

---

[67] Geili Keppi, 'Avalik Huvi, Avalikkuse Huvi Ja Isikuandmete Kaitse' 2024/4 Juridica 297, 302.

[68] Southerington (n 42) 253–254.

[69] Slokenberga (n 7) 146; Shabani and Yilmaz (n 44) 133; Paul Quinn, 'Health Data Access Bodies under the European Health Data Space – A Technocratic Colossus or Rubber Stamp Forum?' (2025) 2025 Technology and Regulation 60 <https://doi.org/10.71265/vbfvpb76>.

[70] Petros Terzis, 'Compromises and Asymmetries in the European Health Data Space' [2022] European Journal of Health Law 1, 11 <https://doi.org/10.1163/15718093-bja10099>; Quinn (n 69) 64–68, 74–76.

need of them.[71] Cervera de la Cruz and Shabani have noted that the EHDS still yields societal benefits by expanding scientific knowledge.[72] Prainsack has argued that by failing to incorporate data solidarity, the EHDS misses the opportunity to ensure that data use aligns with public values and fosters long-term trust.[73]

1.4.3. Publications on the legal basis requirement

In legal literature, there is debate about what constitutes scientific research under the GDPR's scientific research exemption (Article 9(2)(j)) and how broadly it should be interpreted.[74] For example, in the study by Lalova and others, the unclear notion of 'scientific research' in the GDPR has been identified as an issue.[75] To provide explanations, Heidi Beate Bentzen has conducted an analysis to determine what 'scientific research' in the GDPR should mean, drawing on case law from the CJEU and the European Court of Human Rights in contexts outside the GDPR. She has concluded that scientific research in the GDPR should be assessed according to 1) the role of the legal entity; 2) the role of the person(s) carrying out the activity; 3) quality standards, including scientific methodology and scientific publication; 4) an ethical assessment, including respect for context.[76]

At the same time, there is a shortage of focused analysis on whether and to what extent development and innovation activities fall within the concept of scientific research in the GDPR. This gap was addressed in Publication II, where the question was examined using the OECD Frascati Manual, which clarifies the core aspects of scientific research.[77] In a later publication, Köttering has discussed the legal basis issue in the specific context of developing a machine-learning-based

---

[71] Tjaša Petročnik, 'Secondary Use of Health Data in the EHDS: Public Interest and the Role of HDABs' in Santa Slokenberga, Katharina Ó Cathaoir and Mahsa Shabani (eds), *The European Health Data Space* (Routledge 2025) 184.

[72] Patricia Cervera de la Cruz and Mahsa Shabani, 'Fair Enough?: Exploring the Role of Fairness in Secondary Uses of Health Data in the European Health Data Space' in Santa Slokenberga, Katharina Ó Cathaoir and Mahsa Shabani (eds), *The European Health Data Space* (Routledge 2025) 148.

[73] Barbara Prainsack, '"My Data" over "Our Data." Why Do We Need Data Solidarity?' ICT&health Global <https://icthealth.org/news/my-data-over-our-data-why-do-we-need-data-solidarity> accessed 9 July 2025.

[74] Heidi Beate Bentzen, 'In the name of Scientific Advancement. How to Assess What Constitutes "Scientific Research" in the GDPR to Protect Data Subjects and Democracy' in Georgios Terzis and others (eds), Disinformation and Digital Media as a Challenge for Democracy (Intersentia 2020) 348–49; Rossana Ducato, 'Data Protection, Scientific Research, and the Role of Information' (2020) 37 Computer Law & Security Review 105412, 2–4 <https://doi.org/10.1016/j.clsr.2020.105412>.

[75] Lalova (n 43) 40, table 6.

[76] Bentzen (n 74) 364–65.

[77] OECD, *Frascati Manual 2015: Guidelines for Collecting and Reporting Data on Research and Experimental Development* (OECD 2015) <https://doi.org/10.1787/9789264239012-en>.

medical device. Similar to Publication II, she has outlined that product development may constitute scientific research, while mere product manufacturing does not.[78]

There is also a lack of understanding of whether and which development and innovation activities are possible under the public health exemption (Article 9(2)(i) GDPR) and the healthcare field exemption (Article 9(2)(h) GDPR). This gap was filled by Publication II, which analysed potential development and innovation activities involving health data that could be aligned with these legal bases. For a broader background, Spajić has examined the limitations of these legal bases, focusing on the patient's right to medical confidentiality.[79]

Also relevant to the legal basis question in the GDPR, Becker and others have analysed whether controllers conducting scientific research can bypass the legal basis requirement by relying on the exception from the purpose limitation in Article 5(1)(b) GDPR.[80] Becker and others found that a legal basis remains required for further processing of personal data for research purposes.[81] Lalova and others, as well as Sas and others, share this view.[82] Mourby and Molnar-Gabor also share this understanding, though they have noted that there is no clear consensus on this question.[83] In this thesis, it is argued that a legal basis for further processing for scientific research purposes is always necessary.

Considering the Estonian legal context, Kuuskmaa wrote a master's thesis analysing the legal bases of the GDPR and Estonian law for the development of clinical decision support systems. She concluded that the development is possible under the scientific research exemption.[84] While Kuuskmaa focused on a specific development activity, in Publication II, the approach was to brainstorm various development and innovation activities involving health data that could align with three promising legal bases under the GDPR, specifically Article 9(2)(h), (i) and (j) and the linking Estonian legislation. Furthermore, in Publication II, the

---

[78] Lea Köttering, 'Enabling Secondary Use of Health Data for the Development of Medical Devices Based on Machine Learning' in Marcelo Corrales Compagnucci and others (eds), *The Law and Ethics of Data Sharing in Health Sciences* (Springer Singapore 2024) 134.

[79] Daniela Spajić, 'Transforming the Secondary Use of Patient Data in the European Health Data Space: A Challenge for the Patient's Right to Medical Confidentiality?' in Santa Slokenberga, Katharina Ó Cathaoir and Mahsa Shabani (eds) *The European Health Data Space* (Routledge 2025) 96–100.

[80] Regina Becker and others, 'Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers?' (2022) 30 European Journal of Health Law 129 <https://doi.org/10.1163/15718093-bja10094>.

[81] ibid 149–50.

[82] Lalova (n 43) 40, table 6; Martin Sas, Elora Fernandes and Marta Musidlowska, 'Personal Health Data in xR Games: Exploring Purpose Limitation in the General Data Protection Regulation and European Health Data Space Regulation' (2025) 4 Digital Society 13 <https://doi.org/10.1007/s44206-025-00219-1>.

[83] Miranda Mourby and Fruzsina Molnar-Gabor, 'Secondary Uses of Patients' Data in the European Health Data Space: A UK-German Comparison' in Edward S. Dove (ed), *Confidentiality, Privacy, and Data Protection in Biomedicine* (Routledge 2025) 140–141.

[84] Kuuskmaa (n 64) 62.

ethics committee's regulations and practices were explored to understand how the notion of scientific research is interpreted in Estonia. Regarding Finnish national law, the author of the thesis is unaware of earlier publications on the topic. In Publication II, Finnish law and practice were examined to determine how the notion of scientific research is interpreted and to what extent development and innovation activities involving health data are possible in Finland.

Some academic articles have tackled the legal basis issues in the EHDS proposal. Kertesz concluded that the Commission's proposal for the EHDS did not provide clear guidance on how the data access permit is connected to the GDPR's legal bases.[85] Slokenberga drew attention to the fact that the Commission's proposal created a distinction between scientific research, on the one hand, and development and innovation, on the other, thereby causing even more ambiguity than the GDPR about what constitutes scientific research.[86] Terzis wrote that the Commission's proposal enabled development and innovation activities, as well as AI activities, without relying on any of the legal bases specified in Article 9(2) GDPR.[87] Quinn, Ellyne, and Yao have also explained the interactions between the EHDS proposal and the GDPR's legal bases.[88] However, at the time of writing Publication II, there was a lack of a detailed analysis and comparison of the specific legal bases of Article 9(2)(h-j) GDPR and the terms of the EHDS proposal for processing health data for development and innovation activities, necessary for understanding if the EHDS proposal really conflicts with the GDPR. Publication II filled this knowledge gap.

The final version of the EHDS, adopted after Publication II, largely resolves the legal basis issue by classifying development and innovation activities as scientific research, as explained in Section 4.3 of this analytical compendium. Still, questions regarding the interpretation of the notion of scientific research and the limits of the allowed processing purposes under the EHDS remain. For that reason, in Section 4.3 of this analytical compendium, it is analysed and evaluated to what extent the EHDS appropriately balances the freedom of scientific research and the rights to privacy and data protection through the legal basis requirement and the notion of scientific research. The earlier research on the contradiction between the GDPR's legal basis requirement and the Commission's proposal for the EHDS remains relevant, for example, in informing future law-making to avoid similar mistakes. This could be useful for drafting regulations for other Common European data spaces in which personal data will be processed.[89]

---

85 Kertesz (n 48) 501.

86 Slokenberga (n 7) 141–142.

87 Terzis (n 70) 12.

88 Quinn, Ellyne and Yao (n 48) 5–6, 8–10, 14.

89 Commission, 'Common European Data Spaces' <https://digital-strategy.ec.europa.eu/en/policies/data-spaces> accessed 25 August 2025.

1.4.4. Publications on the data subject's objection and opt-out rights

Regarding the GDPR's right to object in the context of scientific research, Taylor and Whitton have discussed the meaning of the 'public interest' in relation to the specific right to object in scientific research (Article 21(6) GDPR). They have found that the research project's contribution to the public interest in general or the reliance of the legal basis of public interest should not yet justify overriding the data subject's objections.[90] That discussion has been relied on in Publication III. The limits of the right to object have also been discussed in different GDPR commentaries.[91] Still, the discussions on the scientific research-specific right to object, as foreseen in Article 21(6) GDPR, and on the scientific research setting have been relatively brief. Publication III discusses the right to object in the context of scientific research, with consideration that controllers of national health databases, national health data access bodies, or similar entities acting in the public interest are the most logical channels through which data subjects can exercise their right to object. In this context, Publication III introduced a novel clarification that both the general and the science-research-specific right to object may be relevant in scientific research.

National examples of implementing the GDPR's right to object in a scientific research context have been analysed by other authors in the book 'GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe'.[92] Although the examples include a reference to Finnish legislation on permitted derogations from the right to object, they do not include the practices of Finland's Findata mechanism and Estonia's National Health Information System. Publication III provides a detailed analysis of the GDPR's right to object, relying on the practices of these channels as examples.

The question of the scope of application of the EHDS, which is particularly important to understand the scope of the EHDS opt-out right, was merely touched upon in legal literature before the publication of Publication III. However, Kogut-Czarkowska and Shabani have briefly discussed this question in the context of federated networks. They are of the view that the EHDS suggests that existing

---

[90] Mark J Taylor and Tess Whitton, 'Public Interest, Health Research and Data Protection Law: Establishing a Legitimate Trade-Off between Individual Control and Research Access to Health Data' (2020) 9 Laws 6, 9, 16 <https://doi.org/10.3390/laws9010006>.

[91] Gabriela Zanfir-Fortuna, 'Article 21 Right to Object' in Christopher Kuner and others (eds), *The EU General Data Protection Regulation (GDPR): A Commentary* (Oxford University Press 2020); Laura Carmichael, Emma Cradock and Sophie Stalla-Bourdillon, 'Right to Object and Automated Individual Decision-Making' in Indra Spiecker gen. Döhmann and others (eds), *General Data Protection Regulation Article-by-Article Commentary* (Bloomsbury Publishing 2023).

[92] Olga Tzortzatou and others, 'Biobanking Across Europe Post-GDPR: A Deliberately Fragmented Landscape' in Santa Slokenberga, Olga Tzortzatou and Jane Reichel (eds), *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe* (Springer Cham 2021) 409–15.

health data repositories may be allowed to operate under contractual agreements and to set their own governance rules for the reuse of deposited data.[93] Becker and others have also referred to the option of processing health data for scientific research purposes outside the EHDS mechanism.[94] Publication III discusses the scope of the EHDS's application in more detail, drawing conclusions about the effectiveness of its opt-out right. Later, Royo and others also expressed the view that the EHDS is an additional, not exclusive, legal basis for data access, and that there are multiple pathways for data reuse.[95]

During the negotiations of the EHDS, several authors suggested how the role of the data subject should be structured in the regulation. Slokenberga criticised the Commission's proposal for the EHDS, which did not foresee any opt-out right for data subjects, for the imbalance between respect for self-determination and interest in accessing data for a presumed common good.[96] Staunton and others suggested that the EHDS could provide either opt-in or opt-out rights to data subjects, allowing them to choose.[97] Mourby and Molnar-Gabor analysed the Council's draft of the EHDS, which would have established opt-out rights at Member States' discretion. They found that this solution risks failing to address regulatory fragmentation across the EU, which currently affects health research under the GDPR.[98]

Publication III analyses the final version of the EHDS and, as a novel contribution, provides suggestions to Member States for implementing the EHDS opt-out mechanism within the borders enabled by the EHDS. A few other publications regarding the opt-out mechanism in the final version of the EHDS are available. For example, Sokol has found that the adopted text on the opt-out right and the permitted exceptions from it struck a good balance between public and individual interests.[99] In contrast, Afra has been critical of the opt-out mechanism foreseen in the EHDS because no exceptions from the opt-out right are foreseen

---

93 Magdalena Kogut-Czarkowska and Mahsa Shabani, 'Federated Networks and Secondary Uses of Health Data: Challenges in Ensuring Appropriate Safeguards for Sharing Health Data under the GDPR and EHDS' in Santa Slokenberga, Katharina Ó Cathaoir and Mahsa Shabani (eds), *The European Health Data Space* (Routledge 2025) 245.

94 Regina Becker, Davit Chokoshvili and Edward S Dove, 'Legal Bases for Effective Secondary Use of Health and Genetic Data in the EU: Time for New Legislative Solutions to Better Harmonize Data for Cross-Border Sharing?' (2024) 14 International Data Privacy Law 223, 239 <https://doi.org/10.1093/idpl/ipae014>.

95 Romina Royo and others, 'Genomic Data Sharing in Research across Europe: Legal Challenges and Upcoming Opportunities within the European Health Data Space' (2025) 35 European Journal of Public Health iii25, iii29 <https://doi.org/10.1093/eurpub/ckaf070>.

96 Slokenberga (n 7) 146.

97 Staunton and others (n 48) 502.

98 Mourby and Molnar-Gabor (n 83) 128.

99 Tomislav Sokol, 'European Health Data Space, Use of Data and Data Subjects' Control over Their Own Health Data: Can an Opt-Out Restore the Balance?' (2024) 31 European Journal of Health Law 365, 384 <https://doi.org/10.1163/15718093-bja10131>.

for private actors, which could limit their access to unbiased data.[100] More recently, Roussos has published an article questioning whether the opt-out right under the EHDS is rather a catalyst or barrier to patient engagement.[101] In Publication III, the scope and exceptions to the opt-out right were explored in detail. It offers a thorough analysis that links the opt-out right under the EHDS and the right to object under the GDPR in practical national settings, which is not available elsewhere at the time of writing the thesis.

1.5. Research methods

This thesis has an ambitious aim to propose a model that Member States can use to balance the freedom of scientific research with the rights to privacy and data protection through the public interest and legal basis requirements, as well as data subjects' objection and opt-out rights. The model will be proposed within the limits of the GDPR and the EHDS, as they stand, to guide Member States on implementing and applying the public interest requirement, the legal basis requirement with a focus on the notion of 'scientific research', and the data subject's objection and opt-out rights in combination. The following established data access mechanisms are evaluated and compared to guide the proposal of the balanced model:

1) the one relying on the GDPR and the Estonian Data Protection Act[102];
2) the one relying on the GDPR and the Finnish Secondary Use Act[103]; and
3) the one relying on the GDPR and the EHDS.

While the primary goal of comparing and evaluating these data access mechanisms is to propose a model, this comparison also enables us to assess whether Estonia's current approach aligns with contemporary trends in digital health data processing in the EU. Both the EHDS and the Finnish Secondary Use Act are new legal instruments that aim to enhance scientific research by providing effective access to electronic health data, thereby providing a useful benchmark for assessing Estonia's current position relative to EU trends. Furthermore, the comparison between the Estonian and Finnish national mechanisms enables us to assess the degree of similarity in the rules governing the processing of health data in scientific research and whether they support cross-border research between these neighbouring Member States. As another aspect, the evaluation of the EHDS data

[100] Maryam Afra, 'An Assessment on Innovator's Ability for Consent-Free Health Data Reuse, In the Context of the GDPR and EHDS: The Netherlands Case Study' (2024) 31 European Journal of Health Law 475, 495 <https://doi.org/10.1163/15718093-bja10136>.

[101] Antonios Roussos, 'The Opt-Out Mechanism from Secondary Use in the European Health Data Space (EHDS) Regulation: Catalyst or Barrier to Patient Engagement?' (2025) 8 European Health & Pharmaceutical Law Review 217.

[102] EDPA, § 6.

[103] The Secondary Use Act.

access mechanism provides insight into expected future changes in the balance between the freedom of scientific research and rights to privacy and data protection.

In addition to the comparative method, this study employs the dogmatic method to address the research questions. The doctrinal analysis enables us to understand the public interest and legal basis requirements, as well as data subjects' objection and opt-out rights in each data access mechanism. As characteristic of legal-dogmatic research, the thesis provides a systematic exposition of these legal limitations governing health data processing for scientific research purposes and analyses these rules with a view to resolving ambiguities in the existing law.[104]

The reasons for including three specific data access mechanisms in the analysis are the following. The EHDS data access mechanism is a novel, recently designed, and detailed mechanism that facilitates access to electronic health data for scientific research across the EU. Considering this, the mechanism has the potential to inform the design of national data access mechanisms in place before the EHDS mechanism becomes available, and possibly in parallel with it thereafter.[105] In addition, as the data access mechanism under the EHDS is planned to be available from 26 March 2029 across the EU, it is important to learn the mechanism to provide suggestions to Member States on how to balance the freedom of scientific research and the rights to privacy and data protection within the borders of the EHDS mechanism.

Estonia and Finland have been selected for this analysis due to their high levels of health data digitisation, as both have rich electronic health data landscapes that support scientific research.[106] Another important reason for including Finland in the analysis is that Finland's Findata mechanism is a modern system for enabling access to electronic health data, widely regarded as a flagship in the EU. Since 2019, Findata has operated as the centralised, one-stop authority for permits for the secondary use of social and health data.[107] The Findata mechanism has also served as a reference point for the EHDS data access mechanism.[108] At the same time, the Findata mechanism has already revealed shortcomings in practice,

---

[104] Jan M Smits, 'What Is Legal Doctrine? On the Aims and Methods of Legal-Dogmatic Research' (Social Science Research Network, 1 September 2015) 5 <https://doi.org/10.2139/ssrn.2644088>.

[105] For the explanation of the interactions between the data access mechanisms, see Section 2.2. of this thesis.

[106] E-Estonia Briefing Centre, 'Digital Healthcare' <https://e-estonia.com/programme/digital-healthcare/> accessed 26 March 2026; Findata, 'The Finnish healthcare system and health data registers' <https://findata.fi/en/course/finnish-health-care-system/> accessed 17 February 2026.

[107] Finnish AI Region 2022-2025, 'Findata and Luxembourg forge an alliance ahead of EU health data reforms' <www.fairedih.fi/en/2025/09/30/findata-and-luxembourg-forge-data-governance-alliance-ahead-of-eu-health-data-reforms/> accessed 17 February 2026.

[108] Commission, 'Commission Staff Working Document Impact Assessment Report Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space' (n 18), paras 2.2, 2.3, 6.1.1, and 6.1.3.2.

which have already prompted amendments to Finland's national law.[109] The practical outcomes of the Findata mechanism are useful for understanding how the EHDS model may function in practice and for informing the model proposed in this thesis.

Regarding Estonia, the national Health Information System has also been analysed as a potential model for the EHDS mechanism in legal literature.[110] However, the Estonian Health Information System is less similar to the EHDS mechanism than the Findata data access mechanism is. In Estonia, there is no central data permit authority, such as Findata in Finland or health data access bodies (HDABs) as foreseen in the EHDS. Still, Estonia's Health Information System, as a central platform, includes patient data from the entire population across all health care providers.[111] Thus, the Health Information System controller determines whether to enable access to a large volume of health data for scientific research.

The data-processing mechanisms of two Member States, Estonia and Finland, and the mechanism under the EHDS enable a meaningful comparison in similar settings. All of these mechanisms enable the processing of health data for scientific research purposes without the data subject's consent. This enables a meaningful comparison of the public interest and legal basis requirements, as well as the data subjects' objection and opt-out rights examined in this doctoral thesis. In contrast, if data processing for scientific research required the data subject's consent, the data subject's autonomy would be broader, thereby affecting the scope of the public interest necessary to justify the processing. In addition, the absence of a consent requirement in each comparable mechanism allows an assessment of the extent to which development and innovation activities fall within the legal basis for scientific research (Article 9(2)(j) GDPR) without the data subject's consent. Furthermore, allowing research without consent is important for analysing the right to object under the GDPR. By comparison, in research based on the legal basis of the data subject's consent, the appropriate remedy for the data subject is withdrawal of consent, not the right to object.

To conduct the analysis, the relevant EU and national laws were first identified for each research question, with respect to the public interest and legal basis requirements, as well as data subjects' objection and opt-out rights. From EU law, the GDPR and the EHDS were relied on, as they regulate the data protection aspects of processing health data for scientific research. It must be borne in mind

---

[109] Government Proposal HE 87/2025 vp to Parliament for an Act amending the Act on the Secondary Use of Social and Health Information and related acts <www.eduskunta.fi:443/FI/vaski/HallituksenEsitys/Sivut/HE_87+2025.aspx> accessed 14 January 2026.

[110] Michael Denga and Thomas Hoffmann, 'The Estonian Electronic Health Record – a Prototype for Data Governance in the European Health Data Space?' (2023) 7 European Health & Pharmaceutical Law Review 5 <https://doi.org/10.21552/ehpl/2023/1/4>.

[111] Statute of the Health Information System (*Tervise infosüsteemi põhimäärus*) adopted on 1 December 2016 (RT I, 06.12.2016, 11).

that a reform of the GDPR, which may affect health data processing in scientific research, is under discussion as the analytical compendium is finalised.[112] Although the proposed amendments have been discussed in this thesis to some extent to highlight their importance, the detailed analysis of these amendments has not been the aim of the thesis.

From Estonian national law, the Estonian Personal Data Protection Act (EDPA)[113] and the Health Services Organisation Act[114] were primarily relied upon. The Finnish Personal Data Protection Act (FDPA)[115] and the Secondary Use Act[116] were analysed under Finnish national law. However, the rules on the processing of health data for scientific research are undergoing transformation in both Member States at the time of writing the thesis. In Estonian national law, certain changes took effect on 1 October 2025 and were not included in the analysis in Publication I. These concern foremost ethics review requirements in scientific research. Further extensive reforms to Estonian national law, including ethics review requirements, are under discussion as the analytical compendium is being finalised.[117] In Finland, on 5 December 2025, amendments to the Secondary Use Act were adopted and will enter into force on 1 May 2026, with some exceptions in the timeline.[118] These amendments do not yet address the implementation of the EHDS data access mechanism, indicating that further amendments are expected in the coming years.

After selecting the relevant provisions of the legislation, they were interpreted to determine their meaning and purpose. When interpreting EU law, the practice of the CJEU, the guidelines of the European Data Protection Board (EDPB)[119], the opinions of the predecessor WP29 working group[120], and the guidelines of the

---

[112] Commission, 'Proposal for a Regulation of the European Parliament and of the Council Amending Regulations (EU) 2016/679, (EU) 2018/1724, (EU) 2018/1725, (EU) 2023/2854 and Directives 2002/58/EC, (EU) 2022/2555 and (EU) 2022/2557 as Regards the Simplification of the Digital Legislative Framework, and Repealing Regulations (EU) 2018/1807, (EU) 2019/1150, (EU) 2022/868 and Directive (EU) 2019/1024 (Digital Omnibus)' COM (2025) 837 final.

[113] EDPA.

[114] Health Services Organisation Act *(Tervishoiuteenuste korraldamise seadus)* adopted on 9 May 2001 (RT I 2001, 50, 284).

[115] Finnish Data Protection Act (*Tietosuojalaki*)1050/2018 (FDPA).

[116] The Secondary Use Act.

[117] Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) (n 32).

[118] Act amending the Act on the Secondary Use of Social and Health Data *(Laki sosiaali- ja terveystietojen toissijaisesta käytöstä annetun lain muuttamisesta)* 1159/2025.

[119] European Data Protection Board, 'Tasks and Duties' <www.edpb.europa.eu/about-edpb/what-we-do/tasks-and-duties_en> accessed 5 February 2026.

[120] European Data Protection Board, 'Legacy: Art 29 Working Party' <www.edpb.europa.eu/about-edpb/who-we-are/legacy-art-29-working-party_en> accessed 5 February 2026.

European Data Protection Supervisor (EDPS)[121] were analysed. In this interpretation exercise, one aim was to determine the extent of discretion that EU law leaves to Member States to establish different or more precise regulations within their respective jurisdictions. For interpreting the EHDS, the draft guidelines developed in the TEHDAS2 project were also analysed. Even though not legally binding, they aim to harmonise the implementation of the EHDS.[122]

When interpreting the Estonian and Finnish national laws, relevant national case law and explanatory memoranda of legislation were considered. However, comparing only legislation is risky without information on how it works in practice.[123] Comparison should not stop at the level of legislation or case law, as social reality may be more different than the rules suggest.[124] Thus, to gain a deeper understanding of the national practices in Estonia and Finland, the author conducted email communications with 1) the data protection authorities in both countries; 2) the national data permit authority Findata in Finland; 3) ethics committees in Estonia; 4) the Ministry of Social Affairs of Estonia (the controller of the Health Information System), and; 5) the Health and Welfare Information Systems Centre TEHIK in Estonia (the processor of the Health Information System). All e-mail communications can be provided by the author upon request. In addition, the public instructions and opinions of the data protection supervisory authorities were analysed.

After explaining the public interest and legal basis requirements, as well as data subjects' objection and opt-out rights under each data access mechanism, it was assessed how these limitations balance the freedom of scientific research with the rights to privacy and data protection in each mechanism. Based on the evaluation, general conclusions were drawn regarding the implementation and application of each legal limitation. After analysing and evaluating each legal limitation separately, it was assessed how the combination of the legal limitations – public interest and legal basis requirements and objection and opt-out rights – balances the freedom of scientific research with the rights to privacy and data protection. Based on this evaluation, a model was proposed to Member States on how to shape the public interest and the legal basis requirements, as well as data subjects' objection and opt-out rights, to appropriately balance the freedom of scientific research with the rights to privacy and data protection in the existing European legal framework.

---

[121] European Data Protection Supervisor <www.edps.europa.eu/_en> accessed 5 February 2026.

[122] TEHDAS2 is carried out by 29 European countries and co-ordinated by the Finnish Innovation Fund, Sitra. The project will end in December 2026. It is based on the European Commission's EU4Health Programme. See: Second Joint Action Towards the European Health Data Space – TEHDAS2 <https://tehdas.eu/> accessed 5 February 2026.

[123] Mark Van Hoecke, 'Methodology of Comparative Legal Research' [2015] Law and Method 1, 6 <https://doi.org/10.5553/REM/.000010>.

[124] ibid 7.

1.6. The structure of this thesis

The thesis comprises previously published articles (Publications I-III) and this analytical compendium. As a prerequisite for answering the research questions identified in Section 1.3, the general legal framework for health data processing for scientific research purposes in the EU, Estonia, and Finland will first be explained in Section 2. This is necessary to provide a better understanding of the research problems and the analysis that answers the research questions. The overview starts with an analysis of the CJEU's judgment in EDPS v SRB[125], as it is relevant for establishing whether data protection rules apply to health data processing in scientific research at all.

The research questions concerning the public interest requirement have been addressed in Publication I and Section 3 of this analytical compendium. Publication I analyses and evaluates the public interest requirement in the GDPR and the Estonian and Finnish national legislation and practice. Section 3 of this analytical compendium adds the evaluation of the public interest requirement in the final version of the EHDS, which was not available at the time of writing Publication I. In Section 3 of the analytical compendium, also general conclusions are drawn regarding how the public interest requirement can optimally balance the freedom of scientific research with the rights to privacy and data protection.

The research questions concerning the legal basis requirement, with the focus on the notion of 'scientific research', have been addressed in Publication II and Section 4 of this analytical compendium. Publication II examines the boundaries of scientific research, using development and innovation activities as examples to see if they qualify as scientific research. Additionally, Publication II analyses two other legal bases of the GDPR to expand the understanding of the possibilities for conducting development and innovation activities that do not qualify as scientific research. While Publication II criticised the EHDS' proposal's approach to the legal basis requirement, Section 4 of this analytical compendium provides an updated evaluation of whether the final version of the EHDS appropriately balances the rights at stake. Additionally, general conclusions are drawn regarding how the legal basis requirement, with the focus on the notion of 'scientific research', can optimally balance the freedom of scientific research with the rights to privacy and data protection.

The research questions concerning the data subject's objection and opt-out rights have been addressed in Publication III and Section 5 of this analytical compendium. Section 5 of the analytical compendium adds some aspects of the EHDS which were not discussed in Publication III. However, at the time of writing Publication III, the final text of the EHDS was already available and was relied on. In Section 5 of the analytical compendium, the overarching conclusions on the rights to object and opt out are summarised.

---

[125] Case C-413/23 P *European Data Protection Supervisor v Single Resolution Board* (CJEU 4 September 2025).

In Section 6 of the analytical compendium, the interactions between the public interest and legal basis requirements and the objection and opt-out rights are analysed and evaluated for each data access mechanism. Based on the synthesis of these evaluations, the thesis proposes a model that optimally balances the freedom of scientific research with the rights to privacy and data protection, guided by public-interest and legal-basis requirements, as well as objection and opt-out rights.

All Sections 3-6 of the analytical compendium also discuss amendments and proposed amendments in Estonian and Finnish national laws, as well as the GDPR, which were not available at the time of writing the publications. The conclusions of the thesis are found in Section 7 of the analytical compendium.

2. LEGAL FRAMEWORK FOR HEALTH DATA PROCESSING FOR SCIENTIFIC RESEARCH

2.1. The effect of the CJEU Judgment in Case C-413/23 P (EDPS v SRB)

The processing of health data for scientific research purposes is regulated by the GDPR, in conjunction with national laws. In the future, the EHDS mechanism, in conjunction with the GDPR, will also be applicable. But first, the question of whether, in the context of scientific research, personal data is processed at all should be addressed, considering the recent case-law by the CJEU in case C-413/23 P (EDPS v SRB).[126] For that reason, this Section 2.1 discusses whether processing health data in a scientific research context, usually in pseudonymised form, constitutes personal data processing that triggers the application of the GDPR. After answering the question affirmatively, Section 2.2 explains the legal framework applicable to health data processing in the scientific research context.

The CJEU's judgment of 4 September 2025 in case C-413/23 P (EDPS v SRB) may have a significant impact on the rules governing the processing of health data for scientific research, even though the case is not in the context of scientific research but in the banking sector instead. The judgment explains when pseudonymised data should be regarded as personal data and when as non-personal data. In scientific research involving health data, pseudonymous data are mainly used. Commonly, the processing of pseudonymised data in health research has been regarded as the processing of personal data in the meaning of the GDPR.[127] In a guideline on pseudonymisation published before the judgement in the EDPS v SRB case, the EDPB expressed the view that pseudonymised data remains personal even if pseudonymised data and additional information are not in the hands of the same person.[128] Should the judgment in the EDPS v SRB case mean that the researcher is not processing pseudonymised data as personal data, the GDPR, together with the personal data protection rules, does not apply to the researcher. However, the judgment, as well as the context in which scientific research is typically conducted, is nuanced and may not result in any loosening of requirements for researchers.

In the EDPS vs SRB case, the CJEU explained that pseudonymised data are not always considered personal data. The CJEU stated that 'the existence of additional information enabling the data subject to be identified does not, in itself,

---

[126] Case C-413/23 P *European Data Protection Supervisor v Single Resolution Board* (CJEU 4 September 2025).

[127] Aliki Edgcumbe and others, '"Potato Potahto"? Disentangling de-Identification, Anonymisation, and Pseudonymisation for Health Research in Africa' (2025) 12 Journal of Law and the Biosciences lsae029, 8 <https://doi.org/10.1093/jlb/lsae029>.

[128] European Data Protection Board, 'Guidelines 01/2025 on Pseudonymisation' (Adopted on 16 January 2025, version for public consultation), para 22.

mean that pseudonymised data must be regarded as constituting, in all cases and for every person, personal data (...)'.[129] This means the CJEU confirmed a relative approach to the notion of personal data and, in principle, researchers may be exempt from the GDPR's application if they process pseudonymised data. The court explained that pseudonymised data should be considered non-personal on the condition that technical and organisational measures are put in place and are such as to prevent the data in question from being attributed to the data subject, in such a way that the data subject is not or is no longer identifiable.[130] As the court explained, this supposes that the controller is not in a position to lift those measures during any processing of pseudonymised data carried out under its control. The measures must be such as to prevent the controller from attributing those pseudonymised data to the data subject, including by recourse to other means of identification, such as cross-checking with other factors, in such a way that, for the controller, the person concerned is not or is no longer identifiable.[131]

For assessing the identifiability, the CJEU relied on its previous case law, stating that '[...] a means of identifying the data subject is not reasonably likely to be used where the risk of identification appears in reality to be insignificant, in that the identification of that data subject is prohibited by law or impossible in practice, for example because it would involve a disproportionate effort in terms of time, cost and labour (...)'.[132] For example, in the OC v Commission case, the CJEU explained that information relating to the gender of a person who is the subject of a press release, that person's nationality, his or her father's occupation, the amount of the grant for a scientific project and the geographical location of the entity hosting that scientific project, taken together, contain information that may allow the person who is the subject of that press release to be identified, in particular by those working in the same scientific field and familiar with that person's professional background.[133] The CJEU therefore found that, in this context, the risk of identifying the data subject cannot be regarded as insignificant.[134]

The judgment in the EDPS vs SRB case does not address health data or the research context. In this thesis, it is argued that, in a scientific research context, pseudonymised health data, even if held without the de-pseudonymisation keys by the specific controller, should be regarded as personal data. Article 89(1) GDPR refers to pseudonymisation as a safeguard for the processing of personal data for scientific research purposes. This suggests that, for processing health data for scientific research purposes, pseudonymisation is a standard minimum requirement, not an exceptional situation in which the GDPR ceases to apply. This adds

[129] Case C-413/23 P *EDPS v SRB*, para 82.

[130] ibid, para 75.

[131] ibid, para 77.

[132] ibid, para 82.

[133] Case C-479/22 P *OC v European Commission*, para 62.

[134] ibid, para 61.

weight to the interpretation that, in a scientific research context, the pseudonymisation of data is a default safeguard for processing personal data, not a measure that changes the nature of the data from personal to non-personal.

The pseudonymised health datasets in researchers' hands are likely those that, in principle, enable linking data to an identifiable person. In the literature, it has been explained that, due to the detailed nature of health data, the risk of re-identification is higher than for other types of personal data.[135] Researchers often combine datasets from different sources to conduct more inclusive and comprehensive analyses. By linking and combining data, a dataset can be enriched with more detailed information, which is more likely to enable the identification of a person. The motivation for such linking is not curiosity but rather the need for extended datasets that enable more accurate or richer research results. There is an especially high risk for re-identifying patients with rare diseases, as there are few individuals with similar attributes. Often, stories of such patients have been published in the media, providing additional information that enables re-identification. The same is true for celebrities whose health conditions have been under media scrutiny. Likewise, family members and friends may be readily re-identified by the researcher using previously known information.

The EDPS v SRB case hints that the pseudonymised data in the hands of the controller should not be considered personal data where the identification of that data subject is prohibited by law.[136] However, it is highly doubtful whether the prohibition in the law actually renders the risk of re-identification insignificant. As the researchers' motivation to use detailed data sets stems from the need for accurate, enriched research, legal prohibitions do not eliminate the risk of accidental or intentional identification of family members, individuals with rare diseases, or celebrities whose health information has been published in the media.

For these reasons, this thesis takes the position that, in a scientific research context, pseudonymised data, even if held by the researcher without the de-pseudonymisation keys, should be considered personal data. At the same time, it is not ruled out that, in some cases, pseudonymised health data in researchers' hands does not constitute personal data. Future research beyond the scope of this thesis is needed to clarify the boundaries of what constitutes personal data in the context of health data research. This thesis covers the instances in which health data in researchers' hands constitutes personal data and the GDPR applies.

With regard to the EHDS data access mechanism, this thesis proceeds on the assumption that data users in this mechanism process personal data. The assumption is made despite the fact that data users in the EHDS data access mechanism can access only pseudonymised data, without the de-pseudonymisation

---

[135] Edgcumbe and others (n 127) 3; Andrea Parziale, Elisabetta Pulice and Deborah Mascalzoni, 'Mass-Scale G2B Data Sharing in an Emergency: Between the GDPR, Data Governance Act, and European Health Data Space' (2025) 1 European Journal of Health Law 1, 9 <https://doi.org/10.1163/15718093-bja10158>.

[136] Case C-413/23 P *EDPS v SRB*, para 82.

keys, in the secure processing environment.[137] According to Recital 79 EHDS, 'Health data users should be deemed controllers for the processing of personal electronic health data in pseudonymised form in the secure processing environment pursuant to their data permits.' Reading the same recital further, health data users use health data access bodies (HDABs) as their processors, as confirmed in Articles 73(1) and 74(1) EHDS. At the same time, HDABs may hold the re-identification keys for health data.[138] In that context, data users should logically be considered personal data controllers if their processors, HDABs, process directly identifiable personal data. In addition, the EHDS, in several provisions, requires data users to have a legal basis under the GDPR for data processing.[139] This suggests that, in the EHDS mechanism, a cautious approach has been taken, treating pseudonymised data as personal data.

However, different interpretations are possible, as the EHDS mechanism aims to prevent data users from re-identifying data subjects, as described by the CJEU in the EDPS v SRB case. Following the EDPS v SRB judgement, the Commission has suggested that an example of a prohibition on re-identification which renders the data non-personal can be found in the EHDS's obligations for health data users.[140] By that, the Commission proposes that, under the EHDS, data users process no personal data at all. The author of the thesis does not support such an approach, as the prohibition in the law does not render the risk of re-identification insignificant. The effects of the approach suggested by the Commission require future research, particularly a comparison of the rights and safeguards available under the GDPR and the EHDS. Even where the GDPR is not applicable, the rights and safeguards under the EHDS remain in effect.

At the time of finalising the thesis, the Commission suggested specifying the definition of personal data in the main body of the GDPR as well.[141] However, the Commission's suggestion goes further than the judgment in EDPS v SRB. In legal literature, the Commission's proposal has already been criticised for a good reason. Stalla-Bourdillon has argued that the Commission has set the standard for the concept of personal data extremely low, thereby tempting controllers to argue that they do not process personal data.[142] Korff has argued that the amendment

---

[137] EHDS, arts 66(3), 73(1).

[138] ibid, art 66(3).

[139] ibid, arts 68(1)(c), 69(2)(f), recitals 52, 79.

[140] Commission, 'Digital Omnibus' (n 112), recital 27.

[141] The suggested wording in the Commission's proposal (n 112), art 3(1)(a): 'Information relating to a natural person is not necessarily personal data for every other person or entity, merely because another entity can identify that natural person. Information shall not be personal for a given entity where that entity cannot identify the natural person to whom the information relates, taking into account the means reasonably likely to be used by that entity. Such information does not become personal for that entity merely because a potential subsequent recipient has means reasonably likely to be used to identify the natural person to whom the information relates.'

[142] Sophie Stalla-Bourdillon, 'Déjà vu in Data Protection Law: The Risks of Rewriting What Counts as Personal Data' (2025) 26 Privacy and Data Protection 9.

conflicts with the overall case-law of the CJEU and breaches the Charter of Fundamental Rights.[143] Therefore, the amendment suggested by the Commission should not be approved, as it would limit the GDPR's scope of application beyond what the CJEU's case law has suggested, undermining the rights to privacy and data protection protected by the Charter.

The Commission has further proposed that it may adopt implementing acts specifying the means and criteria for determining whether data resulting from pseudonymisation no longer constitute personal data for certain entities.[144] This would grant the Commission the interpretive power previously held by the CJEU. Considering the Commission's approach to loosening the standard for what constitutes personal data, this would be a dangerous development from the data subjects' perspective. There is a risk that the implementing acts leave data processing outside the scope of the GDPR, while the risks of re-identification and unjustified processing remain.

2.2. Legislation regulating health data processing for scientific research

The processing of health data for scientific research purposes is regulated by the GDPR, in conjunction with additional national or Union law. As explained in the introduction of the analytical compendium, in the GDPR, scientific research holds a special place, offering more flexible rules for controllers than the GDPR's general standard.[145] The data subject's consent is not necessarily required, even when health data is involved,[146] and extensive limitations to data subjects' rights are possible.[147] For example, the controller may be exempt from applying some basic principles set forth in the GDPR – e.g., those on storage limitations and transparency.[148] In addition, EU or national law may allow derogations from data subjects' rights, such as the right of access to data and the right to object to data processing.[149]

For reliance on the legal basis for scientific research (Article 9(2)(j) GDPR), additional national or Union law is required, as per the wording of the same provision. In Estonia, the processing of health data for scientific research is governed by the Estonian Data Protection Act (EDPA) § 6.[150] According to

[143] Douwe Korff, 'Digital Omnibus: Proposed Changes to the Definition of Personal Data in the EU GDPR Analysed in the Light of the SRB and Earlier CJEU Judgments' (Social Science Research Network, 9 December 2025) 7 <https://doi.org/10.2139/ssrn.5891404>.

[144] Commission, 'Digital Omnibus' (n 112), art 3(10).

[145] Pormeister, 'Genetic Data and the Research Exemption' (n 9) 138–141.

[146] GDPR, art 9(2)(j).

[147] ibid, arts 5(1)(e), 14(5)(b), 17(3)(d), 89(2); van Veen (n 13) 72–73.

[148] GDPR, arts 5(1)(e), 14(5)(b); van Veen (n 13) 72.

[149] GDPR, art 89(2); van Veen (n 13) 73.

[150] EDPA.

EDPA § 6(1), health data may be processed without the data subject's consent for scientific research in a pseudonymised form or in a form that provides an equivalent level of protection. As a general rule, EDPA § 6(4) also requires ethics committee review when scientific research involves health data. Some changes to EDPA § 6 regarding the ethics review requirement took effect from 1 October 2025, differing from the legislation relied upon in Publication I. At the time of finalising the thesis, extensive additional amendments were proposed to the Estonian national legislation.[151] These changes are further discussed under Sections 3.2 and 4.2 of the analytical compendium, as they concern the assessment of the public interest and the scientific nature of the research projects.

In Finland, the secondary use of health data for scientific research is regulated by the Act on the Secondary Use of Social and Health Data[152] (the Secondary Use Act) and the Finnish Data Protection Act (FDPA)[153]. In Finland, there is no general mandatory ethics review requirement for the secondary use of health data in scientific research.[154] The Secondary Use Act establishes the Findata data access mechanism, which is widely regarded as similar to the EHDS data access mechanism. Under the Secondary Use Act, researchers must obtain a data permit to process health data for scientific research.[155] When the required data is from multiple public data controllers, the private sector, or Kanta Services[156], the application for the data permit must be submitted to Findata[157], the Finnish national data permit authority. In other cases, the application must be submitted directly to the public body controlling the health data.[158] This thesis focuses on legislation and practice concerning Findata. However, from 1 May 2026, other public bodies listed in the Secondary Use Act will be granted broader competences than before. Still, Findata remains responsible for processing data permit applications concerning data on Kanta services or the register data of one or more private social or health care service providers.[159] The objective of the amendments is to speed up the processing of data access permits.[160]

---

[151] Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) (n 32).

[152] The Secondary Use Act.

[153] FDPA.

[154] Iina Kohonen, Arja Kuula-Luumi and Sanna-Kaisa Spoof (eds), *The Ethical Principles of Research with Human Participants and Ethical Review in the Human Sciences in Finland. Finnish National Board on Research Integrity TENK Guidelines 2019* (2nd ed, TENK publications 2019) 6, 19, 20.

[155] The Secondary Use Act, § 35, 38.

[156] Kanta produces digital services for the social welfare and healthcare sector <www.kanta.fi/en/what-are-kanta-services> accessed 2 January 2026.

[157] Findata <findata.fi> accessed 2 January 2026.

[158] The Secondary Use Act, § 11.

[159] Act amending the Act on the Secondary Use of Social and Health Information *(Laki sosiaali- ja terveystietojen toissijaisesta käytöstä annetun lain muuttamisesta)* 1159/2025, § 6a.

[160] Government Proposal HE 87/2025 vp (n 109), sections 2.2, 2.3.

As of 26 March 2029, the EU-wide mechanism for secondary use of health data established by the EHDS is expected to be available.[161] As a novelty, this will be EU-wide and a largely harmonised data access mechanism enabling access to the electronic health data across the Member States. The European strategy for data proposed establishing the EHDS as the first of several domain-specific common European data spaces.[162] One of the drivers of the EHDS is the uneven implementation and interpretation of the GDPR by Member States, which creates considerable legal uncertainties and barriers to the secondary use of electronic health data.[163] It is expected that the EHDS data access mechanism will be widely used, as it is designed to facilitate effective access to health data for scientific research. As observed in the legal literature, the provision of specific rules on data access at the EU level shifts the focus from national to EU law.[164]

Procedurally, the EHDS will operate through health data access bodies (HDABs) established in the Member States. An applicant who wishes to access health data must apply to the HDAB for a data permit.[165] If the permit is issued to the applicant, then the health data holder, for example, a health care institution or the controller of the national health registry, is obliged to make the requested health data available to the HDAB that issued the data permit.[166] The HDAB, in turn, organises access to the data for the data user.[167] The data user can access health data only in a secure data processing environment that meets specific requirements, and only in pseudonymised or anonymous form.[168] The categories of health data accessible through the EHDS mechanism are broadly defined. For example, in addition to electronic health data from electronic health records (EHRs), data on factors impacting health, including socioeconomic, environmental, and behavioural determinants of health, are included.[169] To balance data subjects' rights and interests, the EHDS provides an unconditional opt-out right, which may, however, be subject to exceptions.[170]

In legal literature analysing the Commission's proposal for the EHDS, a question was raised about whether access by for-profit entities is permitted in the EHDS mechanism. This was done because the Commission's proposal for the EHDS refers to non-profit entities, but not to for-profit entities.[171] However, as

[161] EHDS, art 105.

[162] Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – A European strategy for data' COM (2020) 66 final (19 February 2020).

[163] Commission, 'Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space' COM (2022) 197 final, explanatory memorandum, ch 1.

[164] Spajić (n 79) 88.

[165] EHDS, art 68.

[166] ibid, arts 2(2)(t), 60(1).

[167] ibid, art 57(1)(a).

[168] ibid, arts 66(2,3), 73.

[169] ibid, art 51(1).

[170] ibid, art 71.

[171] Shabani and Yilmaz (n 44) 132.

both the recital of the proposal and the final version refer to 'private entities', which are often for-profit entities, there should be no question that the EHDS enables access for for-profit entities.[172] The Commission has confirmed that, 'Entities such as SMEs, startups, and larger companies engaged in development, innovation, and AI training can indeed be within the scope of "scientific research" under the EHDS'.[173] This remains consistent with the boundaries established by the GDPR, which does not limit the entities that can conduct scientific research. However, it may differ from national regulations that impose limits on for-profit entities' access to health data for scientific research.

To place the EHDS in the context of existing legislation, it is essential to note that the EHDS is without prejudice to the GDPR.[174] Therefore, the EHDS does not exempt health data processing for scientific research purposes from the GDPR. Rather, it complements it, also functioning as Union law under Article 9(2)(j) GDPR (the legal basis for scientific research). As another point, as explained in Publication III, the EHDS does not prohibit parallel national mechanisms that rely on the GDPR and national laws. The legal basis for processing health data for scientific research, Article 9(2)(j) GDPR, enables data processing not only under EU law, such as the EHDS, but also under national law. No provision in the EHDS prohibits combining the GDPR with national law. Instead, Articles 1(8) and 1(7) EHDS, which govern the scope of the EHDS, support the view that parallel mechanisms under the GDPR and national law are permissible. The same conclusion has been reached in the explanatory memorandum to the amendments to the Secondary Use Act in Finland.[175]

However, the EHDS mechanism will likely be the dominant one, as it would be too burdensome for Member States to maintain multiple systems alongside their own regulations. Additionally, the EHDS data access mechanism has the potential to provide the most effective means of accessing health data across the EU. Other legislation, such as the Data Governance Act (DGA), may set limits on retaining or creating alternative national data access mechanisms. For data processing falling within the scope of the DGA, Member States must ensure that the existence of a parallel national mechanism does not result in discriminatory conditions for the reuse of data.[176] It should also be clarified that, while the EHDS is not necessarily the only possible health data access mechanism for researchers, then for data holders, the EHDS is mandatory. If the national health data access body requests data from them, they must provide it.[177]

---

[172] EHDS, recital 61; Commission, 'Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space' COM (2022) 197 final, recital 41.

[173] Commission, 'Frequently Asked Questions on the European Health Data Space' (n 30) 31.

[174] EHDS, art 1(3).

[175] Government Proposal HE 87/2025 vp (n 109), section 2.8.

[176] Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 [2022] OJ L152/1, art 5(2).

[177] EHDS, art 60(1).

3. PUBLIC INTEREST REQUIREMENT AS A BALANCING TOOL IN HEALTH DATA RESEARCH

3.1. The public interest requirement for health data research in the GDPR

In this thesis, one aim was to critically analyse and evaluate how the public interest requirement limits the processing of health data for scientific research purposes and balances the freedom of scientific research with the rights to privacy and data protection. The input from the evaluation of the GDPR, Estonian and Finnish national laws and the EHDS helps us to learn the optimal approach to balancing the freedom of scientific research with the rights to privacy and data protection in regard to the public interest requirement.

There are various interpretations of public interest in the context of scientific research involving health data.[178] In this thesis, the term 'public interest' has not been limited to a specific definition and is used in a broad sense. It is understood as a contribution to understanding disease mechanisms, improving prevention and treatment, and advancing society's health-related interests. This approach relies on the explanations provided by van Veen, Schaefer, and others. According to van Veen, public interest in the context of scientific research can be explained as 'improving a better understanding of underlying mechanisms leading to ill-health or to better options for prevention or treatment'.[179] Schaefer and others have understood public interest as 'substantial expected advancement of the health-related interests of members of a group whose interests are, or should be, of particular concern to the society in question'.[180]

The question of the public interest requirement in health data research attracted particular attention following the EDPS's 2020 opinion, which stated that the GDPR's flexibility is afforded on the assumption that research occurring within a framework of ethical oversight serves, in principle, the public interest.[181] Controversially, the EDPS was opposing the research carried out 'with the aim of growing society's collective knowledge and wellbeing' and that 'serving primarily one or several private interests'.[182] Such an opposing approach was criticised by Slokenberga, who explained that the contrast element ('primarily

[178] Taylor and Whitton (n 90) 9–17.

[179] van Veen (n 13) 76.

[180] G Owen Schaefer and others, 'Clarifying How to Deploy the Public Interest Criterion in Consent Waivers for Health Data and Tissue Research' (2020) 21 BMC Medical Ethics 23, 2 <https://doi.org/10.1186/s12910-020-00467-5>.

[181] European Data Protection Supervisor, 'A Preliminary Opinion on Data Protection and Scientific Research (6 January 2020)' 11.

[182] ibid 12.

one or several private interests') could be difficult to uphold given the reasons and realities in which scientific research is carried out.[183]

As explained in Publication I, the GDPR does not require that the scientific research exemption (Article 9(2)(j) GDPR) can only be relied upon in cases where the scientific research is in the public interest. In scientific research, it is possible to rely on legitimate interest (Article 6(1)(f) GDPR) as an accompanying legal basis, which does not require a public interest either.[184] The EDPB has clarified that the legitimate interest as a legal basis should not be confused with the general public interest, as it refers to the interests of the controller or specific third parties.[185] However, in many cases, processing the health data for scientific research relies on the legal basis of public interest (Article 6(1)(e) GDPR), accompanying the research exemption of Article 9(2)(j) GDPR. In these cases, it is evident that the health data processing should serve the public interest. Referring to the legal basis of public interest, Slokenberga has explained in the context of biobanking that the GDPR permits Member States to adopt their own policies, as it employs the open-ended concept of public interest.[186]

Regardless of whether the legitimate interest or the public interest as a legal basis from Article 6(1) GDPR is relied on, Recital 53 of the GDPR suggests that the Union or Member State's law accompanying the GDPR for processing health data for scientific research must meet the objective of public interest. This suggests that a public interest standard should be established to justify the processing of health data for scientific research without the data subject's consent. Even though the recitals of the EU regulations are non-binding,[187] the referred recital is relevant for interpreting Article 9(2)(j) GDPR, according to which the EU or Member State law implementing the scientific research exemption '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'. As rightly pointed out by Slokenberga in the context of fundamental rights, balancing the rights at stake should not lead to depriving the data subject of their rights without providing any public good in return.[188]

Given that the GDPR does not directly require scientific research to serve the public interest or contribute to society's general knowledge and well-being, it does not protect data subjects against overly broad data processing under a scientific research regime. Thus, the GDPR's vague approach to the public-interest requirement in health data research strongly favours the freedom of scientific research over data subjects' rights to privacy and data protection.

---

[183] Slokenberga (n 61) 21–22.

[184] European Data Protection Board, 'Guidelines 1/2024 on Processing of Personal Data Based on Article 6(1)(f) GDPR' (version 1.0 adopted on 8 October 2024), para 24.

[185] ibid, para 25.

[186] Slokenberga (n 61) 24.

[187] Case C-162/97 Nilsson and others [1998] ECR I-07477, para 54.

[188] Slokenberga (n 61) 22.

As a positive development, at the time of finalising the thesis, the Commission has suggested adding the definition of 'scientific research' to the GDPR, which also touches upon the public interest requirements:

> 'scientific research' means any research which can also support innovation, such as technological development and demonstration. These actions shall contribute to existing scientific knowledge or apply existing knowledge in novel ways, be carried out with the aim of contributing to the growth of society's general knowledge and wellbeing and adhere to ethical standards in the relevant research area. This does not exclude that the research may also aim to further a commercial interest.[189]

Even though the suggested definition does not directly mention 'public interest', it requires the research to have 'the aim of contributing to the growth of society's general knowledge and wellbeing', as well as 'adhering to ethical standards', which may be regarded as the public-interest requirements in the context of scientific research. If the definition is adopted as suggested, the GDPR would more clearly set the public-interest standard through its definition of scientific research. Referring explicitly to 'public interest' in the definition would not add practical value, as the meaning of 'public interest' still needs to be explained. At the same time, the proposed definition makes it clear that the research may also serve a commercial interest. This is not disputed, as even the EDPS, in its critical 2020 opinion, has not ruled out the possibility of partial commercial interests in scientific research.[190] Thus, defining 'scientific research' as suggested by the Commission would help limit scientific research to projects of a certain quality and public-interest contribution. Still, the requirement to contribute to the public interest itself does not ensure its application. Procedural mechanisms for its application must be established in additional national or Union laws.

3.2. The public interest requirement for health data research in Estonian and Finnish national legislations

As analysed in Publication I, neither the Estonian nor the Finnish national legislation explicitly requires that processing health data for scientific research be in the public interest in all cases. However, Publication I also demonstrated, based on the examples of Estonia and Finland, that data access procedures may include a public-interest assessment, even if not explicitly stated. The Estonian example showed that the existence of public interest is, in practice, assessed in mandatory ethics review. Although the ethics committees' structure has changed in Estonia as of 1 January 2026, it is expected that the new ethics committees will

[189] Commission, 'Digital Omnibus' (n 112), art 3(1)(b).

[190] European Data Protection Supervisor (n 181) 11–12.

follow similar practices.[191] In Finland, there is no general ethics review requirement for accessing health data for scientific research.[192] However, the Finnish example showed that by assessing the criteria of 'scientific research' in a national data permit procedure, the criteria of public interest are also assessed to some extent, even if this is not explicitly framed.

While the existence of such procedures can balance the freedom of scientific research with the rights to privacy and data protection, their removal would have far-reaching negative effects on data subjects' privacy and the right to data protection. This will be further analysed and explained in this section, drawing on the amendments and the proposed amendments to Estonian legislation.

In Estonian national law, certain changes took effect on 1 October 2025 and were not included in the analysis in Publication I. One of the problems discussed in Publication I was the lack of regulation governing the establishment of ethics committees, which allowed any voluntary ethics committee to approve research projects, resulting in inconsistent assessments. This issue has been remedied by EDPA § 6(4), which now requires that the relevant ethics committee be established by law or on the basis of law. According to the explanatory memorandum of the law, this refers, for example, to the ethics committee established by the Research, Development and Innovation Organisation Act.[193] This adds certainty that ethics reviews are of higher quality and more uniform in their assessment of the public interest.

However, harmonising ethics review practices is of little value if ethics reviews are eliminated or reduced. As a negative change for data subjects, from 1 October 2025, scientific research conducted for policy development purposes by state authorities with executive power will, as a general rule, no longer require ethics review.[194] Even though state authorities rely on the public interest as a legal basis (Article 6(1)(e) GDPR), the removal of the ethics review requirement results in the absence of an independent control mechanism for assessing the public interest. Public interest cannot be established solely by the researcher's intention. It must also be supported by an assessment of whether the project's scientific standards and methodology plausibly lead to the intended societal benefit.[195] Although such research projects conducted by state authorities are subject to review by the Estonian Data Protection Authority, the authority lacks the competence to

---

[191] Procedure for the formation and assessment of the Research Ethics Committee and the Committee for the Processing of Cases of Research Ethics Misconduct (*Teaduseetika komitee ja teaduseetika väärkäitumisjuhtumite menetlemise komisjoni moodustamise ja hinnangute andmise kord*) adopted on 2 December 2025 (RT I, 09.12.2025, 16).

[192] Iina Kohonen, Arja Kuula-Luumi, and Sanna-Kaisa Spoof (n 154) 6, 19–20.

[193] Explanatory Memorandum of the Draft of the Organisation of Research and Development and Innovation Act, 41 <www.riigikogu.ee/tegevus/eelnoud/eelnou/27f4fde2-15e8-4441-adb2-813f5fc64fe1/teadus--ja-arendustegevuse-ning-innovatsiooni-korralduse-seadus/> accessed 3 January 2026.

[194] EDPA, § 6(5[1]).

[195] Hartlev (n 12) 575.

evaluate ethical aspects that reflect public-interest requirements. As an option, not an obligation, the Data Protection Authority may consult the ethics committee if it considers it necessary. Thus, while other researchers must always pass ethics review, state authorities holding executive power need not do so, at the discretion of the data protection authority. Such a distinction is not justified, as there is no evidence or convincing assumption that state authorities holding executive power, including the future ones, always follow ethical standards and public interests.

Furthermore, in addition to bypassing the ethics review, the law permits bypassing even the Data Protection Authority's assessment when the objectives of the research conducted for policy development and the scope of processing personal data are determined by legislation.[196] This is highly problematic from a privacy and data protection perspective, as it enables state authorities holding executive power to process health data without any external oversight. The fact that the law specifies the processing purposes and the scope of the data does not, in practice, protect against unethical studies, as there is no independent control over the processing activity. Previously, before the amendments took effect on 1 October 2025, the exception from the Data Protection Authority's assessment was in place as well, but in health data research, this was balanced with a mandatory ethics review requirement.

It is essential to highlight that, according to the explanatory memorandum of the law, supported by the wording of EDPA § 6(5^1), the ethics review requirement remains in effect where another law requires it. This is, for example, the case with the issuance of data from the Estonian National Health Information System, which is one of the main sources for research involving health data.[197] Likewise, the specific ethics review requirement applies to the issuance of data from the national population health databases, such as the pregnancy information system and the tuberculosis registry.[198] However, relying on the wording of the provisions, the specific legislation on ethics review requirements concerns only the 'issuance' of the data. This means that when the controller of the database intends to use the database for policy development, and there is no need to 'issue' the data, the controllers can bypass the ethics review requirement. Additionally, there is a risk of bypassing the Data Protection Authority's assessment, as a law may specify the objectives of data processing and the scope of the data. This approach is not justified, as it exposes health data to arbitrary use.

At the time of finalising the thesis, even more far-reaching amendments to the legislation have been proposed, further diminishing the role of ethics committees in scientific research involving health data.[199] For example, no ethics review

---

[196] EDPA, § 6(5).

[197] Explanatory Memorandum of the Draft of the Organisation of Research and Development and Innovation Act (n 193) 42.

[198] Public Health Act (*Rahvatervishoiu seadus*) adopted on 11 December 2024 (RT I, 02.01.2025, 3), § 30(1).

[199] Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) (n 32).

would be required if scientific research were conducted using health data in a pseudonymised form, regardless of the researcher's identity.[200] In health data research, it is common to process health data exactly in pseudonymised form, as it is a standard safeguard. This means that the ethics review requirement will be removed from a vast number of research projects solely because they employ a standard safeguard.

Although the proposed amendments require, as a general rule, notification to the Estonian Data Protection Authority of planned research projects, this does not mean that the authority will conduct a prior assessment of such projects. Instead, the authority is only required to publish the information on its webpage.[201] The authority can also use the information for monitoring purposes related to data protection, but this does not constitute an ethics review that assesses the research projects in detail, including the genuineness of the scientific research and its contribution to the public interest. In addition, although the proposed amendments specify the standard for pseudonymisation,[202] this is a technical safeguard that does not replace a substantial ethics review. Technical safeguards help protect against data leakage and re-identification, but they do not ensure a justification for processing health data.

As another dangerous proposal, no ethics review, notification to the authority, or even pseudonymisation as a safeguard would be required when controllers process data from a single database they control.[203] The proposal does not specify which types of controllers should have this privilege or which databases can be processed in this manner. Based on the wording of the proposed provision, any controller may process the health data it controls for scientific research without external oversight or the need to pseudonymise the data. However, as communicated by the authors of this suggestion, the privilege is intended to apply to databases in the meaning of the Public Information Act[204] and their controllers only.[205] However, the concept of 'database' in the referred act is very broad, covering a vast number of databases used in the public sector.[206] As of 1 March 2022, at least 821 such databases were registered, but the exact number is

---

[200] ibid, § 6(7).

[201] ibid, § 6(5).

[202] ibid, § 6(3), § 6^1(2).

[203] ibid, § 6(9).

[204] Public Information Act (*Avaliku teabe seadus*) adopted on 15 November 2000 (RT I 2000, 92, 597).

[205] E-mail from the Estonian Ministry of Justice and Digital Affairs to the Author (13 January 2026).

[206] Public Information Act, § 43^1(1): 'A database is a structured body of data processed within an information system of the state, local government or other person in public law or person in private law performing public duties which is established and used for the performance of functions provided in an Act, legislation issued on the basis thereof or an international agreement.'

unknown.[207] This proposed amendment would leave data subjects without the protection afforded by pseudonymisation as a technical safeguard, and without any external control over whether the processing activity constitutes scientific research at all or contributes to the public interest. This situation would pose extreme risks to data subjects' privacy.

Problematically, the relationship between the proposed § 6 of the EDPA and the special legislation remains unclear. For example, the Health Services Organisation Act provides specific rules for ethics review, which could potentially protect the data it covers from arbitrary processing.[208] However, as explained earlier, the wording of the act refers to the need for specific ethics review only for the 'issuance' of personal data from the Health Information System, not for processing within the system. Considering this wording and the proposed amendment, the controllers of the Health Information System would get the right to process the health data of the Health Information System of Estonia, containing the patient data of the whole population, without the need to pseudonymise it and with no external control over whether the processing constitutes genuine scientific research or whether the research project is in the public interest. Such a situation must be avoided, as it would constitute a serious breach of privacy and data protection.

As another interaction, the proposed amendments suggest that EDPA § 6, together with its requirements, should not apply at all where the objectives of the research and the scope of the data processing are specified by law.[209] However, stating the objectives and the scope of the data processing does not provide any safeguards or oversight for the data processing. Such a pathway to health data without oversight should be avoided, and an external control mechanism over health data processing for scientific research must always be retained, as it has been to date through the general mandatory ethics review requirement when special categories of data, such as health data, are concerned.

Taken together, the amendments already made and especially those proposed in Estonian legislation diminish the role of ethics review in health data research and, in many cases, leave processing activities without independent oversight. By opening up the health data use in that manner, the data subjects' rights to privacy and data protection are not protected. Moreover, it is unclear whether these amendments protect the freedom of scientific research. This is because, without an external control mechanism, health data can be accessed for purposes that do not constitute genuine scientific research but rather a random experiment or political endeavour. Such activities should not be protected by the freedom of scientific research. Although loosening ethics review requirements may expedite genuine scientific research as well and, in this way, support the freedom of

---

[207] E-mail from Estonian Information System Authority to the Author (26 February 2026).

[208] Health Services Organisation Act (*Tervishoiuteenuste korraldamise seadus*) adopted on 9 May 2001 (RT I 2001, 50, 284), § 59^4.

[209] Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) (n 32), § 6(10).

scientific research, for the protection of data subjects' rights, it is not appropriate to remove the control mechanisms governing research projects. Instead, it is appropriate to provide additional resources to ethics committees to accelerate assessment and enable the prioritisation of time-critical projects.

While the analysis of Finnish law and practice beyond the scope of the Secondary Use Act and Findata practices is beyond the scope of this thesis, it must be noted that, in Finland, in specific cases, routes for accessing health data for research purposes that do not require Findata data permits exist. For example, the Finnish Institute for Health and Welfare can access health data from public-sector databases under its own special legislation.[210] These procedures beyond the Findata data permit mechanism require further analysis to determine how the genuineness and contribution to the public interest of the projects are assessed. This analysis exceeds the scope of this thesis.

In sum, as demonstrated in Publication I, the balance between the freedom of scientific research and the rights to privacy and data protection can be effectively achieved through data access procedures, such as ethics review or data permit procedures. While in ethics reviews it is common to assess what could be understood as the public interest in the context of scientific research, the assessment criteria for data-permit procedures require specification in regulations or established case law. Still, there is no reason to omit the explicit public interest requirement from the law, as it offers solid guidance to those deciding on access to the data. For example, the legislation's clear requirement to assess contributions to the public interest, together with practical guidelines, could help ethics committees or data permit authorities shape their practices and avoid criticism for setting higher standards than the law requires.

The role of the ethics review and data permit procedures must not be underestimated. Diminishing the role of such procedures, as exemplified in this section based on developments in Estonia, does not mean simply loosening the administrative burden, which can be replaced by technical safeguards. Instead, it entails losing control over the content of processing activities conducted on health data, seriously affecting data subjects' rights to privacy and data protection.

3.3. The public interest requirement for health data research in the EHDS

3.3.1. The limitations of the processing purposes in the EHDS

The EHDS does not explicitly state that scientific research conducted under the EHDS should serve the public interest. However, it acknowledges the need to contribute to the general interest of society, which can also be understood as public interest. Recital 61 EHDS states,

[210] Act on the National Institute for Health and Welfare (*Laki Terveyden ja hyvinvoinnin laitoksesta*) 668/2008, § 2, § 5.

> Access to data for secondary use should contribute to the general interest of society. In particular, the secondary use of health data for research and development purposes should contribute to benefiting society in the form of new medicines, medical devices, and healthcare products and services at affordable and fair prices for Union citizens, as well as to enhancing access to and the availability of such products and services in all Member States.

In the following subsections, it will be shown how the EHDS sets the public interest standard through 1) specifying the allowed purposes of scientific research; 2) requiring that the research results or outputs be made public; and 3) requiring mechanisms to inform natural persons of significant findings concerning their health.

The boundaries that Article 53(1)(e) EHDS sets on the type of scientific research that can be conducted through the EHDS mechanism can be seen as requirements for public interest: 1) contribution to public health or health technology assessments; or 2) ensuring high levels of quality and safety of healthcare, of medicinal products or of medical devices; and 3) aiming to benefit end-users, such as patients, health professionals and health administrators. Article 54 EHDS also specifies the prohibited uses, including developing products or services that may harm individuals, public health or society at large. This also serves to limit the permitted processing purposes to those that serve the public interest.

The EHDS does not foresee any uniform, mandatory ethics review requirement that could serve as an assessment of public-interest requirements. Instead, it leaves the inclusion of ethical review, along with its own rules, to the choice of Member States.[211] However, the EHDS foresees a data permit procedure to be carried out by the HDABs, in which the processing purposes must be assessed.[212]

The limitations set in the EHDS for processing purposes have been criticised for a lack of clarity. Due to uncertainty, the limitations might not effectively ensure that the public interest is met. Quinn has explained that the EHDS leaves considerable discretion to Member States in interpreting the allowed purposes.[213] Santamaría Echeverría has argued that the EHDS model lacks a clear definition and procedural mechanisms to determine what constitutes public and general interests.[214] Petročnik argues that the lack of clear substantive guidance on this matter could result in either an 'anything goes' situation or in individual public officials applying their personal values in decision-making.[215]

---

[211] EHDS, arts 55(2), 67(2)(j), recital 69.

[212] ibid, art 68(1)(a).

[213] Quinn (n 69) 64–68, 74–76.

[214] Enrique Santamaría Echeverría, 'The European Health Data Space: A New Paradigm for Secondary Uses of Health Data for Scientific Research?' in Santa Slokenberga, Katharina Ó Cathaoir, Mahsa Shabani (eds), *The European Health Data Space* (Routledge 2025) 171.

[215] Petročnik (n 71) 190.

Several authors share the view that clear guidelines are needed for identifying what constitutes the public interest in the EHDS.[216] At the same time, developing such guidance is challenging because it is difficult to encompass all possible research projects and examples within a single guideline. However, an effort could be made as a guideline developed by the EHDS Board[217], or as part of the TEHDAS2 project's guidelines package.[218] The guideline could include a variety of examples of research projects that either do or do not qualify under the EHDS's allowed processing purposes. Even though the TEHDAS2 Draft guideline for HDABs on the limitations on the reuse of health data (16 September 2025) explains the allowed processing purposes under the EHDS to some extent, it does not explain how 'the contribution to public health or health technology assessments', 'ensuring high levels of quality and safety of healthcare, of medicinal products or of medical devices' and 'the aim of benefiting end-users, such as patients, health professionals and health administrators' shall be interpreted.[219] At this point, the draft guideline only suggests that neither basic nor applied research needs to have direct benefits for end-users or patients, but rather to unfold their societal benefits over the long term.[220]

Another aspect regarding the clarity of the allowed processing purposes, Raposo has raised the question of whether the public interest must be the prevailing interest at issue, or whether its mere existence is sufficient, even if secondary to the private interest.[221] As there is no specific limitation in the EHDS, it should be assumed that the existence of a contribution to the general interest of society is enough. The existence of private interests does not diminish the contribution to society's general interest. It should therefore not be an obstacle to accessing the EHDS data access mechanism. The draft guideline in TEHDAS2 project takes the same view, by stating that '[c]ommercial interest does not disqualify a project per se, but scientific rigor must be demonstrated [...]'.[222] Still, in situations where the expected contribution to society's general interest is low, and the datasets sought are sensitive or large, the HDABs should refuse to grant a data permit on

---

[216] Cervera de la Cruz and Shabani (n 72) 140; Santamaría Echeverría (n 214) 172; Petročnik (n 71) 193.

[217] EHDS, art 94(2).

[218] Although non-binding, the TEHDAS2 guidelines could clarify and harmonise the assessment of permitted processing purposes under the EHDS. See <https://tehdas.eu/> accessed 11 March 2026.

[219] TEHDAS2, 'Draft Guideline for Health Data Access Bodies on Minimum Categories and Limitations on the Reuse of Health Data' 28 <https://tehdas.eu/wp-content/uploads/2025/09/draft-guideline-for-health-data-access-bodies-on-minimum-categories-and-limitations-on-the-reuse-of-health-data.pdf> accessed 9 February 2026.

[220] ibid 29.

[221] Raposo (n 46) 10.

[222] TEHDAS2 (n 219) 29.

proportionality grounds.[223] In legal literature, it has been concluded that the importance attached to the public interest will always be context-dependent and needs to be balanced against the rights and interests of research participants. Consequently, public interest cannot be assessed isolated from the interests and rights of the data subject.[224]

In addition to uncertainty, the bar the EHDS sets for the public interest has been criticised in legal literature as being too low. Prainsack, the spokesperson for data solidarity, has highlighted that the EHDS does not address how commercial benefits will be shared with people and communities.[225] Similarly, McMahon and Staunton have claimed that the EHDS proposal does not sufficiently address the equity of benefit in downstream access to therapies and knowledge.[226] In this regard, the final version of the EHDS does not differ from the Commission's proposal. In a similar spirit, Santamaría Echeverría has also observed that 'the EHDS misses a set of rules on the expectations in terms of giving back (reseeding) the commons and how the possible benefits arising from the use of health data ought to be distributed, particularly by big market players'.[227] Petročnik has suggested that the HDABs should take the initiative to ensure that data processing benefits society, endorsing Prainsack's views.[228] She has suggested HDABs could set open-access requirements and measures to ensure affordable access to innovative treatments, products, or services developed through the data access mechanism.[229]

Indeed, in a mechanism such as the EHDS, which enables large-scale, mandatory access to health data across the EU and attracts Big Tech and other commercial actors, the public interest requirement must be taken seriously and equipped with clear assessment mechanisms that enable flexibility. Currently, under the EHDS, Member States and the HDABs need to be careful not to impose requirements stricter than those permitted by the EHDS, except for the data categories specified in the EHDS, where stricter rules are allowed.[230] For example, it is doubtful whether the HDABs could require legally binding benefit-sharing arrangements from data applicants. Data applicants can easily argue that HDABs are not allowed to set any specific conditions for granting access to the data and appeal the HDAB's decision on this ground. This may limit HDABs from striking a fair balance between the interests at stake through their practice.

---

223 EHDS, art 68(1)(b).

224 Hartlev (n 12) 576.

225 Prainsack (n 73).

226 Aisling McMahon and Ciara Staunton, 'Managing Access to Health Data for Research and Innovation in the EU: Is a Better Regulatory Approach Possible?' in Edward S Dove (ed), *Confidentiality, Privacy, and Data Protection in Biomedicine* (Routledge 2025) 122.

227 Santamaría Echeverría (n 214) 169.

228 Petročnik (n 71) 192; Barbara Prainsack, 'Research for Personalised Medicine: Time for Solidarity' (2017) 36/1 Medicine & Law 87.

229 Petročnik (n 71) 193.

230 EHDS, art 51(4), recital 52.

Considering the uncertainty of the HDABs data permit procedure in ensuring an appropriate public-interest standard, the national ethics review requirement could serve as an additional layer of protection.[231] The decision to allow national laws to require ethics review under their own rules is especially interesting, as, under the EHDS mechanism, Member States generally do not have the right to impose additional conditions or safeguards under Article 9(4) GDPR.[232] The question of the extent to which the ethics review can result in stricter rules than foreseen by the EHDS remains. Additionally, since there is no uniform ethics review requirement in the EHDS, it is not a harmonised solution. Even Member States that require ethics reviews may set different ethical standards, affecting the harmonised implementation of the EHDS, as explained by Sas and others.[233] Still, given the uncertainty of the HDAB data permit procedure in ensuring the appropriate public interest standard, it is advisable for Member States to foresee national ethics review requirements as an additional layer, balancing the freedom of scientific research and the rights to privacy and data protection.

In sum, the EHDS shapes the public interest standard to some extent by requiring scientific research to meet certain conditions, such as aiming to benefit end-users. At the same time, these limitations are rather general, not assuring that HDABs can, in each case, strike a fair balance between the interests of the data applicant and data subjects. Given this background, it is advisable for Member States to make ethics review an additional requirement. However, the national ethics review requirements may easily lead to fragmentation of the data access requirements across the EU, which is contrary to the purposes of the regulation. To mitigate this risk, Member States could work to harmonise ethics procedures to the extent possible, taking into account cultural values and backgrounds.

3.3.2. The requirement to publish the research results

As another condition, the EHDS' requirement to publish research results could contribute to the public interest. According to Article 61(4) EHDS, 'Health data users shall make public the results or output of secondary use, including information relevant for the provision of healthcare [...]'. According to the same provision, they shall also inform the HDABs about the results or output. However, the EHDS does not require open access to journal articles, meaning that the results or outputs may also be behind a paywall. Still, the requirement to make research results public could favour open science and broader dissemination, potentially leading to the development of products and services that benefit end-users. In this way, the requirement serves the public interest. However, uncertainties remain regarding this requirement. In the TEHDAS2 project, the guideline

[231] ibid, art 55(2).

[232] ibid, recital 52.

[233] Sas, Fernandes and Musidlowska (n 82) 58.

on this topic is planned for public consultation in 2026.[234] At the time of writing this thesis, the draft of the guideline is not yet available.

From a critical perspective, it is unclear whether the requirement adds significant value beyond transparency. When conducting scientific research with health data, the results are typically published when there is sufficient analysis and data to warrant publication. This is true regardless of whether the EHDS requires it. The motivation for publishing is not compliance with the law but rather the advancement of science itself. In situations where performing scientific research does not yield results worth publishing, which may also be the case, it is unclear whether the EHDS requires publishing something that researchers would not typically publish. As Santamaría Echeverría rightly observed, it remains unclear what constitutes 'results or output'.[235] Even if the EHDS adds a requirement to publish 'results or output' that would not otherwise be published as a scientific publication, it is questionable whether publishing such information has high value or quality.

Still, the EHDS' requirement to publish the results or output may bring additional value when commercial entities conduct the research. As commercial entities may not always be motivated to publish scientific articles, even when valuable research findings are involved, the EHDS obligation may provide other researchers with additional information. Even though the EHDS does not specify the level of detail required for the results or outputs, HDABs should require that research results be published in detail to maximise the public value of the processing activity. Making research results available in detail helps avoid repetitive health data research and allows reliance on previous results. Considering that according to the EHDS, data users can keep the results of their research secret for 18 months from the completion of data processing, and in some cases longer[236], this may be enough to retain the competitive advantage that motivated the research in the first place. Thus, while the requirement to publish research results is not the clearest under the EHDS, it has the potential to balance the freedom of scientific research with the data subjects' interest in maximising the public value of the research.

3.3.3. The requirement to inform natural persons of significant findings

Another way the EHDS could contribute to the public interest is by providing data subjects with information on significant findings concerning their health. In this way, data subjects who contribute their health data to scientific research under the EHDS mechanism can benefit directly by receiving information about their health.

---

[234] TEHDAS2, 'Public consultations' <https://tehdas.eu/public-consultations/> accessed 9 February 2026.

[235] Echeverría (n 214) 169.

[236] EHDS, art 61(4).

Providing information to data subjects on significant findings concerning their health is regulated under the EHDS, Articles 58(3) and 61(5). According to the EHDS, researchers shall inform the HDAB of any significant finding related to the health of the natural person whose data are included in the dataset.[237] The HDAB, in turn, shall inform the health data holder about that finding. The health data holder shall, under the conditions laid down by national law, inform the natural person or health professional treating the natural person concerned.[238] At the time of writing this thesis, a draft guideline for HDABs on significant findings has been published in the TEHDAS2 project. However, it does not address data users' responsibilities for deciding when and how to report significant findings to HDABs.[239] Development of such guidelines is also the task of the EHDS Board.[240]

The effective functioning of such a mechanism is questionable. Firstly, it is unclear whether researchers are motivated to notify HDABs of any significant findings related to the health of natural persons, as this does not add value to their own scientific research. It is also challenging to envision how such a notification obligation could be effectively monitored or enforced. In comparison, in Finland, under the Findata mechanism, the data permit holder has the right, but not the obligation, to notify of a clinically significant finding that would prevent a risk to the health of a specific patient or significantly improve the quality of care.[241] The choice to treat the notification of significant findings as a right rather than an obligation is more realistic.

Even if the researcher notifies the HDAB, several steps remain before the information can become valuable to the natural person. Article 58(3) EHDS stipulates that the HDAB shall inform the health data holder of the finding, who, under the conditions laid down by national law, shall notify the natural person or the health professional treating the natural person concerned. In this lengthy chain, there is a risk that the information may not reach the data subject. If the national law lacks an effective mechanism for informing the natural person, then the natural person cannot benefit from information about their health. At the same time, the findings from individual research projects are not intended for direct clinical practice. Before they can be communicated to data subjects, extensive work must be done, which may not be the most optimal way to screen patients and suggest treatments. Thus, given the complications associated with this requirement, it is unlikely to have significant potential to advance the public interest.

---

[237] ibid, art 61(5).

[238] ibid, art 58(3).

[239] TEHDAS2, 'Draft Guideline to Health Data Access Bodies on Implementing the Obligation of Notifying the Natural Person on a Significant Finding from the Secondary Use of Health Data' 5 <https://tehdas.eu/wp-content/uploads/2025/09/draft-guideline-to-health-data-access-bodies-on-implementing-the-obligation-of-notifying-the-natural-person-on-a-significant-finding-from-the-secondary-use-of-health-data.pdf> accessed 9 February 2026.

[240] EHDS, art 94(2)(c).

[241] The Secondary Use Act, § 55.

3.4. Conclusions on the public interest requirement as a balancing tool in health data research

To balance the freedom of scientific research with the rights to privacy and data protection, it is essential to ensure that scientific research using health data without the data subjects' consent serves the public interest. Considering that genuine scientific research related to health generally contributes to the public interest by generating new scientific knowledge that supports the understanding of health, illnesses and treatment options, the public interest requirement does not overly limit the freedom of scientific research. For data subjects, the public interest requirement is an important justification for their data use, as it would not be fair to process health data with risks of re-identification remaining for purposes that do not aim to provide any value to society. While the contribution to genuine scientific knowledge can already be seen as a contribution to the public interest, the assessment of public interest should be context-specific, weighing the risks and benefits of the research project involved.

Considering that the GDPR does not ensure that health data is processed for scientific research only where justified by public interests, Member States must foresee optimal requirements and mechanisms in their national laws to balance the freedom of scientific research with the rights to privacy and data protection. Based on the synthesis of the analysed data access mechanisms, the following is proposed for national data access mechanisms that rely on the GDPR.

1. The public interest requirement should be foreseen in the national legislation together with an explanation of what is meant by it, for example, referring to the aim of contributing to the growth of society's general knowledge and well-being and adhering to ethical standards.
2. The contribution to the public interest must be assessed in independent assessment procedures, such as ethics reviews or data-permit procedures by qualified members. No exceptions from this requirement should be allowed, even where the data is processed by state authorities or protected by technical safeguards.
3. Guidelines on what constitutes public interest in the context of scientific research, together with practical examples, must be developed in cooperation with ethics committees and representatives of researchers and data subjects.
4. In assessing the public interest, the risk-benefit ratio must be considered. The higher the research project's value to society, the more justified the risks to privacy and data protection are. Projects with no or very low societal value do not justify taking risks to privacy and data protection.
5. The requirement to publish the research results, with a sufficient timeline retaining the competitive advantage to the researcher, should be set.

While the EHDS leaves Member States with less discretion in shaping the EHDS data access mechanism, this analysis offers suggestions to Member States and the HDABs within the EHDS.

1. The ethics review requirement should be foreseen in the national legislation to ensure a fair balance between the interests of the data users and data subjects. The practices of ethics reviews should be harmonised across the EU to the extent possible to avoid imposing undue restrictions on cross-border research.
2. Guidelines on what kind of research projects contribute to the general interest of society and are allowed under the EHDS must be developed uniformly across the EU.
3. In assessing data applications, HDABs must consider the risk-benefit ratio of the research project, as they have the obligation to assess whether the requested data is proportionate for the purposes described.[242]
4. The requirement to make the research results public should be applied strictly by the HDABs, requiring the publishing of the results in detail.

[242] EHDS, art 68(2)(b).

4. THE LEGAL BASIS REQUIREMENT AND THE LIMITS OF THE NOTION 'SCIENTIFIC RESEARCH' AS A BALANCING TOOL IN HEALTH DATA RESEARCH

4.1. The legal basis for development and innovation activities in the GDPR

In this thesis, one aim was to critically analyse and evaluate how the legal basis requirement, with a focus on the notion 'scientific research', limits the processing of health data for scientific research purposes and balances the freedom of scientific research with the rights to privacy and data protection. Given that the boundaries of development and innovation activities that qualify as scientific research provide a good understanding of how far scientific research, as a legal basis (Article 9(2)(j) GDPR), extends, the thesis examines these boundaries within the GDPR as an overarching framework, as well as in the national laws of Estonia and Finland, and the EHDS. The input from the evaluation helps to design the optimal approach for balancing the rights at stake.

In Publication II, the boundaries of the legal basis for scientific research (Article 9(2)(j) GDPR) were examined by analysing the extent to which development and innovation activities fall within the notion of 'scientific research'. The analysis revealed that, in principle, the scientific research exemption (Article 9(2)(j) GDPR) accommodates development and innovation activities involving health data. As the GDPR does not define scientific research and offers only a broad explanation in Recital 159, nor is there established CJEU case law, the limits of what can be considered scientific research must be determined otherwise. In Publication II, reliance on the R&D criteria outlined in the Frascati Manual was suggested. Relying on these, for a development or innovation activity to qualify as scientific research, it should be 1) novel; 2) creative; 3) uncertain; 4) systematic; and 5) transferable and/or reproducible.[243] In addition, in Publication II, it was suggested that the criteria developed by the EDPB and the EDPS for scientific research should also be considered, including the sector-related methodological and ethical standards and the need to contribute to the public interest.[244]

Considering that these criteria are not established in the GDPR, it does not provide a strong foundation for limiting the boundaries of scientific research as a justification for data processing. In this regard, the GDPR falls short in protecting the rights to privacy and data protection, as there is a risk of overly broad interpretation of scientific research, enabling the processing of health data for

[243] OECD (n 77) 45.

[244] European Data Protection Board, 'Guidelines 05/2020 on Consent under Regulation 2016/679' (Version 1.1, Adopted on 4 May 2020)' para 153; European Data Protection Supervisor (n 181) 11–12.

unjustified purposes, such as mere product manufacturing. Furthermore, as reliance on the legal basis for scientific research means significant limitations to data subjects' rights,[245] the lack of definition of what constitutes scientific research has an even more far-reaching negative effect on data subjects. At the same time, the broad approach taken by the GDPR to the notion of scientific research strongly favours the freedom of scientific research, as it acknowledges the need to extend it beyond fundamental research. However, the problem with this approach is that the privilege the GDPR provides may, in practice, extend beyond what is considered scientific research, for example, to market research or political planning of a non-scientific nature.

To enable development and innovation activities that do not fit under the GDPR's scientific research notion, other GDPR's legal bases, such as the public health exemption (Article 9(2)(i) GDPR), or the health care exemption (Article 9(2)(h) GDPR), can be appropriate under certain conditions, as analysed in Publication II. Instead of trying to fit all development activities with health data under the umbrella of scientific research, Member States should consider the options to rely on legal bases other than scientific research. If there is no appropriate legal basis for processing health data under Article 9(2) GDPR, the processing activity is not permitted and must not be carried out.

The Commission's suggestion to define 'scientific research' in the GDPR[246] is a positive development. The proposed definition, which requires contributions to existing scientific knowledge or the application of existing knowledge in novel ways, aligns with the Frascati Manual's conditions that scientific research must be novel and creative. More indirectly, the proposed definition's reference to ethical standards aligns with the rest of the Frascati Manual's criteria for scientific research: it must be uncertain, systematic, and transferable and/or reproducible. Adherence to ethical standards means that these criteria also must be met. Still, the criteria of the Frascati manual or methodological standards more generally could be more clearly and directly reflected in the definition, as Member States may interpret ethical standards differently. The definition suggested by the Commission also requires aiming to contribute to society's well-being, which can be seen as a public interest requirement. Thus, the suggested definition more strongly protects data subjects' rights by setting boundaries on what constitutes scientific research. At the same time, the suggested definition confirms that development and innovation activities can sometimes be considered scientific research, continuing to protect the freedom of scientific research.

---

[245] GDPR, arts 5(1)(e), 14(5)(b), 17(3)(d), 89(2); van Veen (n 13) 72–73.

[246] Commission, 'Digital Omnibus' (n 112) has suggested the following definition for scientific research: '"scientific research" means any research which can also support innovation, such as technological development and demonstration. These actions shall contribute to existing scientific knowledge or apply existing knowledge in novel ways, be carried out with the aim of contributing to the growth of society's general knowledge and wellbeing and adhere to ethical standards in the relevant research area. This does not exclude that the research may also aim to further a commercial interest' (art 3(1)(b)).

Although the definition proposed by the Commission can be criticised for its lack of systematic approach and clarity, it is not feasible to include all details in the legal acts. Instead, uniform application of detailed guidelines is appropriate. For this reason, this thesis recommends relying on the OECD Frascati Manual's guidance for interpreting what constitutes scientific research in practical settings and borderline cases. In addition, given the rapid development of technology and research methods, including AI, additional renewed guidance is needed. Although the Frascati Manual provides useful practical guidance, it dates back to 2015 and does not address recent technological advancements. The additional guidelines, which address recent developments in technology and research methods, could be developed by the EDPB to offer uniform guidance to Member States.

4.2. The legal basis for development and innovation activities under Estonian and Finnish national legislations

The concept of scientific research must be interpreted autonomously in the EU and cannot be extended in national legislations. Still, in a situation where there is no binding definition or established case law by the CJEU on what constitutes 'scientific research' under the GDPR, Member States choose their own approach to interpreting the notion.

The Estonian and Finnish examples analysed in Publication II show that conducting development and innovation activities under the legal basis of the scientific research exemption (Article 9(2)(j) GDPR) is, in practice, possible. This complies with the broad explanation of scientific research in Recital 159 GDPR. While there was no indication of an overly broad interpretation of the concept of scientific research, the conclusions that can be drawn in this thesis are limited due to reliance on regulations and communication, while no data applications or decisions were analysed, which exceeds the scope of this thesis.[247]

Setting boundaries to the notion of 'scientific research' can only protect privacy and data protection rights where independent assessment procedures are in place. In Publication II, it was shown that in Estonia, ethics committees, and in Finland, the data permit authority Findata, assess whether the proposed project is genuine scientific research. The existence of such independent assessment procedures in conjunction with the appropriate interpretation of 'scientific research' balances well the freedom of scientific research and the rights to privacy and data protection.

In contrast, the pathways for accessing health data without such independent control mechanisms pose a risk that the data will be used under the guise of scientific research for something other than genuine scientific research. Therefore, the proposed reduction of the role of ethics committees in Estonia in health

[247] E-mail from the Research Ethics Committee of the National Institute for Health Development to the Author (4 January 2023), e-mails from Findata to the Author (24 May 2023, 9 February 2026). For more detailed analysis, see Publication II.

data research[248] is a dangerous development from the perspectives of privacy and data protection. The critique of the proposed amendments to the Estonian legislation in Section 3.2 of the analytical compendium is equally relevant here and will not be repeated in full. In short, removing the ethics review requirement as an independent control mechanism means neither the contribution to the public interest nor the genuine nature of the research project will be reliably assessed. For example, the proposed amendments enable the developer of a health application to access pseudonymised patient data without third-party control over whether the proposed activity is scientific research or non-scientific software development. While the controllers holding the health data have a responsibility to ensure there is a legal basis for enabling the data access, they often lack the resources and qualifications to assess whether the legal basis for scientific research is actually met. As a result, there is a risk of enabling access to health data under the guise of scientific research, where the actual activity is something else.

It must be stressed that the risk of carrying out activities other than scientific research under the guise of scientific research is significant, given the broad explanation of scientific research in the GDPR and its overlaps with development and innovation activities. The explanatory memorandum to the proposed amendments in Estonia further increases the risk, giving the impression that any kind of research, as well as AI activities, always falls under the GDPR's notion of scientific research.[249] Considering this, it is of utmost importance that the law requires independent control mechanisms to assess whether the proposed research projects constitute genuine scientific research.

In Estonia, there is also a risk that public sector entities rely on EDPA § 6 when the law has assigned them no tasks of conducting scientific research. The referred provision does not assign the conduct of scientific research as a task of public interest to any public bodies.[250] It states that '[...] scientific research is deemed to also include analyses and studies by executive power which are carried out for the purposes of policy development. In order to prepare these, the executive power has the right to make queries to databases of another controller or processor and process the personal data received [...]'.[251] This may give a false impression that, for the executive power, this provision alone is a sufficient legal basis for processing personal data for scientific research. According to Recital 41 GDPR, the legal basis adopted in the Member State's legislation should be clear and precise, and its application should be foreseeable to persons subject to it.[252]

---

[248] Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) (n 32).

[249] Explanatory Memorandum of the Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) 4 <https://eelnoud.valitsus.ee/main/mount/docList/1461fdb4-9e8b-4860-a015-92a741384a90> accessed 5 February 2026.

[250] EDPA, § 6.

[251] ibid, § 6(5).

[252] Furthermore, in a case in which a state authority processed an individual's health data, the European Court of Human Rights ruled that domestic law must be formulated with sufficient

In conducting scientific research, public bodies must rely on Article 6(1)(e) GDPR as a legal basis, meaning that the public bodies must ensure that the law has assigned them a task of public interest, which justifies the data processing. EDPA § 6 does not assign such tasks, but these tasks must be assigned by other specific laws, which must be relied on in conjunction with EDPA § 6.

4.3. The legal basis for development and innovation activities in the EHDS

In Publication II, the issues concerning the legal basis requirement in the Commission's proposal for the EHDS were examined. The analysis of the Commission's proposal and its comparison with the GDPR revealed that the proposal did not meet the GDPR's legal basis requirements. The reason is that the development and innovation activities that would have been possible under the Commission's proposal did not necessarily meet any of the legal bases set out in Article 9(2)(h-j) GDPR, including the legal basis for scientific research. As the final version of the EHDS underwent significant changes, the legal basis for scientific research and development and innovation activities in the EHDS warrants reconsideration.

The legal bases for the secondary use of data are explained in detail in Recital 52 EHDS. According to the recital, the EHDS provides a legal basis for the secondary use of personal electronic health data, including the safeguards required under Article 9(2), points (g) to (j), of the GDPR. Thus, the EHDS also functions as the Union law linked to Article 9(2)(j) GDPR, aiming to meet the requirements specified in that article. For example, it foresees safeguards such as a safe processing environment, anonymisation or pseudonymisation, and opt-out rights for data subjects.[253] Recital 52 EHDS distinguishes the legal bases relevant to data holders, health data access bodies (HDABs), and data users. In this thesis, the legal basis for data users is analysed.

The EHDS requires the applicant to provide a description of how the processing would comply with applicable Union and national law on data protection and privacy, in particular with Article 6(1) GDPR.[254] Mirroring this requirement, from the HDAB, it requires an assessment of whether the intended processing complies with Article 6(1) GDPR.[255] The burden the EHDS places on the HDABs in assessing the legal basis has been criticised in the legal literature.[256] At the same time, the obligation to demonstrate or assess compliance with the legal basis

precision and afford adequate legal protection against arbitrariness. The court stressed that the domestic law must indicate with sufficient clarity the scope of discretion conferred on the competent authorities and the manner of its exercise. See *L.H. v Latvia* App no 52019/07 (ECtHR, 29 April 2014), para 47.

253 EHDS, arts 66(2,3), 71, 73.

254 ibid, art 67(4).

255 ibid, art 68(1)(c).

256 Quinn (n 69) 69–72.

under Article 9(2) GDPR has not been stated in the EHDS. However, even if the EHDS does not require such an explanation from the data applicant, the health data processing cannot contravene the legal basis requirement under Article 9(2) GDPR. The aim of the EHDS has probably been to make the application procedure convenient for data applicants by assuming that the processing purposes and safeguards in the EHDS already comply with the requirements of the legal bases under Article 9(2) GDPR. However, as the EHDS does not remove the legal basis requirement under Article 9(2) GDPR, data users must still ensure compliance with it.

Similar to the GDPR, the EHDS does not define 'scientific research', but it explains it broadly in Recital 61 EHDS.[257] In its explanatory document, the Commission has clarified that the notion of 'scientific research' in the EHDS is identical to that in the GDPR.[258] A uniform interpretation of the GDPR and the EHDS is welcome to avoid further confusion about the notion. The examples of scientific research that the EHDS lists in the main body of the regulation include both development and innovation activities for products or services, as well as training, testing and evaluation of algorithms.[259] Thus, the processing purpose of scientific research under the EHDS clearly accommodates development and innovation activities, continuing to support the freedom of scientific research. However, it must be remembered that not every development or innovation activity, or the training, testing, and evaluation of algorithms, automatically constitutes scientific research. As argued in Publication II, for qualifying as scientific research, the characteristics developed in the Frascati Manual, as well as additional criteria developed by the EDPB and the EDPS, should be met. The EHDS could have been clearer in defining scientific research to avoid overextending the term. Considering that, as with the GDPR, the EHDS does not set specific criteria for scientific research, the risk of overextending the term persists, which poses a threat to privacy and data protection. To mitigate the risk, detailed practical guidelines on what constitutes scientific research in contemporary health data research are needed. These would be helpful for HDABs in shaping their practices.

While the EHDS does not change the notion of 'scientific research', it limits the processing purposes permitted under the EHDS data access mechanism compared to the GDPR's general requirements. Under the EHDS mechanism, scientific research must relate to the health or care sectors and aim to benefit end-users,

---

[257] Recital 61 EHDS: '[...] The notion of scientific research purposes should be interpreted in a broad manner, including technological development and demonstration, fundamental research, applied research and privately funded research. Activities related to scientific research include innovation activities such as training of AI algorithms that could be used in healthcare or the care of natural persons, as well as the evaluation and further development of existing algorithms and products for such purposes. It is necessary that the EHDS also contribute to fundamental research, and, although its benefits to end-users and patients might be less direct, such fundamental research is crucial for societal benefits in the longer term. [...]'

[258] Commission, 'Frequently Asked Questions on the European Health Data Space' (n 30) 31.

[259] EHDS, art 53(1)(e).

such as patients, health professionals, and health administrators. Additionally, it must contribute to public health or health technology assessments, or ensure high levels of quality and safety of healthcare, of medicinal products or of medical devices.[260] Thus, the EHDS, as a linking Union law to the legal basis under Article 9(2)(j) GDPR, limits the freedom of scientific research to the extent it concretises the allowed purposes of the scientific research. However, these limitations are not overly strict or impossible to meet in genuine scientific research, including development and innovation activities. To enhance clarity, guidance concerning these limitations should be developed. This overlaps with the recommendation given in Section 3.4 of the analytical compendium regarding the assessment of the public interest. Thus, the EHDS does not significantly limit the freedom of scientific research, while the concretisation of the permitted processing purposes is in the interests of data subjects for predictability, privacy, and data protection.

As stated earlier, the interpretation of the scope of scientific research is meaningless without procedures for assessing it. Under the EHDS data access mechanism, HDABs must assess whether the purposes described in the health data access application align with the permitted processing purposes.[261] Thus, HDABs should also assess whether the planned project is scientific research of the type allowed by the EHDS. Additionally, the HDABs are required to assess the qualifications of the applicants.[262] This requirement adds certainty that the research project can be conducted with adequate methods and quality. Considering that the EHDS foresees an assessment mechanism for identifying whether the data applicants aim to conduct genuine scientific research, it strikes a good balance between the freedom of scientific research and the rights to privacy and data protection. However, this is conditional on the quality and efficiency of the HDABs' procedures. To enable meaningful assessment of the applications, HDABs need highly qualified staff and financial resources. In Finland, Findata's experience shows that the workload of the data permit authority can be heavy.[263] In principle, this may also affect the quality of assessment of the scientific nature of the proposed research projects.

To explain the balance the EHDS sets through the legal basis requirement, the aspects of the linking legal basis under Article 6(1) GDPR need to be analysed as well. Under the EHDS data access mechanism, if the data user relies on legitimate interest as a linking legal basis under Article 6(1)(f) GDPR, no additional law is required. In this regard, the EHDS strongly supports the freedom of scientific research, enabling data applicants to directly benefit from the data access mechanism without the need to provide additional justification under national or other Union law.

---

[260] ibid, art 53(1)(e).

[261] ibid, art 68(1)(a).

[262] ibid, art 68(1)(d).

[263] Government Proposal HE 87/2025 vp (n 109), section 2.2.

In case the applicant relies on the legal basis of public interest foreseen in Article 6(1)(e) GDPR as a linking legal basis, the question arises whether the EHDS itself is sufficient for meeting the condition of Article 6(3) GDPR, requiring additional specific EU or national law to rely on this legal basis. The answer should be no, as the EHDS assigns no tasks of public interest to data users. In comparison, the EHDS assigns tasks in the public interest to HDABs.[264] The Commission's proposal for the EHDS included a sentence, '[i]f the user relies upon a legal basis offered by Article 6(1), point (e), it should make reference to another EU or national law, different from this Regulation, mandating the user to process personal health data for the compliance of its tasks.'[265] Confusingly, the sentence was removed from the final version of the EHDS. However, this should not mean that the reliance on the legal basis of Article 6(1)(e) GDPR will be possible without any additional law that assigns a task of public interest. Otherwise, anyone could choose to act on the legal basis of the public interest foreseen in Article 6(1)(e) GDPR, contradicting the requirement of Article 6(3) GDPR to reserve this legal basis for specific cases.[266] Despite the need to rely on additional law, the availability of the EHDS data access mechanism for scientific research as a public-interest task strongly favours the freedom of scientific research.

Taken together, the EHDS creates new opportunities for conducting scientific research, including development and innovation activities, strongly favouring the freedom of scientific research. Even though the EHDS limits the freedom of scientific research to the extent that it concretises the permitted purposes of scientific research, these limitations are not overly strict and, at the same time, contribute to foreseeability. The data permit procedure foreseen in the EHDS, which assesses compliance with the legal basis, can be seen as a burden on conducting scientific research, yet the external procedure is necessary to protect rights to privacy and data protection. Uncertainty persists about how the HDABs will interpret the notion of scientific research and the limitations on processing purposes under the EHDS, which is especially worrying from the perspective of data subjects. To tackle this issue, guidelines should be developed.

4.4. Conclusions on the legal basis requirement and limits of the notion 'scientific research' as a balancing tool in health data research

The requirement for a legal basis is important for limiting the processing of health data to the purposes and conditions set out in the legislation, both in the GDPR as a general framework and in additional national and Union laws. Health data, by

[264] EHDS, recital 52.

[265] Commission, 'Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space' COM (2022) 197 final (EHDS Proposal), recital 37.

[266] GDPR, recital 45.

their nature, are not tools for random experiments, and their use must be specifically justified at the legislative level. The legal basis requirement raises the chances that the processing is justified and in accordance with society's expectations. The concept of 'scientific research' in the legal basis and the requirement to contribute to the public interest may overlap if one assumes that scientific research, by its nature, always benefits the public interest. It must be ensured that the contribution to the public interest is evaluated at least once, either as part of the scientific nature of the project or separately. A separate evaluation of public interest is recommended, given that it should be assessed in the context of the risk-benefit ratio, as suggested in the previous section analysing the public interest requirement.

Because the GDPR does not establish criteria for scientific research, it does not provide a strong foundation for limiting the scope of scientific research as a justification for data processing. For that reason, Member States must foresee optimal requirements and mechanisms in their national laws to balance the freedom of scientific research with the rights to privacy and data protection. Based on the synthesis of the analysed data access mechanisms, the following is proposed for national data access mechanisms that rely on the GDPR.

1. The genuineness of the scientific research must be assessed in independent assessment procedures, such as ethics reviews or data permit procedures, with qualified staff and financial resources. No exceptions from this requirement should be allowed, even where the data is processed by state authorities or protected by technical safeguards.
2. For the interpretation of scientific research, the Frascati Manual and the criteria developed by the EDPB and the EDPS should be relied on. According to these, the scientific research must be 1) novel; 2) creative; 3) uncertain; 4) systematic; and 5) transferable and/or reproducible[267] and adhere to the methodological and ethics standards and contribute to the public interest.[268] However, serving private interests alongside does not exclude public interests.
3. Member States should encourage developing additional modern guidelines on the EU level to explain the boundaries of scientific research, considering the rapid development of technology and research methods.

While the EHDS foresees a data permit procedure by HDABs in which compliance with the legal basis for scientific research is assessed, the second and third suggestions are also relevant for shaping HDABs' national practices under the EHDS data access mechanism.

[267] OECD (n 77) 45.

[268] European Data Protection Board, 'Guidelines 05/2020 on Consent under Regulation 2016/679' (Version 1.1, Adopted on 4 May 2020)' (n 244) para 153; European Data Protection Supervisor (n 181) 11–12.

5. DATA SUBJECT'S OBJECTION AND OPT-OUT RIGHTS AS BALANCING TOOLS IN HEALTH DATA RESEARCH

5.1. The GDPR's right to object in the context of health data research

In this thesis, one aim was to critically analyse and evaluate how data subjects' objection and opt-out rights limit the processing of health data for scientific research purposes, and balance the freedom of scientific research with the rights to privacy and data protection. The input from the evaluation of the GDPR, Estonian and Finnish national laws, and the EHDS is used for designing the optimal approach to this balance.

The right to object is provided for under Article 21 GDPR. According to this, the data subject has a conditional right to object to the processing of their personal data for scientific research purposes. In Publication III, it was concluded that the right to object under the GDPR does not offer strong protection to data subjects' privacy and data protection rights in the context of scientific research. The reasons are that the right to object is conditional and leaves much room for interpretation. Furthermore, the right to object is subject to further limitations under Union or Member State law pursuant to Article 89(2) GDPR.

Therefore, the GDPR's right to object does not provide data subjects with confidence that their self-determination is respected in scientific research. Instead, it prioritises access to unbiased datasets and the freedom of scientific research over data subjects' autonomy.

5.2. The GDPR's right to object in the Estonian and Finnish national legislations in the context of health data research

The fact that the GDPR's right to object is, in practice, open to various interpretations and approaches is well illustrated by the legislation and practices of Estonia and Finland. In Publication III, it was explained that, in Estonia, data subjects' objections to the processing of health data for scientific research in the Health Information System are rejected.[269] This means that data subjects cannot hinder the processing of their health data available in the central national platform, which includes patient data from health care providers across the country. In contrast, in Finland, exercising the right to object is, in practice, unconditional in the Findata system.[270]

However, these approaches to the right to object are not fixed in the law and may change over time. To confirm the practice of the controller of the Estonian Health Information System, on 11 January 2026, the author of the thesis submitted an official objection under Article 21(1, 6) GDPR. In this request, the author

[269] E-Mail from TEHIK to the Author (9 February 2024).

[270] E-mail from Findata to the Author (21 February 2024).

objected to the processing of her health data held in the Health Information System for scientific research purposes in general. The objection was rejected. Acceptance on the basis of Article 21(6) GDPR (scientific-research-specific right to object) was denied because the processing of health data in the Health Information System, including for the purposes of making it available for scientific research, is a task in the public interest. The objection was also rejected under Article 21(1) GDPR (the general right to object). The reasoning was that the data researchers can access is pseudonymised, privacy-enhancing technologies are used, and access to the data is controlled, meaning it is provided only where there is an ethics committee approval and a legal basis. In the response, it was concluded that the public interest in research and the promotion of public health, combined with the privacy protection measures implemented, outweigh the objection.[271] This reasoning aligns with the previous explanations by the processor of the Health Information System, which were relied on in Publication III.[272]

The choice to deny objection rights in the Estonian Health Information System strongly favours the freedom of scientific research, ensuring the representativeness of the datasets across all research projects. At the same time, it significantly limits privacy and data protection rights. Even though pseudonymisation and technical safeguards reduce the risk of re-identification and data leakage, data subjects' autonomy and self-determination regarding their health data should extend beyond directly identifiable data. The risk of re-identification in scientific research contexts, where large datasets are processed, cannot be ruled out, especially given rapid technological advances.[273] The fear of re-identification or misuse of data, with no objection rights available, may cause unbearable anxiety or even lead to avoidance of seeking medical help.[274] This concerns, especially, for example, data such as psychotherapy notes, abortion records, sexual assault or rape examination details, information related to domestic violence or treatment for alcohol or drug dependence. Thus, applying technical safeguards that reduce re-identification risks alone does not justify eliminating data subjects' autonomy.

To some extent, the general ethics review requirement justifies limiting data subjects' right to object. This is so because, in ethics reviews, the balance between the fundamental rights of individuals and the benefits of the research project should already be weighed. This means that, on a general level, the representation of data subjects' interests is outsourced to ethics committees. However, while ethics

---

[271] Response from the Ministry of Social Affairs to the Author's request (13 February 2026).

[272] E-Mail from TEHIK to the Author (9 February 2024).

[273] The risk of re-identification in scientific research contexts has also been explained in Section 2.1 of the analytical compendium.

[274] The importance of preserving a patient's confidence in the medical profession and in health services in general has also been stressed by the European Court of Human Rights. The court has stressed that without such confidence, those in need of medical assistance may be deterred from seeking medical assistance, thereby endangering their own health and, in the case of transmissible diseases, that of the community. See *Z v Finland* App no 22009/93 (ECtHR, 25 February 1997), para 95; *I v Finland* App no 20511/03 (ECtHR, 17 July 2008), para 38.

committees can consider the interests of data subjects in general, they cannot consider individual situations. For example, patients at high re-identification risk, such as politicians or rare-disease patients, may have a justified reason to object to processing their specific sensitive health data, even where the ethics committee has approved the research project in general. Therefore, the ethical assessment of the research project in general does not justify the complete elimination of the right to object. Furthermore, not every research project requires overriding data subjects' objection rights, as the current approach is taken by the controller of the Estonian Health Information System. The need to override data subjects' objection rights should be assessed on a case-by-case basis for each research project, not assumed in every case involving data from the Health Information System.

The proposed amendments to the Estonian Data Protection Act suggest substantially reducing the ethics review requirements, as explained in Section 3.2 of this analytical compendium.[275] In light of this, it would be logical to enhance data subjects' objection rights concurrently to balance the interests of researchers and data subjects. Unfortunately, this has not been suggested in the proposed amendments. Instead, the current approach is retained, where the controller themselves have the discretion to decide whether the right to object should be limited.[276] This means, based on the example of the Estonian Health Information System, that for data subjects, the right to object is not necessarily available, as controllers themselves, without external assessment, may easily decide to limit it. The overall outcome, where there is no objection right and no independent assessment of the research project is required for the data access in the first place, would mean an extreme imbalance between the data subject's right to self-determination and the controller's interest in processing data for scientific research. As explained in Section 3.2, in some situations, there would be no pseudonymisation requirement either when the controller processes data from its own database.[277] This situation raises serious doubts about compromising the essence of fundamental rights to privacy and data protection.[278]

Regarding Finland, in Publication III, it was explained that, in practice, exercising the right to object is possible and unconditional in the Findata system.[279] Still, as explained in Publication III, the inconvenience of exercising the objection

---

[275] Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) (n 32).

[276] ibid, § 6(11).

[277] ibid, § 6(9). According to the proposed amendments, no ethics review, notification to the authority, or even pseudonymisation as a safeguard would be required when controllers process data from a single database they control.

[278] For comparison, see: Case C-362/14 *Maximillian Schrems v Data Protection Commissioner* [2015] ECLI:EU:C:2015:650, paras 92, 94. In the referred case, the CJEU ruled that the legislation permitting the public authorities to have access on a generalised basis to the content of electronic communications must be regarded as compromising the essence of the fundamental right to respect for private life, as guaranteed by Article 7 of the Charter.

[279] E-mail from Findata to the Author (21 February 2024).

right across several controllers, beyond Findata, limits the effectiveness of the right. From the perspective of researchers, in cases of extensive objections, there is a risk of data bias, that significantly limits the freedom of scientific research. In practice, the risk has not materialised on a large scale. In Findata, as of 2025, the number of objections was approximately 2000,[280] meaning approximately 0,035% of the population. The risk of extensive objections affecting the representativeness of the datasets is mitigated by an exception in the law that allows derogation from the right to object. However, this assumes that a data protection impact assessment considering the need for the specific deviation has been carried out and submitted to the Data Protection Ombudsman before processing commences.[281] The choice to generally accept data subjects' objections while enabling derogations for specific projects, subject to safeguards, appropriately balances the freedom of scientific research with the rights to privacy and data protection.

The explanatory memorandum on the amendments to the Secondary Use Act governing the Findata data access mechanism suggests that the practice of granting generous objection rights to data subjects will continue.[282] Additionally, the explanatory memorandum covers the point raised in Publication III, which suggests that data subjects should have the ability to exercise their right to object via a centralised procedure service.[283] As a positive development, the establishment of a national centralised service to exercise data subjects' rights will be examined in Finland.[284]

Taken together, the examples of Estonia and Finland show that the GDPR's right to object can be applied in radically different ways in practice, placing the freedom of scientific research and the data subject's rights to privacy and data protection in different directions. The regulation may vary across Member States, as the GDPR's right to object leaves room for interpretation.[285]

5.3. The EHDS' opt-out right in the context of health data research

The EHDS introduces an opt-out right for the secondary use of data, under which data subjects may opt out at any time without stating reasons.[286] After exercising the opt-out right, the health data relating to the data subject must not be processed pursuant to data permits or requests under the EHDS.[287] The necessity of the opt-out right has been explained in Recital 54 EHDS as a means of balancing the interests of health data users in accessing datasets with the autonomy of natural

[280] Government Proposal HE 87/2025 vp (n 109), section 4.2.7.4.

[281] FDPA, § 31.

[282] Government Proposal HE 87/2025 vp (n 109), section 4.2.3.

[283] ibid, section 6.1.

[284] ibid, section 6.2.

[285] For examples, see Olga Tzortzatou and others (n 92) 397–421, 409–412.

[286] EHDS, art 71.

[287] ibid, art 71(3).

persons over their personal electronic health data, which is considered particularly sensitive.

This opt-out right can be considered a safeguard under Article 89(1) of the GDPR. The absence of the need to explain one's particular situation, which often requires revealing even more sensitive data, is a welcome solution from the data subject's perspective. In the legal literature, the importance of the opt-out right has been recognised. Hartlev has concluded that while the GDPR's framework for data-based medical research assigns higher priority to public and scientific interests over the individual's autonomy, integrity, and interests in controlling personal data, the opt-out solution provided by the EHDS returns some control to the data subject, albeit with limitations.[288]

The opt-out right in the secondary use of data must not be confused with the opt-out right in the primary use of data. Namely, the EHDS also provides an opt-out right for the primary use of data, meaning that data subjects can prohibit their data from being processed for their treatment.[289] The Commission has explained that the right to opt out in primary use is separate from the right to opt out in secondary use. When a patient has opted out for primary use, that does not automatically mean they have opted out for secondary use, and vice versa.[290]

In Publication III, it was explained that the opt-out right introduced by the EHDS applies when the researchers choose to use the EHDS data access mechanism. As an alternative, Member States may maintain or establish parallel data access mechanisms relying on the GDPR and national laws.[291] In cases where researchers rely on these parallel mechanisms, the EHDS opt-out right does not apply, whereas the GDPR's right to object remains relevant.

Furthermore, under the EHDS mechanism, Member States may provide exceptions to the EHDS opt-out right in various ways, meaning that, in some cases, data subjects' opt-outs may not have effect even within the EHDS mechanism.[292] In Publication III, it was argued that there is a risk of excessive broadening of the exception from the opt-out right. In these cases, the right to object under the GDPR remains in place, but in practice may not, by virtue of Member States' choices, protect data subjects' autonomy.

Another case where the opt-out right is not effective is where access to data held in pseudonymised form is applied for. According to Article 71(8) EHDS,

> When the purposes of the processing of personal electronic health data by a health data holder do not or no longer require the identification of a data subject by the controller, that health data holder shall not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with the right to opt out under this Article.

---

288 Hartlev (n 12) 569.

289 EHDS, art 10.

290 Commission, 'Frequently Asked Questions on the European Health Data Space' (n 30) 13.

291 EHDS, arts 1(7), 1(8), recital 52.

292 ibid, art 71(4).

This may mean a wide backdoor for removing data subjects' opt-out rights. For example, in a situation where a research institution, as a data holder, holds a vast database of pseudonymised health data without the re-identification keys, data subjects cannot exercise any opt-out rights regarding this data. However, the Commission has explained that the HDABs may still make efforts to remove the data of persons who have exercised the opt-out by screening the data against additional attributes the opted-out person provided or other information available to the HDAB. However, the Commission has admitted that in some cases identifying the data subject and removing the data of the person is not possible.[293] To protect data subjects' autonomy, at least serious efforts must be made to screen the data to identify data subjects who have opted out. However, such a screening exercise itself poses additional privacy risks and requires specifically designed technical safeguards. From the researchers' perspective, if they want to avoid data bias caused by extensive opt-outs, they may apply for access to data held in a pseudonymised form, for which giving effect to the opt-outs exercised is unlikely.

In sum, while the EHDS shows a trend towards stronger protection of data subjects' autonomy and self-determination, thereby contributing to the rights to privacy and data protection, it also contains exceptions that may leave data subjects without effective rights. At the same time, the risk of extensive opt-outs in the EHDS mechanism persists, reducing the value of the available data. To mitigate these risks, Member States should establish, in their national laws, a uniform but narrow exception from the opt-out right for scientific research for important reasons of public interest, as enabled by the EHDS.[294]

5.4. Conclusions on the data subject's objection and opt-out rights as balancing tools in health data research

The analysis shows the importance of data subjects' right to object and opt out, thereby balancing the freedom of scientific research with the right to privacy and data protection. Without these rights, the data subject's will and situation are ignored. This strongly interferes with the rights to privacy and data protection, as patients have trusted their health data to health care providers under medical confidentiality for treatment purposes, which can now be used for other purposes against their will. Even though technical safeguards such as pseudonymisation reduce the risk of re-identification and misuse, the risks cannot be ruled out. While external procedures such as ethics reviews also reduce the risks of using the data against the data subjects' probable expectations, they can only consider the interests of data subjects as a group, not individual will or situations. Living in constant fear that highly sensitive health information could be exposed can cause individuals ongoing anxiety, avoidance of healthcare, and retraumatisation. This harm continues even if no breach actually happens.

---

[293] Commission, 'Frequently Asked Questions on the European Health Data Space' (n 30) 33.

[294] EHDS, art 71(4).

From the perspective of scientific research freedom, exercising the right to object and opt out poses a risk to the representativeness of datasets. This may hinder high-quality research, including cases where conducting the research is in the public interest. To avoid excessive objections and opt-outs from data subjects, data subjects' trust must be earned. This places the responsibility on the researchers to conduct only ethical research and communicate it to the public. However, sometimes the extensive objections and opt-outs may rely on irrational reasons, such as media scandals, even where the data processing has been lawful. To mitigate the risk of excessive objections and opt-outs that hinder scientific research in the public interest, it is essential to foresee exceptions that allow derogation from exercised objections and opt-outs. However, these exceptions must be subject to special safeguards, such as an ethical assessment that weighs the need to derogate from the data subject's objection and opt-out rights.

Even in such cases, where the derogation from the exercised objections and opt-outs is generally justified in the research project, a route must remain available for individuals to give effect to their objection when the particular situation requires it. However, in practice, ensuring such a route is complicated, as it requires efficient transparency towards data subjects and resources from the data controller to weigh each objection request against specific research projects.

Based on the synthesis of the analysed data access mechanisms, the following suggestions were proposed in Publication III for Member States to balance the freedom of scientific research and the rights to privacy and data protection through the approach to objection and opt-out rights. Considering the interactions between the GDPR's right to object and the EHDS' opt-out right, the suggestions address both simultaneously.

1. The data subjects' position to intervene in the health data processing in scientific research should be comparable in cases where the researchers have chosen to use the EHDS data access mechanism and where they have chosen to use other frameworks. This means that, as a general rule, the data subjects' objections/opt-outs must be accepted.
2. Inclusion of the data concerning data subjects who have objected/opted out should be possible in specific research projects, regarding which the need for such derogation has been assessed independently, for example, by an ethics committee or HDAB. In the EHDS data access mechanism, this means that Member States should foresee the exception from the EHDS' opt-out right for scientific research for important reasons of public interest as enabled by Article 71(4) EHDS.
3. Even in cases where the derogation from the exercised objections and opt-outs is generally justified in the research project, a route must remain available for individuals to give effect to their objection when the particular situation requires it.
4. Member States should provide one central source for getting all information and a channel (for example, a web portal) for exercising either the opt-out right in the meaning of the EHDS or the right to object in the sense of the GDPR.

6. EFFECT OF THE COMBINATION OF THE LEGAL LIMITATIONS

6.1. The interaction of the legal limitations under the GDPR, Estonian and Finnish national legislations, and the EHDS

The analysis in the thesis showed close connections between the objection and opt-out rights and the legal basis and public-interest requirements. The GDPR does not directly require scientific research to be in the public interest, while it encourages the national and Union law implementing the legal basis for scientific research to meet the objective of public interest. Furthermore, limiting the scientific-research-specific objection right under Article 21(6) GDPR suggests that in the case of scientific research, public interest can justify weaker individual rights.

In Estonia, the legislation does not require that processing pseudonymised data for scientific research be in the public interest.[295] However, in practice, the ethics review, which is currently generally mandatory in Estonia for processing health data for scientific research purposes,[296] has served as an external, independent control mechanism that assesses both the proposed research project's scientific nature and its contribution to the public interest, even if it is not explicitly required by the law. To some extent, this justifies the absence of data subjects' objection rights in the Estonian Health Information System. Even though the ethics review cannot assess each data subject's individual situation, it balances the overall risk-to-benefit ratio of the research projects. However, the choice to automatically override the data subjects' objection rights without assessing the need for it does not meet the principle of data minimisation foreseen in Article 5(1)(c) GDPR.[297] Thus, the balance currently favours the freedom of scientific research over the rights to privacy and data protection.

At the time of finalising the thesis, amendments have been proposed to the Estonian legislation that, on some occasions, remove ethics review as an independent control mechanism and the pseudonymisation requirement as a technical safeguard, with no data subject objection rights ensured, thereby tilting the balance to the extreme detriment of data subjects.[298] Even where the technical safeguards are in place or enhanced, they do not justify the absence of objection rights and

[295] EDPA, § 6.

[296] ibid, § 6(4).

[297] According to the data minimisation principle, personal data shall be limited to what is necessary in relation to the purposes for which they are processed. Processing data which is not necessary for the purpose, especially in a situation where the data subject has objected to it, is not justified.

[298] Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) (n 32), § 6(9).

the independent control mechanism over data use, as argued in Sections 3.2, 4.2 and 5.2 of the analytical compendium. A solution that removes an independent control mechanism over the data use, as well as data subjects' objection rights and only retains technical safeguards, means that in practice, health data may be easily used for any purpose outside the legal bases of the GDPR, with no option for data subjects to intervene in such processing. Even though technical safeguards reduce the risk of re-identifying individual data subjects, the risk of re-identification in a scientific research context, where large datasets are processed, can never be entirely ruled out. As explained before, living in fear that highly sensitive health information could be re-identified and exposed can cause individuals ongoing anxiety, avoidance of healthcare, and re-traumatisation. Furthermore, the research results may lead to group discrimination affecting the individuals whose health data were processed. Therefore, the approach to rely only on technical safeguards leads to a strong imbalance between the freedom of scientific research and the rights to privacy and data protection.

In Finland, the legislation does not require that processing health data for scientific research must contribute to the public interest, unless the processing relies on the legal basis of public interest.[299] However, in practice, the scientific nature and, to some extent, the contribution to the public interest, as they overlap, are assessed in the Findata data access procedure, as argued in Publication I. This does not exclude data subjects' right to object. To the contrary, the data subjects' objections are possible and can be exercised generally unconditionally in practice in Findata mechanism. To mitigate the risk of extensive objections affecting the representativity of datasets, the objections can be overridden in some cases, subject to an impact assessment.[300]

In the EHDS data access mechanism, both the scientific nature of the research project and its contribution to the public interest are assessed by national health data access bodies (HDABs) during data permit procedures.[301] In addition, the EHDS enables Member States to foresee ethics review assessment, which also contributes to the assessment of public interest.[302] While in the EHDS, the data permit procedure is present as an independent pre-assessment of the proposed research projects, and ethics review may be added as an additional layer of protection, this does not exclude data subjects' intervention rights. On the contrary, data subjects are generally offered unconditional opt-out rights, which is a significant step towards protecting their autonomy. To mitigate the risk that extensive opt-outs hinder scientific research for important reasons of public interest, the EHDS enables exceptions to the opt-out right that Member States must foresee.[303] These exceptions must be well-balanced by the Member States, to avoid extensive

[299] FDPA, § 4(3), § 6(7).

[300] ibid, § 31.

[301] EHDS, art 68(1)(a).

[302] ibid, arts 55(2), 67(2)(j).

[303] ibid, art 71(4).

overriding of data subjects' rights, but still retaining access to representative datasets where justified. The EHDS has the potential to appropriately balance the freedom of scientific research with the rights to privacy and data protection, but much depends on the Member States' choices and practices.

Regarding all data access mechanisms, those subject to national laws, as well as the EHDS, the public interest and legal basis requirements likely affect the extent to which the right to object and the right to opt-out are exercised in practice. The confidence that health data is processed only on a lawful basis and in the public interest may reduce the number of objections and opt-outs. The appropriate procedures, such as ethics review or data permit procedures, in which the research plan is assessed, increase the likelihood that data subjects find their data processing justified and choose not to object or opt out. In contrast, when processing is enabled without a clear legal basis or without an assessment of its contribution to public interests, data subjects are more likely to object and opt out. In that case, the data subjects can only see risks to their privacy, with no meaningful contribution to society's well-being. This encourages objections and opt-outs. However, other variables, such as the security level of data processing and communication strategies, play a crucial role for data subjects in deciding whether to object and opt out. Sometimes, the well-defined legal bases or public-interest requirements in the law, together with the assessment procedures, are not enough to avoid extensive objections or opt-outs, as people may also be guided by irrational fears.

6.2. Model for balancing the freedom of scientific research with the rights to privacy and data protection through the public interest and legal basis requirements, and the data subject's objection and opt-out rights

To protect the rights to privacy and data protection, the assessment of the genuineness of scientific research, as well as of public interest, needs to be in place, along with a general right for data subjects to prohibit the processing of their data. The concept of 'scientific research' in the legal basis and the requirement to contribute to the public interest may overlap if one takes the position that scientific research, by its nature, always needs to contribute to the public interest. A separate evaluation of public interest is recommended, given that it should be assessed in the context of the risk-benefit ratio. To protect access to representative datasets and the freedom of scientific research, overriding data subjects' rights to prohibit the processing of their data must be permissible when justified for specific research projects. However, this should require an independent assessment of whether there is an actual need for such a derogation and if weighing the risks and benefits of the research justifies such overriding. Even if there is a general need and justification to derogate from the right, the data subject's particular situation may still require additional weighing of the rights and justify excluding the specific data subject's data from the research project.

Both levels, the independent pre-assessment of the proposed research project by the ethics committee or data permit authority, as well as the data subject's individual intervention rights, must be present to protect the rights to privacy and data protection. Not all data subjects are aware of their data protection rights or able to exercise them. In such cases, the independent pre-assessment of the research project must provide satisfactory confidence that the research project generally meets the data subjects' expectations. Thus, the result would be satisfactory even where the data subjects remain passive. At the same time, the removal of the data subjects' rights would not be justified. Not all research projects require access to the data regarding which the data subjects have exercised their objections. The need to override the objections must be assessed in each research project and confirmed by the independent pre-assessment. Even in these cases, a route must remain available to weigh the data subject's objections on a case-by-case basis.

Considering the previous, in the following, a model is proposed to optimally balance the freedom of scientific research with the rights to privacy and data protection. This model is based on the legal limitations analysed in this thesis and the synthesis of the data access mechanisms examined.

1. Before granting access to the health data, the scientific nature of the research project, as well as the contribution to the public interest, must be assessed in an independent assessment procedure. No exceptions from this requirement should be allowed, even where the data is processed by state authorities or protected by technical safeguards. In the context of the EHDS data access mechanism, this means the HDAB's data permit procedure. In the context of national data access mechanisms, this may mean either ethics reviews or data permit procedures.

2. For verifying that the proposed project falls within the legal basis of scientific research and is of a scientific nature, the Frascati Manual and the criteria developed by the EDPB and the EDPS should be relied on. According to these, the scientific research must be 1) novel; 2) creative; 3) uncertain; 4) systematic; and 5) transferable and/or reproducible[304] and adhere to the methodological and ethics standards and contribute to the public interest.[305] However, serving private interests alongside does not exclude public interests. Additional modern EU-level guidelines to clarify the boundaries of scientific research, given the rapid development of technology and research methods, including AI, are needed.

3. Guidelines on what constitutes public interest in the context of scientific research, together with practical examples, must be developed. For national data access mechanisms, these may take into account the cultural values of the

[304] OECD (n 77) 45.

[305] European Data Protection Board, 'Guidelines 05/2020 on Consent under Regulation 2016/679' (Version 1.1, Adopted on 4 May 2020)' (n 244) para 153; European Data Protection Supervisor (n 181) 11–12.

Member State and be developed in cooperation with ethics committees and representatives of researchers and data subjects. Guidelines on which research projects contribute to the general interest of society and are allowed under the EHDS must be developed uniformly across the EU. To maintain the protection of ethical values not covered by the EHDS, Member States should establish a national ethics review requirement, as enabled by the EHDS.[306]

4. In assessing the public interest, the risk-benefit ratio must be considered. The higher the research project's value to society, the more justified the risks to privacy and data protection are. Projects with no or very low societal value do not justify taking risks to privacy and data protection.
5. In national data access mechanisms, the requirement to publish the research results, with a reasonable embargo period to preserve legitimate competitive interests, should be set.[307]
6. As a general rule, the data subjects' objections and opt-outs must be accepted under both national data access mechanisms and the EHDS data access mechanism. Overriding these rights should be possible in specific research projects, where the need for such derogation has been assessed independently, weighing also the risks and benefits of such overriding. In the EHDS data access mechanism, this means that Member States should foresee the exception from the EHDS opt-out right for scientific research for important reasons of public interest, as enabled by Article 71(4) EHDS. Even in cases where derogation from exercised objections and opt-outs is generally justified, a route must remain available for individuals to give effect to their objections when the particular situation requires it.
7. Member States should establish a central channel (e.g., via a web portal) for information and the exercise of the opt-out right as defined in the EHDS, as well as the right to object foreseen in the GDPR.

[306] EHDS, art 55(2).

[307] In the EHDS data access mechanism, the requirement is already present (Article 61(4) EHDS). Under the EHDS data access mechanism, the requirement to make the research results public should be applied strictly by the HDABs, requiring the publishing of the results in detail.

7. CONCLUSIONS

7.1. The Member States' role in balancing the rights

The research problem addressed in the thesis was the need to find an optimal balance between the freedom of scientific research and the rights to privacy and data protection in health data research conducted without the data subject's consent. This balance is not established in the GDPR, as it leaves a wide margin of discretion to Member States. This concerns, above all, setting the threshold of the public interest as a justification for data access and determining the extent of data-subject intervention rights. In practice, the notion of 'scientific research', a central part of the legal basis for processing, also needs to be determined by Member States.

The EHDS, as a new instrument establishing a common data access mechanism in the EU, sets more specific rules. Still, it enables Member States to shape the public interest standard by foreseeing the ethics review requirement under national law,[308] and, in practice, leaves the interpretation of 'scientific research' to national health data access bodies (HDABs).[309] Additionally, the EHDS enables Member States to foresee exceptions to the otherwise unconditional opt-out right, which significantly shape data subjects' autonomy.[310]

Given this background, this doctoral thesis aimed to critically analyse and evaluate how the public interest requirement, the notion of 'scientific research' in the legal basis, as well as data subjects' objection and opt-out rights, limit the processing of health data for scientific research purposes and balance the freedom of scientific research with the rights to privacy and data protection. As the main original contribution, the thesis proposed a model that balances these fundamental rights through the public interest requirement and the notion of 'scientific research' in the legal basis, as well as data subjects' objection and opt-out rights. This model was proposed based on the assessments of the national data access mechanisms in Estonia[311] and Finland[312], as well as the EU data access mechanism established by the EHDS. The following paragraphs first summarise the assessments of the data access mechanisms before proceeding to the proposed model.

7.2. Evaluation of the public interest requirement

Regarding the public interest requirement, the thesis demonstrated that, as the GDPR does not specify the public interest standard, Member States are responsible for establishing it themselves within their national data access mechanisms.

[308] EHDS, arts 55(2), 67(2)(j), recital 69.

[309] ibid, art 68(1)(a).

[310] ibid, art 71(4).

[311] EDPA, § 6.

[312] The Secondary Use Act.

Considering that reliance on the legal basis of scientific research enables processing health data without data subjects' consent and with significant limitations on data subjects' rights, such processing must be justified by its contribution to the public interest.[313] To ensure the public interest standard is met, establishing procedures for the independent assessment of the public interest is of utmost importance. The Estonian example demonstrated that ethics review can serve this purpose, whereas Finland's example showed that data permit procedures can be employed.[314] While in ethics reviews it is common to assess what could be understood as the public interest in the context of scientific research, the assessment criteria for data-permit procedures must be specified in regulations or established case law.

Although data access procedures can ensure the assessment of public interest even without an explicit legal requirement, there is no reason to exclude the public interest requirement from legislation. The requirement to assess the contribution to the public interest could help ethics committees or data permit authorities shape their practice and avoid criticism for setting higher standards than referred to by the law. However, as it is not possible to include every possible situation and detail in the law, practical guidelines are needed.

Concerning the EHDS data access mechanism, which is likely to become dominant, the thesis revealed that the EHDS sets the public interest standard by requiring that the research must aim to benefit end-users and either contribute to public health or health technology assessments, or ensure high levels of quality and safety of healthcare, of medicinal products or of medical devices.[315] The data permit procedure, in which the processing purposes are assessed,[316] functions as a public-interest evaluation. Given the broad formulation of the EHDS requirements, detailed EU-level practical guidance is needed. Furthermore, the EHDS may not ensure the public interest standard that reflects national ethical expectations. In these cases, Member States should consider requiring ethics review, as enabled by the EHDS.[317] Given that, as a general rule, Member States may not impose stricter rules than those laid down in the EHDS itself,[318] the question remains as to how much national ethical review requirements may restrict access to data.

The analysis of the EHDS also drew attention to the benefits of the requirement to make the research outcomes public.[319] Detailed disclosure of research results can accelerate further research and thus serve public interest. However, before the results are made public, a reasonable embargo period must be enabled to preserve competitive interests. Regarding the EHDS' requirement to inform

---

[313] GDPR, arts 5(1)(e), 14(5)(b), 17(3)(d), 89(2); see also the discussion on the topic by Slokenberga (n 61) 22.

[314] For more detailed analysis, see Publication I.

[315] EHDS, art 53(1)(e).

[316] ibid, art 68(1)(a).

[317] ibid, art 55(2).

[318] ibid, recital 52.

[319] ibid, art 61(4).

natural persons of significant findings concerning their health,[320] the thesis concluded that implementing this requirement effectively, in a way that benefits the public interest, is challenging. For this reason, the requirement was not considered a suitable example for national data access mechanisms.

7.3. Evaluation of the notion of 'scientific research' in the legal basis

Regarding the legal basis and the notion of 'scientific research' in the GDPR, it was found that the GDPR inadequately protects privacy and data protection rights, risking overly broad interpretation of scientific research. The risk of an unduly narrow interpretation is lower, as Recital 159 GDPR explains it broadly, including technological development and demonstration. The Commission has clarified that the notion of 'scientific research' in the EHDS and the GDPR is identical,[321] which is a welcome choice for a uniform approach. However, the EHDS does not define scientific research either. The examples of scientific research listed in the EHDS's main body of the regulation include both product and service development and innovation activities, as well as the training, testing, and evaluation of algorithms.[322] This broad approach continues to support the freedom of scientific research.

In Estonia and Finland, conducting development and innovation activities under the legal basis of the scientific research exemption has been possible in practice. While there was no indication of an overly broad interpretation of the concept of scientific research, the conclusions that can be drawn in this thesis are limited due to reliance on regulations and communication, while no data applications or decisions were analysed, which exceeds the scope of this thesis.[323] Nevertheless, standard criteria for defining what qualifies as scientific research would improve the predictability of data processing for both data subjects and researchers. This is especially relevant given the borderline cases in which health data is used for development and innovation activities or policy planning. For that reason, the thesis suggested relying on the criteria developed by the Frascati Manual[324] and those of the EDPB and the EDPS.[325] Furthermore, updated guidance

---

[320] ibid, art 58(3).

[321] Commission, 'Frequently Asked Questions on the European Health Data Space' (n 30) 31.

[322] EHDS, art 53(1)(e).

[323] E-mail from the Research Ethics Committee of the National Institute for Health Development to the Author (4 January 2023), e-mails from Findata to the Author (24 May 2023, 9 February 2026). For more detailed analysis, see Publication II.

[324] OECD (n 77) 45.

[325] European Data Protection Board, 'Guidelines 05/2020 on Consent under Regulation 2016/679' (Version 1.1, Adopted on 4 May 2020)' (n 244) para 153; European Data Protection Supervisor (n 181) 11–12.

on how 'scientific research' applies in contemporary health data projects, including those using AI-based analysis, would be welcome.

Similarly to the public interest requirement, setting the boundaries to the notion of 'scientific research' can only protect privacy and data protection rights where independent assessment procedures are in place. In Estonia, ethics committees, and in Finland, the data permit authority assess whether the proposed project is of a scientific nature. The existence of such independent assessment procedures, together with an appropriate interpretation of 'scientific research', appropriately balances the freedom of scientific research with the rights to privacy and data protection. The removal of such procedures would have far-reaching negative effects on data subjects' privacy and data protection rights. The proposed amendments to Estonian legislation, which would eliminate the ethics review requirement in many cases,[326] could enable arbitrary uses of health data, with neither scientific merit nor public interest reliably evaluated.

By now, the ethics review requirement in Estonia has functioned as an independent assessment mechanism to ensure that proposed research projects qualify as genuine scientific research and serve the public interest. This aligns with the approach taken by the EHDS and Finnish Findata data access mechanisms, which also involve independent assessments through data permit procedures. Based on the comparison, the removal of the independent review requirement, in some instances replaced by stronger technical safeguards, as proposed in the amendments to the Estonian legislation,[327] does not align with contemporary trends in digital health data processing in the EU.[328] In the EHDS and Findata data access mechanisms, independent assessment procedures are in place, despite the researcher being able to access the data only in pseudonymised or anonymous form in a secure processing environment.[329] Thus, even technical safeguards do not justify the removal of independent assessment procedures.

7.4. Evaluation of the rights to object and opt out

The analysis further demonstrated the importance of data subjects' rights to object and opt out, as well as the need to override these rights in specific cases. Given that the GDPR does not foresee an opt-out right or a strong objection right for data subjects, it does not strike an appropriate balance. The fact that the GDPR's right

---

[326] Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) (n 32).

[327] ibid.

[328] The comparison with Finland is limited, as it considers the Secondary Use Act only. For specific state authorities, routes for accessing health data for research purposes that do not require Findata data permits exist. For example, the Finnish Institute for Health and Welfare can access health data from public-sector databases under its own special legislation, the analysis of which exceeds the scope of this thesis. See: Act on the National Institute for Health and Welfare (*Laki Terveyden ja hyvinvoinnin laitoksesta*) 668/2008, § 2, § 5.

[329] EHDS, arts 66, 68, 73; The Secondary Use Act, § 14, § 20, § 38.

to object is weak and, in practice, open to various interpretations is well illustrated by the legislation and practices of Estonia and Finland. In Estonia, objections from data subjects to the processing of health data for scientific research within the central national patient data platform, the Estonian Health Information System, are rejected.[330] In contrast, in Finland, exercising the right to object is, in practice, unconditional in the Findata mechanism.[331] Still, the inconvenience of exercising the objection right across several controllers, beyond Findata, limits the effectiveness of the right. In Finland, the risk of extensive objections affecting the representativeness of the datasets is mitigated by an exception in the law that allows derogation from the right to object.[332] The choice to generally accept data subjects' objections while enabling derogations for specific projects, subject to safeguards, appropriately balances the freedom of scientific research with the rights to privacy and data protection.

The EHDS introduces an opt-out right for the secondary use of data, under which data subjects may opt out at any time without stating reasons.[333] Although the right is generally unconditional, exceptions are allowed.[334] In Publication III, it was argued that there is a risk of excessive broadening of the exceptions from the opt-out right. In these cases, the GDPR's right to object remains, but, in practice, it may not effectively protect data subjects' autonomy depending on the Member State's choices. Thus, while the EHDS shows a trend towards stronger protection of data subjects' autonomy, it also conceals exceptions which may leave data subjects without efficient rights. At the same time, the risk of extensive opt-outs in the EHDS mechanism persists, reducing the value of the available data. To mitigate these risks, Member States should establish, in their national laws, a uniform but narrow exception to the opt-out right for scientific research in important public interest cases, as enabled by the EHDS.[335] The complexity of the interactions between the right to object and the right to opt out also revealed the necessity of a central channel where data subjects can exercise both rights.

A comparison of the data access mechanisms shows that Estonia's approach to the right to object does not align with contemporary EU trends in digital health data processing. While in the EHDS and Findata data access mechanisms, generally unconditional opt-out or objection rights are available, in Estonia, based on the example of the Estonian Health Information System, the approach is the opposite. In the proposed amendments to Estonian legislation, there are no signs of changing it. This is despite the fact that the ethics review requirements, which were used to justify the absence of the right to object in the Health Information

330 E-Mail from TEHIK to the Author (9 February 2024).

331 E-mail from Findata to the Author (21 February 2024).

332 FDPA, § 31.

333 EHDS, art 71.

334 ibid, arts 1(7), 1(8), 71(4).

335 ibid, art 71(4).

System, are proposed to be limited.[336] The misalignment of Estonia's approach is even more obvious when the absence of the right to object is combined with the absence of an independent assessment procedure preceding data access, as well as the absence of the requirement to pseudonymise the data, as would be possible in some instances under the proposed amendments to Estonian legislation.[337]

7.5. Model for balancing the rights

On the basis of these findings about the national data access mechanisms of Estonia and Finland, as well as the EU one established by the EHDS, the thesis proposed the following model that balances the freedom of scientific research with the rights to privacy and data protection through the public interest requirement, the notion of 'scientific research' in the legal basis, as well as data subjects' objection and opt-out rights.

1. Before granting access to the health data, the scientific nature of the research project, as well as the contribution to the public interest, must be assessed in an independent assessment procedure. No exceptions from this requirement should be allowed, even where the data is processed by state authorities or protected by technical safeguards. In the context of the EHDS data access mechanism, this means the HDAB's data permit procedure. In the context of national data access mechanisms, this may mean either ethics reviews or data permit procedures.
2. For verifying that the proposed project falls within the legal basis of scientific research and is of a scientific nature, the Frascati Manual and the criteria developed by the EDPB and the EDPS should be relied on. According to these, the scientific research must be 1) novel; 2) creative; 3) uncertain; 4) systematic; and 5) transferable and/or reproducible[338] and adhere to the methodological and ethics standards and contribute to the public interest.[339] However, serving private interests alongside does not exclude public interests. Additional modern EU-level guidelines to clarify the boundaries of scientific research, given the rapid development of technology and research methods, including AI, are needed.

---

[336] Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) (n 32).

[337] No ethics review, notification of the data protection authority or pseudonymisation would be required when controllers process data of a single dataset they control. See: Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) (n 32), § 6(9).

[338] OECD (n 77) 45.

[339] European Data Protection Board, 'Guidelines 05/2020 on Consent under Regulation 2016/679' (Version 1.1, Adopted on 4 May 2020)' (n 244) para 153; European Data Protection Supervisor (n 181) 11–12.

3. Guidelines on what constitutes public interest in the context of scientific research, together with practical examples, must be developed. For national data access mechanisms, these may take into account the cultural values of the Member State and be developed in cooperation with ethics committees and representatives of researchers and data subjects. Guidelines on which research projects contribute to the general interest of society and are allowed under the EHDS must be developed uniformly across the EU. To maintain the protection of ethical values not covered by the EHDS, Member States should establish a national ethics review requirement, as enabled by the EHDS.[340]
4. In assessing the public interest, the risk-benefit ratio must be considered. The higher the research project's value to society, the more justified the risks to privacy and data protection are. Projects with no or very low societal value do not justify taking risks to privacy and data protection.
5. In national data access mechanisms, the requirement to publish the research results, with a reasonable embargo period to preserve legitimate competitive interests, should be set.[341]
6. As a general rule, the data subjects' objections and opt-outs must be accepted under both national data access mechanisms and the EHDS data access mechanism. Overriding these rights should be possible in specific research projects, where the need for such derogation has been assessed independently, weighing also the risks and benefits of such overriding. In the EHDS data access mechanism, this means that Member States should foresee the exception from the EHDS opt-out right for scientific research for important reasons of public interest, as enabled by Article 71(4) EHDS. Even in cases where derogation from exercised objections and opt-outs is generally justified, a route must remain available for individuals to give effect to their objections when the particular situation requires it.
7. Member States should establish a central channel (e.g., via a web portal) for information and the exercise of the opt-out right as defined in the EHDS, as well as the right to object foreseen in the GDPR.

7.6. Future outlook

While the primary aim of comparing the three data access mechanisms was to inform the design of the optimal model, the comparison also provides insight into expected future changes. Compared to the current Estonian and Finnish national data access mechanisms, in the EHDS data access mechanism, no major changes

[340] EHDS, art 55(2).

[341] In the EHDS data access mechanism, the requirement is already present (Article 61(4) EHDS). Under the EHDS data access mechanism, the requirement to make the research results public should be applied strictly by the HDABs, requiring the publishing of the results in detail.

are expected in the assessment of public interest or in the interpretation of what constitutes scientific research.[342] However, compared to the Estonian national regulation, a major change is expected regarding the generally unconditional opt-out right under the EHDS mechanism, marking a shift towards protecting data subjects' autonomy and self-determination. However, as warned in Publication III, there is a risk that Member States, including Estonia, may foresee broad exceptions to the opt-out right in the EHDS data access mechanism. Still, the overall trend indicated by the EHDS is toward greater protection of the data subject's autonomy.

The comparison between the Estonian and Finnish national mechanisms also allows us to assess the similarity of the rules relevant for cross-border research. Based on the findings of this thesis, there is no reason to believe that the public interest requirement or the interpretation of the scope of scientific research in the legal basis hinders cross-border research involving these two Member States. Rather, the fact that in both Estonia and Finland it is possible to conduct development and innovation activities under the legal basis for scientific research refers to similar interpretations.[343] Even though the approaches to the right to object differ radically between the Estonian Health Information System and Findata's practices, this does not necessarily hinder cross-border research. In Findata mechanism, as of 2025, the number of objections was approximately 2000,[344] meaning 0,035% of the population, which does not necessarily compromise dataset representativeness or comparability. Furthermore, access to complete datasets in Finland is possible under an exception, where required.[345] Thus, the legal limitations analysed in this thesis do not hinder the cross-border research. However, other aspects, such as Finland's legislation requiring the use of specific secure processing environments, may still limit cross-border research. To improve cross-border collaboration, amendments that increase flexibility have been adopted regarding this requirement.[346]

In the years ahead, researchers and data subjects need to operate in a rapidly evolving legal environment. In future research, the question of when pseudonymised health data constitutes personal data in scientific research warrants further analysis, considering the CJEU's case law and proposed changes to the

[342] While the Estonian and Finnish legislations do not explicitly require scientific research to contribute to the public interest in all cases, at least some aspects of it are assessed in data access procedures, as explained in more detail in Publication I. While the EHDS sets criteria for scientific research which can be seen as requirements to contribute to the public interest, the criteria are not overly strict, as explained in Section 3.3.1 of the analytical compendium.

[343] For more detailed analysis, see Publication II.

[344] Government Proposal HE 87/2025 vp (n 109), section 4.2.7.4.

[345] FDPA, § 31.

[346] Government Proposal HE 87/2025 vp (n 109), para 7.1, section 51c; Act amending the Act on the Secondary Use of Social and Health Information (*Laki sosiaali- ja terveystietojen toissijaisesta käytöstä annetun lain muuttamisesta*) 1159/2025, § 51c.

definition of personal data in the GDPR.[347] Furthermore, the Commission has proposed defining scientific research in the GDPR, which may further reshape the legal framework.[348] In Finland, amendments to the Secondary Use Act will generally take effect on 1 May 2026.[349] In Estonia, extensive amendments have been proposed for the data-protection-related aspects of scientific research.[350] These amendments do not yet concern the implementation of the EHDS, indicating that further substantial amendments are expected.

Relevant to all data mechanisms now and in the future, the findings of this thesis show that the freedom of scientific research and the rights to privacy and data protection can be balanced appropriately through the combined approach developed herein. The proposed model provides Member States with a practical framework for refining their national data-access mechanisms and for implementing the EHDS within the margins of discretion it permits. By combining independent assessment procedures, clearer criteria for interpreting the notion of scientific research, practical guidance on the public-interest requirement, and meaningful but proportionate intervention rights for data subjects, the model resolves gaps left open by the GDPR and the EHDS.

[347] Case C-413/23 P *EDPS v SRB* (CJEU 4 September 2025); Commission, 'Digital Omnibus' (n 112), art 3(1)(a). See the discussion covering the CJEU case-law more broadly by Line Lundström and Santa Slokenberga, 'Evolution of Personal Data in the Court of Justice's Case Law and Implications for Scientific Research' (2026) 9 Nordic Journal of European Law 25 <https://doi.org/10.36969/njel.v9i1.28394>.

[348] Commission, 'Digital Omnibus' (n 112), art 3(1)(b).

[349] Act amending the Act on the Secondary Use of Social and Health Data *(Laki sosiaali- ja terveystietojen toissijaisesta käytöstä annetun lain muuttamisesta)* 1159/2025, § 60.

[350] Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) (n 32).

REFERENCES

Literature and publications

1. Afra M, 'An Assessment on Innovator's Ability for Consent-Free Health Data Reuse, In the Context of the GDPR and EHDS: The Netherlands Case Study' (2024) 31 European Journal of Health Law 475.
2. Åm H and others, 'The Politics of Constructing Health Data Spaces: Border Work and the Stickiness of Fragmentation' (2025) 12 Big Data & Society 20539517251320012.
3. Becker R and others, 'Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers?' (2022) 30 European Journal of Health Law 129.
4. Becker R, Chokoshvili D and Dove ES, 'Legal Bases for Effective Secondary Use of Health and Genetic Data in the EU: Time for New Legislative Solutions to Better Harmonize Data for Cross-Border Sharing?' (2024) 14 International Data Privacy Law 223.
5. Bentzen HB, 'In the name of Scientific Advancement. How to Assess What Constitutes "Scientific Research" in the GDPR to Protect Data Subjects and Democracy' in Terzis G and others (eds), *Disinformation and Digital Media as a Challenge for Democracy* (Intersentia 2020).
6. Brück O and others, 'European Health Regulations Reduce Registry-Based Research' (2024) 22 Health Research Policy and Systems 135.
7. Carmichael L, Cradock E and Stalla-Bourdillon S, 'Right to Object and Automated Individual Decision-Making' in Spiecker gen. Döhmann I and others (eds), *General Data Protection Regulation Article-by-Article Commentary* (Bloomsbury Publishing 2023).
8. Cascini F, *Secondary Use of Electronic Health Data: Public Health Perspectives, Use Cases and Challenges* (Springer Cham 2025).
9. Cervera de la Cruz P and Shabani M, 'Fair Enough?: Exploring the Role of Fairness in Secondary Uses of Health Data in the European Health Data Space' in Slokenberga S, Ó Cathaoir K and Shabani M (eds), *The European Health Data Space* (Routledge 2025).
10. Denga M and Hoffmann T, 'The Estonian Electronic Health Record – a Prototype for Data Governance in the European Health Data Space?' (2023) 7 European Health & Pharmaceutical Law Review 5.
11. Doetsch JN and others, 'Record Linkage of Population-Based Cohort Data from Minors with National Register Data: A Scoping Review and Comparative Legal Analysis of Four European Countries' (2021) 1 Open Research Europe.
12. Donnelly M and McDonagh M, 'Health Research, Consent and the GDPR Exemption' (2019) 26 European Journal of Health Law 97.
13. Dove ES, 'The EU General Data Protection Regulation: Implications for International Scientific Research in the Digital Era' (2018) 46 Journal of Law, Medicine & Ethics 1013.
14. Dove ES (ed), *Confidentiality, Privacy, and Data Protection in Biomedicine: International Concepts and Issues* (Routledge 2025).
15. Ducato R, 'Data Protection, Scientific Research, and the Role of Information' (2020) 37 Computer Law & Security Review 105412.

16. Santamaria Echeverría E, 'The European Health Data Space: A New Paradigm for Secondary Uses of Health Data for Scientific Research?' in Slokenberga S, Ó Cathaoir K and Shabani M (eds), *The European Health Data Space* (Routledge 2025).
17. Edgcumbe A and others, '"Potato Potahto"? Disentangling de-Identification, Anonymisation, and Pseudonymisation for Health Research in Africa' (2025) 12 Journal of Law and the Biosciences lsae029.
18. Fåhraeus D, Reichel J and Slokenberga S, 'The European Health Data Space: Challenges and Opportunities' (2024) Swedish Institute for European Policy Studies <https://sieps.se/media/qgkapq2t/2024_2epa.pdf> accessed 8 February 2026.
19. Georgieva L and Kuner C, 'Article 9 Processing of Special Categories of Personal Data' in Kuner C and others (eds), *The EU general data protection regulation (GDPR): a commentary* (Oxford University Press 2020).
20. Hartlev M, 'Health Data-Driven Research — Time for a Stronger Human Rights Governance Structure?' (2025) 32 European Journal of Health Law 559.
21. Keppi G, 'Avalik Huvi, Avalikkuse Huvi Ja Isikuandmete Kaitse' 2024/4 Juridica 297.
22. Kertesz F, 'Collaboration in Healthcare: Implications of Data Sharing for Secondary Use in the European Union' (2024) 31 European Journal of Health Law 497.
23. Kogut-Czarkowska M and Shabani M, 'Federated Networks and Secondary Uses of Health Data: Challenges in Ensuring Appropriate Safeguards for Sharing Health Data under the GDPR and EHDS' in Slokenberga S, Ó Cathaoir K and Shabani M (eds), *The European Health Data Space* (Routledge 2025).
24. Kohonen I, Kuula-Luumi A and Spoof S-K (eds), *The Ethical Principles of Research with Human Participants and Ethical Review in the Human Sciences in Finland. Finnish National Board on Research Integrity TENK Guidelines 2019* (2nd ed, TENK publications 2019).
25. Korff D, 'Digital Omnibus: Proposed Changes to the Definition of Personal Data in the EU GDPR Analysed in the Light of the SRB and Earlier CJEU Judgments' (Social Science Research Network, 9 December 2025) <https://papers.ssrn.com/abstract=5891404> accessed 5 February 2026.
26. Kranenborg H, 'Article 8 – Protection of Personal Data' in Peers S and others (eds), *The EU Charter of Fundamental Rights. A Commentary* (Bloomsbury Publishing 2021).
27. Köttering L, 'Enabling Secondary Use of Health Data for the Development of Medical Devices Based on Machine Learning' in Compagnucci MC and others (eds), *The Law and Ethics of Data Sharing in Health Sciences* (Springer Singapore 2024).
28. Kuuskmaa LM, 'Isikuandmete töötlemise õiguslik alus ning andmesubjekti õiguste kaitse tervise infosüsteemi kogutud terviseandmete kasutamisel kliiniliste otsuste tugisüsteemide arendamiseks ja rakendamiseks' (Tartu Ülikool 2020) <http://hdl.handle.net/10062/68545> accessed 25 August 2025.
29. Lalova T, 'Study on the Secondary Use of Personal Data in the Context of Scientific Research. Final Report EDPS/2019/02-04' (2020) <www.edpb.europa.eu/system/files/2025-04/20250401_study_on_the_secondary_use_of_personal_data_in_the_context_of_scientific_research_23102020_en.pdf> accessed 5 February 2026.
30. Lundström L and Slokenberga S, 'Evolution of Personal Data in the Court of Justice's Case Law and Implications for Scientific Research' (2026) 9 Nordic Journal of European Law 25 <https://doi.org/10.36969/njel.v9i1.28394>.

31. Marelli L and others, 'The European Health Data Space: Too Big to Succeed?' (2023) 135 Health Policy 104861.
32. McMahon A and Staunton C, 'Managing Access to Health Data for Research and Innovation in the EU: Is a Better Regulatory Approach Possible?' in Dove ES (ed), *Confidentiality, Privacy, and Data Protection in Biomedicine* (Routledge 2025).
33. Mészáros J and Ho C, 'Big Data and Scientific Research: The Secondary Use of Personal Data under the Research Exemption in the GDPR' (2018) 59 Hungarian Journal of Legal Studies 403.
34. Meszaros J and Ho C, 'AI Research and Data Protection: Can the Same Rules Apply for Commercial and Academic Research under the GDPR?' (2021) 41 Computer Law & Security Review 105532.
35. Mourby M and Molnar-Gabor F, 'Secondary Uses of Patients' Data in the European Health Data Space: A UK-German Comparison' in Dove ES (ed), *Confidentiality, Privacy, and Data Protection in Biomedicine* (Routledge 2025).
36. OECD, *Frascati Manual 2015: Guidelines for Collecting and Reporting Data on Research and Experimental Development* (OECD 2015) <www.oecd-ilibrary.org/science-and-technology/frascati-manual-2015_9789264239012-en> accessed 26 March 2026.
37. Parziale A, Pulice E and Mascalzoni D, 'Mass-Scale G2B Data Sharing in an Emergency: Between the GDPR, Data Governance Act, and European Health Data Space' (2025) 1 European Journal of Health Law 1.
38. Petročnik T, 'Secondary Use of Health Data in the EHDS: Public Interest and the Role of HDABs' in Slokenberga S, Ó Cathaoir K and Shabani M (eds), *The European Health Data Space* (Routledge 2025).
39. Pormeister K, 'Genetic Data and the Research Exemption: Is the GDPR Going Too Far?' (2017) 7 International Data Privacy Law 137.
40. Pormeister K, *Transparency in Relation to the Data Subject in Genetic Research – an Analysis on the Example of Estonia* (2019) <http://hdl.handle.net/10062/66697> accessed 26 March 2026.
41. Pormeister K, 'Regulatory Environment for Biobanking in Estonia' in Slokenberga S, Tzortzatou O and Reichel J (eds), *GDPR and Biobanking* (Springer Cham 2021).
42. Pormeister K, 'Uus isikuandmete kaitse seadus ja isikuandmed teaduses: kolm näidet probleemsest õigusloomest' 2019/4 Juridica 239.
43. Prainsack B, 'Research for Personalised Medicine: Time for Solidarity' (2017) 36/1 Medicine & Law 87.
44. Prainsack B, '"My Data" over "Our Data." Why Do We Need Data Solidarity?' ICT&health Global <https://icthealth.org/news/my-data-over-our-data-why-do-we-need-data-solidarity> accessed 9 July 2025.
45. Roussos A, 'The Opt-Out Mechanism from Secondary Use in the European Health Data Space (EHDS) Regulation: Catalyst or Barrier to Patient Engagement?' (2025) 8 European Health & Pharmaceutical Law Review 217.
46. Quinn P, 'Research under the GDPR – a Level Playing Field for Public and Private Sector Research?' (2021) 17 Life Sciences, Society and Policy 4.
47. Quinn P, 'Health Data Access Bodies under the European Health Data Space – A Technocratic Colossus or Rubber Stamp Forum?' (2025) 2025 Technology and Regulation 60.
48. Quinn P, Ellyne E and Yao C, 'Will the GDPR Restrain Health Data Access Bodies Under the European Health Data Space (EHDS)?' (2024) 54 Computer Law & Security Review 105993.

49. Raposo VL, ‘Can Personal Data Be Recycled? The Reuse and Repurposing of Data under the EHDS’ (2025) 33 International Journal of Law and Information Technology eaae016.
50. Royo R and others, ‘Genomic Data Sharing in Research across Europe: Legal Challenges and Upcoming Opportunities within the European Health Data Space’ (2025) 35 European Journal of Public Health iii25.
51. Sas M, Fernandes E and Musidlowska M, ‘Personal Health Data in xR Games: Exploring Purpose Limitation in the General Data Protection Regulation and European Health Data Space Regulation’ (2025) 4 Digital Society.
52. Sayers D, ‘Article 13 – Freedom of the Arts and Sciences’ in Peers S and others (eds), *The EU Charter of Fundamental Rights. A Commentary* (Bloomsbury Publishing 2021).
53. Schaefer GO and others, ‘Clarifying How to Deploy the Public Interest Criterion in Consent Waivers for Health Data and Tissue Research’ (2020) 21 BMC Medical Ethics 23.
54. Schneider G, ‘Health Data Pools under European Policy and Data Protection Law: Research as a New Efficiency Defence?’ (2020) 11 JIPITEC – Journal of Intellectual Property, Information Technology and E-Commerce Law 49.
55. Shabani M and Yilmaz S, ‘Lawfulness in Secondary Use of Health Data: Interplay between Three Regulatory Frameworks of GDPR, DGA & EHDS’ (2022) 2022 Technology and Regulation 128.
56. Slokenberga S, ‘Setting the Foundations: Individual Rights, Public Interest, Scientific Research and Biobanking’ in Slokenberga S, Tzortzatou O and Reichel J (eds), *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe* (Springer Cham 2021).
57. Slokenberga S, ‘Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject That the Proposed EHDS Regulation Promises to Bring Along’ [2022] Technology and Regulation 135.
58. Slokenberga S, Ó Cathaoir K and Shabani M (eds), *The European Health Data Space: Examining A New Era in Data Protection* (Routledge 2025).
59. Slokenberga S, Tzortzatou O and Reichel J (eds), *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe* (Springer Cham 2021).
60. Smits JM, ‘What Is Legal Doctrine? On the Aims and Methods of Legal-Dogmatic Research’ (Social Science Research Network, 1 September 2015) <https://papers.ssrn.com/abstract=2644088> accessed 21 January 2026.
61. Sokol T, ‘European Health Data Space, Use of Data and Data Subjects’ Control over Their Own Health Data: Can an Opt-Out Restore the Balance?’ (2024) 31 European Journal of Health Law 365.
62. Southerington T, ‘Access to Biomedical Research Material and the Right to Data Protection in Finland’ in Slokenberga S, Tzortzatou O and Reichel J (eds), *GDPR and Biobanking* (Springer Cham 2021).
63. Spajić D, ‘Transforming the Secondary Use of Patient Data in the European Health Data Space: A Challenge for the Patient’s Right to Medical Confidentiality?’ in Slokenberga S, Ó Cathaoir K and Shabani M (eds), *The European Health Data Space* (Routledge 2025).
64. Stalla-Bourdillon S, ‘Déjà vu in Data Protection Law: The Risks of Rewriting What Counts as Personal Data’ (2025) 26 Privacy and Data Protection 9.

65. Staunton C and others, ‘Ethical and Social Reflections on the Proposed European Health Data Space’ (2024) 32 European Journal of Human Genetics 498.
66. Taylor MJ and Whitton T, ‘Public Interest, Health Research and Data Protection Law: Establishing a Legitimate Trade-Off between Individual Control and Research Access to Health Data’ (2020) 9 Laws 6.
67. Terzis P, ‘Compromises and Asymmetries in the European Health Data Space’ (2022) 30 European Journal of Health Law 345.
68. Van Hoecke M, ‘Methodology of Comparative Legal Research’ [2015] Law and Method 1.
69. Van Veen E-B, ‘Observational Health Research in Europe: Understanding the General Data Protection Regulation and Underlying Debate’ (2018) 104 European Journal of Cancer 70.
70. Verhenneman G, *The Patient, Data Protection and Changing Healthcare Models: The Impact of e-Health on Informed Consent, Anonymisation and Purpose Limitation* (Intersentia 2021).
71. Zanfir-Fortuna G, ‘Article 21 Right to Object’ in Kuner C and others (eds), *The EU General Data Protection Regulation (GDPR): A Commentary* (Oxford University Press 2020).

Normative documents and official commentary

72. Act amending the Finnish Act on the Secondary Use of Social and Health Data (*Laki sosiaali- ja terveystietojen toissijaisesta käytöstä annetun lain muuttamisesta*) 1159/2025.
73. Act on the Finnish National Institute for Health and Welfare (*Laki Terveyden ja hyvinvoinnin laitoksesta*) 668/2008.
74. Charter of Fundamental Rights of the European Union OJ C 326 [2012].
75. Estonian Data Protection Act (*Isikuandmete kaitse seadus*) adopted on 12 December 2018 (RT I, 04.01.2019, 11).
76. Estonian Health Services Organisation Act (*Tervishoiuteenuste korraldamise seadus*) adopted on 9 May 2001 (RT I 2001, 50, 284).
77. Estonian Human Genes Research Act (*Inimgeeniuuringute seadus*) adopted on 13.12.2000 (RT I 2000, 104, 685).
78. Estonian Public Health Act (*Rahvatervishoiu seadus*) adopted on 11 December 2024 (RT I, 02.01.2025, 3).
79. Estonian Public Information Act (*Avaliku teabe seadus*) adopted on 15 November 2000 (RT I 2000, 92, 597).
80. European Data Protection Board, ‘Guidelines 05/2020 on Consent under Regulation 2016/679’ (Version 1.1, adopted on 4 May 2020).
81. European Data Protection Board, ‘Guidelines 1/2024 on Processing of Personal Data Based on Article 6(1)(f) GDPR’ (version 1.0 adopted on 8 October 2024).
82. European Data Protection Board, ‘Guidelines 01/2025 on Pseudonymisation’.
83. European Data Protection Supervisor, ‘A Preliminary Opinion on Data Protection and Scientific Research (6 January 2020)’.
84. Explanatory Memorandum of the Draft of the Organisation of Research and Development and Innovation Act <www.riigikogu.ee/tegevus/eelnoud/eelnou/27f4fde2-15e8-4441-adb2-813f5fc64fe1/teadus--ja-arendustegevuse-ning-innovatsiooni-korralduse-seadus/> accessed 3 January 2026.

85. Finnish Act on the Secondary Use of Social and Health Data (*Laki sosiaali- ja terveystietojen toissijaisesta käytöstä*) 552/2019 (The Secondary Use Act).
86. Finnish Data Protection Act (*Tietosuojalaki*)1050/2018.
87. Government Proposal HE 87/2025 vp to Parliament for an Act amending the Act on the Secondary Use of Social and Health Information and related acts <www.eduskunta.fi:443/FI/vaski/HallituksenEsitys/Sivut/HE_87+2025.aspx> accessed 14 January 2026.
88. Regulation (EU) 2016/679 of the European Parliament and 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) [2016] OJ L119/1.
89. Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) [2022] OJ L152/1.
90. Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 [2025] OJ L 2025/327.
91. Procedure for the formation and assessment of the Research Ethics Committee and the Committee for the Processing of Cases of Research Ethics Misconduct *(Teaduseetika komitee ja teaduseetika väärkäitumisjuhtumite menetlemise komisjoni moodustamise ja hinnangute andmise kord)* adopted on 2 December 2025 (RT I, 09.12.2025, 16).
92. Statute of the Estonian Health Information System *(Tervise infosüsteemi põhimäärus)* adopted on 1 December 2016 (RT I, 06.12.2016, 11).

Case law

93. Case C-162/97 *Nilsson and others* [1998] ECR I-07477.
94. Case C-362/14 *Maximillian Schrems v Data Protection Commissioner* [2015] ECLI:EU:C:2015:650.
95. Case C-479/22 *P OC v European Commission* [2024] EU:C:2024:215 (ECJ).
96. C 21/23, *Lindenapotheke* (Grand Chamber, 4 October 2024).
97. Case C-413/23 P *European Data Protection Supervisor v Single Resolution Board* (CJEU 4 September 2025).
98. *Z v Finland* App no 22009/93 (ECtHR, 25 February 1997).
99. *I v Finland* App no 20511/03 (ECtHR, 17 July 2008).
100. *L.H. v Latvia* App no 52019/07 (ECtHR, 29 April 2014).

Official e-mail communications

101. E-mail from Estonian Information System Authority to the Author (26 February 2026).
102. E-mail from the Estonian Ministry of Justice and Digital Affairs to the Author (13 January 2026).
103. E-mails from Findata to the Author (24 May 2023, 21 February 2024, 9 February 2026).
104. E-mail from the Research Ethics Committee of the Estonian National Institute for Health Development to the Author (4 January 2023).

105. E-Mail from TEHIK to the Author (9 February 2024).
106. Response from the Data Protection Inspectorate of Estonia to the Author's request for clarification (26 January 2023).
107. Response from the Ministry of Social Affairs to the Author's request (13 February 2026).

Other sources

108. Commission, 'Assessment of the EU Member States' Rules on Health Data in the Light of GDPR' <https://data.europa.eu/doi/10.2818/546193> accessed 26 March 2026.
109. Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – A European strategy for data' COM(2020) 66 final (19 February 2020).
110. Commission, 'Commission Staff Working Document Impact Assessment Report Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space' SWD (2022) 131 final.
111. Commission, 'Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space' COM (2022) 197 final.
112. Commission, 'Frequently Asked Questions on the European Health Data Space' <https://health.ec.europa.eu/latest-updates/frequently-asked-questions-european-health-data-space-2025-03-05_en> accessed 30 December 2025.
113. Commission, 'Common European Data Spaces' <https://digital-strategy.ec.europa.eu/en/policies/data-spaces> accessed 25 August 2025.
114. Commission, 'Proposal for a Regulation of the European Parliament and of the Council Amending Regulations (EU) 2016/679, (EU) 2018/1724, (EU) 2018/1725, (EU) 2023/2854 and Directives 2002/58/EC, (EU) 2022/2555 and (EU) 2022/2557 as Regards the Simplification of the Digital Legislative Framework, and Repealing Regulations (EU) 2018/1807, (EU) 2019/1150, (EU) 2022/868 and Directive (EU) 2019/1024 (Digital Omnibus)' COM(2025) 837 final.
115. Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) <https://eelnoud.valitsus.ee/main/mount/docList/1461fdb4-9e8b-4860-a015-92a741384a90> accessed 5 February 2026.
116. European Data Protection Board, 'Legacy: Art 29 Working Party' <www.edpb.europa.eu/about-edpb/who-we-are/legacy-art-29-working-party_en> accessed 5 February 2026.
117. European Data Protection Board, 'Tasks and Duties' <www.edpb.europa.eu/about-edpb/what-we-do/tasks-and-duties_en> accessed 5 February 2026.
118. European Data Protection Supervisor, official web page <www.edps.europa.eu/_en> accessed 5 February 2026 2025.
119. Explanatory Memorandum of the Draft Act on Amendments to the Personal Data Protection Act and the Research, Development and Innovation Organisation Act (6 November 2025) <https://eelnoud.valitsus.ee/main/mount/docList/1461fdb4-9e8b-4860-a015-92a741384a90> accessed 5 February 2026.
120. E-Estonia Briefing Centre, 'Digital Healthcare' <https://e-estonia.com/programme/digital-healthcare/> accessed 26 March 2026.

121. Finnish AI Region 2022-2025, ‘Findata and Luxembourg forge an alliance ahead of EU health data reforms’ <www.fairedih.fi/en/2025/09/30/findata-and-luxembourg-forge-data-governance-alliance-ahead-of-eu-health-data-reforms/> accessed 17 February 2026.
122. Findata, ‘Finnish Social and Health Data Permit Authority Findata’ <findata.fi> accessed 2 January 2026.
123. Findata, ‘The Finnish healthcare system and health data registers’ <https://findata.fi/en/course/finnish-health-care-system/> accessed 17 February 2026.
124. Kanta-Palvelut, Kansaneläkelaitos, ‘What are the Kanta Services?’ <www.kanta.fi/en/what-are-kanta-services> accessed 2 January 2026.
125. TEHDAS2, ‘Draft Guideline to Health Data Access Bodies on Implementing the Obligation of Notifying the Natural Person on a Significant Finding from the Secondary Use of Health Data’ <https://tehdas.eu/wp-content/uploads/2025/09/draft-guideline-to-health-data-access-bodies-on-implementing-the-obligation-of-notifying-the-natural-person-on-a-significant-finding-from-the-secondary-use-of-health-data.pdf> accessed 9 February 2026.
126. TEHDAS2, ‘Draft Guideline for Health Data Access Bodies on Minimum Categories and Limitations on the Reuse of Health Data’ <https://tehdas.eu/wp-content/uploads/2025/09/draft-guideline-for-health-data-access-bodies-on-minimum-categories-and-limitations-on-the-reuse-of-health-data.pdf> accessed 9 February 2026.
127. TEHDAS2, ‘Public consultations’ <https://tehdas.eu/public-consultations/> accessed 9 February 2026.
128. TEHDAS2, ‘Second Joint Action Towards the European Health Data Space – TEHDAS2’ <https://tehdas.eu/> accessed 5 February 2026.
129. TEHIK, ‘Data Requests’ <www.tehik.ee/en/data-requests> accessed 26 March 2026.

SUMMARY IN ESTONIAN

Teadusuuringute vabaduse ja privaatsuse tasakaalustamine terviseandmetega tehtavates teadusuuringutes: avalik huvi, õiguslikud alused ning vastuväidete esitamise ja loobumise õigused

1. Uurimisprobleem ja eesmärk

Inimese terviseandmete kasutamine teadusuuringutes kiirendab uute teadmiste saamist tervishoiu valdkonnas. See toetab ravimite kiiremat avastamist ja haiguste kulgemise paremat mõistmist.[351] Teadusuuringute jaoks kasulike terviseandmete maht kasvab kiiresti ning andmete töötlemise tehnoloogia ja teaduslikud meetodid arenevad pidevalt.[352] See kombinatsioon tekitab suuri ootusi läbimurreteks tervishoiu valdkonnas, kuid samal ajal ka murekohti andmesubjektide privaatsuse kaitse osas.

Terviseandmete kasutamine teadusuuringutes tekitab paratamatult pingeid teadusuuringute vabaduse ning eraelu puutumatuse ja isikuandmete kaitse põhiõiguste vahel, mis on kõik Euroopa Liidu põhiõiguste hartaga kaitstavad põhiõigused.[353] Teadusuuringu läbiviija huvides on kiire juurdepääs üksikasjalikele esinduslikele andmetele rangete piiranguteta teadusuuringu sisu üle. Andmesubjekti huvides on andmesubjekti kontroll oma andmete üle ja selged piirid lubatud andmetöötlustegevustele. Samas on andmesubjektidel ka huvi saada kasu terviseandmetel põhinevast uurimistööst, sealhulgas uute ravimite, ravimeetodite ja personaliseeritud tagasiside kaudu.

Teadusuuringutes terviseandmete töötlemise andmekaitsealaseid aspekte reguleerib isikuandmete kaitse üldmäärus (IKÜM) koostoimes liikmesriigi või liidu õigusega.[354] Seetõttu on liikmesriigid, sh doktoritöös vaatluse all olevad Eesti ja Soome, kehtestanud täpsemad reeglid terviseandmete töötlemiseks teadusuuringute eesmärgil. Euroopa Liit pani 2025. aastal aluse ka Euroopa Liidu ülesele ühtsete reeglitega andmetele juurdepääsu mehhanismile, kui võttis vastu terviseandmeruumi määruse. See mehhanism peab määruse kohaselt olema liikmesriikides kättesaadav 26. märtsist 2029,[355] kuid ei välista paralleelseid riigisisesel õigusel põhinevaid andmetele juurdepääsu mehhanisme.[356]

---

[351] Cascini (n 1) 83.

[352] ibid 3, 58, 83.

[353] Euroopa Liidu põhiõiguste harta ELT C 326 [2012], artiklid 7, 8, 13.

[354] Euroopa Parlamendi ja Nõukogu määrus 2016/679, 27. aprill 2016, füüsiliste isikute kaitse kohta isikuandmete töötlemisel ja selliste andmete vaba liikumise ning direktiivi 95/46/EÜ kehtetuks tunnistamise kohta (isikuandmete kaitse üldmäärus) OJ L 119 (IKÜM), artikkel 9(2)(j).

[355] Euroopa Parlamendi ja Nõukogu määrus 2025/327, 11. veebruar 2025, mis käsitleb Euroopa terviseandmeruumi ning millega muudetakse direktiivi 2011/24/EL ja määrust (EL) 2024/2847 OJ L, 2025/327 (Euroopa terviseandmeruumi määrus), artikkel 105.

[356] Euroopa terviseandmeruumi määrus, artiklid 1(7), 1(8), põhjenduspunkt 52.

Doktoritöö uurimisprobleemiks on väljakutse leida optimaalne regulatiivne tasakaal teadusuuringute vabaduse ning eraelu puutumatuse ja isikuandmete kaitse õiguste vahel terviseandmetega tehtavates teadusuuringutes, mis toimuvad andmesubjekti nõusolekuta. See tasakaal ei ole IKÜM-s fikseeritud, kuna IKÜM jätab liikmesriikidele laia otsustusõiguse. Kuigi õiguslik alus terviseandmete töötlemiseks teadusuuringute eesmärgil tuleneb IKÜM-st (artikkel 9 lg 2 p j), võivad liikmesriigid ise seada avaliku huvi standardi, millele teadusprojekt peab vastama, et õigustada juurdepääsu terviseandmetele.[357] Samuti saavad liikmesriigid ise kujundada andmesubjektide õigust keelata nende terviseandmete kasutamine teadusuuringutes vastuväidete esitamise kaudu.[358] Praktikas peavad liikmesriigid sisustama ka mõiste „teadusuuring", mis on isikuandmete töötlemise õigusliku aluse (IKÜM artikkel 9 lg 2 p j) keskne osa.[359] Kuigi „teadusuuring" on Euroopa Liidu õiguse autonoomne mõiste, ei ole see doktoritöö kirjutamise hetkel IKÜM-s defineeritud. Samuti ei ole Euroopa Kohus seda mõistet IKÜM kontekstis selgitanud.

Euroopa terviseandmeruumi määrus, millega luuakse Euroopa Liidus ühtne mehhanism terviseandmetele juurdepääsu saamiseks teadusuuringuteks, sätestab konkreetsemad reeglid kui IKÜM. Siiski jätab Euroopa terviseandmeruumi määrus ka Euroopa Liidu üleses mehhanismis liikmesriikidele õiguse kujundada avaliku huvi standardit, mis õigustab andmetele juurdepääsu, võimaldades näha riigisiseses õiguses ette eetilise hindamise kohustuse.[360] Ka jätab Euroopa terviseandmeruumi määrus praktikas mõiste „teadusuuring" tõlgendamise riigisiseste andmeloa asutuste hooleks.[361] Kuigi Euroopa terviseandmeruumi määrus näeb andmesubjektidele ette üldreeglina tingimusteta loobumisõiguse (*opt-out*), võimaldab määrus liikmesriikidel sellest õigusest näha ette erandeid, mis mõjutab oluliselt andmesubjektide autonoomiat.[362]

Eelnevat arvestades on doktoritöö eesmärk kriitiliselt analüüsida ja hinnata, kuidas avaliku huvi nõue, õiguslikus aluses sisalduv mõiste „teadusuuring" ning andmesubjekti õigus keelata tema andmete kasutamine piiravad terviseandmete töötlemist teadusuuringutes ning tasakaalustavad teadusuuringute vabadust põhiõigustega eraelu puutumatusele ja isikuandmete kaitsele. Doktoritöö lõppeesmärk ja olulisim originaalne panus on autori loodud mudel, mis aitab liikmesriikidel optimaalselt tasakaalustada teadusuuringute põhivabadust eraelu puutumatuse ja isikuandmete kaitse põhiõigustega doktoritöös uuritud piirangute (avaliku huvi nõue, õiguslikus aluses sisalduva mõiste „teadusuuring" ulatus, andmesubjekti vastuväidete ja loobumisõigused) kaudu. Selle mudeli väljatöötamisel on aluseks võetud hinnangud, mille autor on käesolevas töös andnud

[357] IKÜM, artiklid 9(2)(j), 9(4), põhjenduspunkt 53.

[358] ibid, artikkel 89(2).

[359] ibid, artikkel 9(2)(j).

[360] Euroopa terviseandmeruumi määrus, artiklid 55(2), 67(2)(j), põhjenduspunkt 69.

[361] ibid, artikkel 68(1)(a).

[362] ibid, artikkel 71(4).

Eesti[363] ja Soome[364] riigisisestele andmetele juurdepääsu mehhanismidele ning Euroopa terviseandmeruumi mehhanismile. Igas uuritud mehhanismis tehtud valikutele antakse doktoritöös hinnang ning sünteesitakse välja parimad lahendused, et pakkuda välja doktoritöö eesmärgiks olev optimaalne mudel.

Doktoritöö uurimisküsimused on sõnastatud nii, et iga uuritud õigusliku piirangu kohta on esmalt püstitatud küsimus, kuidas see piirang tasakaalustab teadusuuringute vabadust ja eraelu puutumatust ning õigust isikuandmete kaitsele IKÜM-s, Eesti ja Soome riigisisestes õigustes ning Euroopa terviseandmeruumi määruses. Seejärel on iga õigusliku piirangu kohta püstitatud küsimus, kuidas selle õigusliku piirangu abil vastavaid põhiõigusi optimaalselt tasakaalustada. Viimase uurimisküsimusena on püstitatud küsimus, milline on optimaalne mudel vaatluse all olevate põhiõiguste tasakaalustamiseks kõikide töös uuritud piirangute kaudu kogumis.

Kõikides töös uuritud andmetele juurdepääsu mehhanismides on võimalik töödelda terviseandmeid teadusuuringute eesmärgil andmesubjekti nõusolekuta. Soomet peetakse terviseandmete teisesel kasutamisel Euroopas liidriks tänu 2019. aastal loodud Findata andmetele juurdepääsu mehhanismile, mis on keskne riiklik andmeloa süsteem. Findata mehhanism on olnud eeskujuks ka Euroopa terviseandmeruumi määruse väljatöötamisel.[365] Seetõttu on sellel mehhanismil potentsiaali olla eeskujuks doktoritöös eesmärgiks võetud optimaalse mudeli loomisel. Eestis ei ole sarnast keskset andmetele juurdepääsu mehhanismi, kuid teadusuuringute läbiviimiseks kasutatakse mh terviseinfosüsteemi, mis sisaldab kogu elanikkonna terviseandmeid.[366] Vastavalt Euroopa terviseandmeruumi määrusele on alates 26. märtsist 2029 võimalik teadusuuringuteks kasutada ka vastava määrusega loodud Euroopa Liidu ülest andmetele juurdepääsu mehhanismi.[367] Järgnevalt esitatakse kokkuvõte nendele mehhanismidele antud hinnangutest ning seejärel vastavaid hinnanguid arvestav põhiõigusi tasakaalustav mudel.

2. Avaliku huvi nõue põhiõiguste tasakaalustajana

Kuna teadusuuringute tegemiseks ette nähtud õiguslikule alusele, IKÜM artikkel 9 lg 2 p-le j, tuginemine võimaldab terviseandmeid töödelda ilma andmesubjekti nõusolekuta ning piirab oluliselt andmesubjektide õigusi, peab selline töötlemine olema avaliku huviga põhjendatud.[368] Arvestades, et IKÜM ei sea avaliku huvi standardit, mis õigustab terviseandmete töötlemist teadusuuringutes, peavad

---

[363] Isikuandmete kaitse seadus (vastu võetud 12. detsember 2018) RT I, 04.01.2019, 11, § 6.

[364] *Laki sosiaali- ja terveystietojen toissijaisesta käytöstä* 552/2019.

[365] Commission, 'Commission Staff Working Document Impact Assessment Report Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space' SWD (2022) 131 final, paras 2.2, 2.3, 6.1.1, and 6.1.3.2.

[366] TEHIK, „Andmepäringud" <www.tehik.ee/andmeparingud> vaadatud 26. märtsil 2026.

[367] Euroopa terviseandmeruumi määrus, artikkel 105.

[368] IKÜM, artiklid 5(1)(e), 14(5)(b), 17(3)(d), 89(2); vt sel teemal arutelu ka Slokenberga (n 61) 22.

liikmesriigid selle riigisiseses õiguses ise seadma. Selleks, et tagada, et terviseandmete töötlemine teadusuuringutes on avalikes huvides, on äärmiselt oluline teadusprojekti vastavust avalikule huvile sõltumatult hinnata. Tuginedes Eesti näitele, on selline sõltumatu avaliku huvi hindamine võimalik eetikakomitee hindamise kaudu. Soome Findata andmeloa menetluse näitele tuginedes on võimalik hinnata avalikku huvi ka andmeloa menetluse kaudu.[369] Kuigi sellised menetlused võivad sisaldada avaliku huvi hindamist isegi siis, kui õigusaktid seda otsesõnu ei nõua, pole põhjust avaliku huvi nõuet riigisisesest õigusest välja jätta. Õigusaktidest tulenev avaliku huvi hindamise nõue aitab eetikakomiteedel ja andmeloa asutustel kujundada oma praktikat ja vältida kriitikat õigusaktide nõuetest kõrgemate standardite seadmise eest. Samas, kuna õigusaktides ei ole võimalik kõiki avaliku huvi juhtumeid ette näha, tuleb läbipaistvuse tagamiseks välja töötada praktilised suunised.

Tulevikus tõenäoliselt domineeriv Euroopa terviseandmeruumi mehhanism kujundab avaliku huvi standardi konkreetsete tingimuste kaudu. Nimetatud määruses on nõutud, et teadusuuringute eesmärk peab olema kasu toomine lõppkasutajatele, näiteks patsientidele või tervishoiutöötajatele. Samuti on nõutav, et teadusuuring aitaks kaasa rahvatervise edendamisele või tervisetehnoloogia hindamisele või tagaks tervishoiu, ravimite või meditsiiniseadmete kõrge kvaliteedi ja ohutuse.[370] Doktoritöös jõuti järeldusele, et Euroopa terviseandmeruumi määruses ette nähtud andmeloa menetlus, mille käigus hinnatakse kavandatud andmetöötluse eesmärke, toimib ka avaliku huvi hindamisena.[371] Samas arvestades määruse laia sõnastust, on tingimuste ühtse sisustamise jaoks vaja praktilisi suuniseid. Esineb ka risk, et Euroopa terviseandmeruumi määrus ei taga sellist avaliku huvi standardit, mis peegeldab liikmesriigi eetilisi ootusi. Sellistel juhtudel võivad liikmesriigid riigisiseses õiguses ette näha teadusprojektide eetilise hindamise kohustuse.[372] Arvestades, et üldreeglina ei või liikmesriigid seada Euroopa Liidu ülesele andmetele juurdepääsu mehhanismile rangemaid reegleid kui Euroopa terviseandmeruumi määrus ise ette näeb,[373] jääb praktikas lahendada küsimus, kui palju võib riigisisene eetilise hindamise nõue andmetele juurdepääsu piirata.

Doktoritöös leiti, et ka Euroopa terviseandmeruumi määruses ette nähtud nõue teadusuuringute tulemused avalikuks teha[374] teenib avaliku huvi eesmärki. Teadustöö tulemuste avalikustamine võib kiirendada edasist teadustööd ja seega panustab avalikku huvisse. Samas on teadusuuringu läbiviija konkurentsieelise säilitamiseks vajalik ette näha mõistlik tähtaeg, mille jooksul tulemusi avalikustama ei

369 Täpsem analüüs on esitatud doktoritöö osaks olevas Publikatsioonis I.

370 Euroopa terviseandmeruumi määrus, artikkel 53 lg 1 p e.

371 ibid, artikkel 68(1)(a).

372 ibid, artikkel 55(2).

373 ibid, põhjenduspunkt 52.

374 ibid, artikkel 61(4).

pea. Selline valik on tehtud ka Euroopa terviseandmeruumi määruses.[375] Doktoritöös analüüsiti ka Euroopa terviseandmeruumi määruses kehtestatud nõuet teavitada füüsilisi isikuid nende tervisega seotud olulistest leidudest.[376] Doktoritöös jõuti järeldusele, et selle nõude tõhus rakendamine nii, et see teeniks avalikke huve, on keeruline. Seetõttu ei peetud seda nõuet sobivaks eeskujuks, mida kasutada riigisisestes andmetele juurdepääsu mehhanismides.

3. Õiguslikus aluses sisalduv mõiste „teadusuuring" põhiõiguste tasakaalustajana

IKÜM-s teadusuuringuteks ette nähtud õiguslikus aluses (artikkel 9 lg 2 p j) sisalduva mõiste „teadusuuring" osas leiti doktoritöös, et IKÜM ei kaitse eraelu puutumatust ja õigust isikuandmete kaitsele, kuna on oht, et teadusuuringu mõistet tõlgendatakse liiga laialt. Seejuures liiga kitsa tõlgendamise oht on väiksem, kuna IKÜM põhjenduspunktis 159 selgitatakse teadusuuringu mõistet laialt, hõlmates ka tehnoloogiaarendust ja tutvustamistegevust. Euroopa Komisjon on selgitanud, et „teadusuuringu" mõiste on IKÜM-s ja Euroopa terviseandmeruumi määruses sama.[377] Samas ei ole ka Euroopa terviseandmeruumi määruses teadusuuringu mõistet defineeritud, kuid määruse põhiosas loetletud teadusuuringute näited hõlmavad toodete ja teenuste väljatöötamist ja innovatsiooni, samuti algoritmide treenimist, testimist ja hindamist, sealhulgas meditsiiniseadmetes, *in vitro* diagnostikameditsiiniseadmetes, tehisintellektisüsteemides ja digitaalsetes terviserakendustes.[378] Selline lai lähenemisviis toetab jätkuvalt teadusuuringute vabadust.

Doktoritöös uuriti „teadusuuringu" mõiste piire küsimuse kaudu, millistel juhtudel on arendus- ja innovatsioonitegevuste puhul tegemist teadusuuringuga. Nii Eestis kui ka Soomes on praktikas võimalik teadusuuringute õiguslikule alusele tuginedes viia läbi ka arendus- ja innovatsioonitegevusi, näiteks arendada tervishoiuvaldkonna tooteid ja teenuseid.[379] Samas parandaksid ühtsed kriteeriumid teadusuuringu mõiste määratlemiseks andmete töötlemise ettenähtavust nii andmesubjektide kui ka uuringute tegijate jaoks. See on eriti oluline piiripealsete juhtumite puhul, kus terviseandmeid kasutatakse arendus- ja innovatsioonitegevuses või poliitika kujundamisel. Seetõttu soovitati doktoritöös tugineda teadusuuringu piiritlemisel Frascati käsiraamatu[380] ning lisaks Euroopa Andmekaitsenõukogu ning Euroopa Andmekaitseinspektori välja töötatud

---

375 ibid.

376 ibid, artikkel 58(3).

377 Commission, 'Frequently Asked Questions on the European Health Data Space' (n 30) 31.

378 Euroopa terviseandmeruumi määrus, artikkel 53(1)(e).

379 Tervise Arengu Instituudi eetikakomitee e-kiri autorile (4. jaanuar 2023), Findata e-kirjad autorile (24. mai 2023, 9. veebruar 2026). Täpsem analüüs on esitatud doktoritöö osaks olevas Publikatsioonis II.

380 Teadusuuring peab olema 1) uudne; 2) loominguline; 3) ettemääramatu tulemusega; 4) süstemaatiline; ja 5) ülekantav ja/või korratav. OECD (n 77) 45.

tingimustele.[381] Arvestades tehnoloogia, sealhulgas tehisintellekti, ja teadusuuringutes kasutatavate meetodite kiiret arengut, on vajalikud ka ajakohastatud juhised selle kohta, kuidas piiritleda teadusuuringu mõistet tänapäevastes terviseandmeid hõlmavates projektides.

Teadusprojekti vastavuse hindamiseks teadusuuringu mõistele on vaja sõltumatut hindamismenetlust, sarnaselt avaliku huvi sõltumatule hindamisele. Eestis hindavad eetikakomiteed ja Soomes andmeloa asutus, kas kavandatav projekt on teaduslikku laadi. Selliste sõltumatute hindamismenetluste olemasolu koos „teadusuuringu" mõiste selgepiirilise tõlgendamisega tasakaalustab asjakohaselt teadusuuringute vabadust ning eraelu puutumatuse ja isikuandmete kaitse põhiõigusi. Samas selliste menetluste puudumine avaldab andmesubjektidele negatiivset mõju, kuna kaob kontroll andmetöötluse eesmärkide üle. Eesti isikuandmete kaitse seaduse kavandatavad muudatused, millega kaotataks paljudel juhtudel eetikakomitee hindamise nõue,[382] võimaldavad praktikas terviseandmete õigustamatut kasutamist, ilma et projekti teaduslikku olemust või avalikku huvi usaldusväärselt hinnataks.

Täpsemalt on doktoritöö kirjutamise lõpufaasis Eestis arutluse all ulatuslikud seadusemuudatused, mis vähendavad eetikakomiteede rolli terviseandmetega tehtavates teadusuuringutes.[383] Näiteks ei ole muudatuste kohaselt eetikakomitee kooskõlastuse saamine vajalik, kui teadusuuring viiakse läbi pseudonüümitud terviseandmetega, sõltumata uurija isikust.[384] See tähendab, et eetikakomitee kooskõlastuse saamise nõue kaotataks ainuüksi seetõttu, et teadusprojektis kasutatakse pseudonüümimist kui standardset kaitsemeedet. Kuigi kavandatavate muudatuste kohaselt on siiski vajalik enne teadusuuringu alustamist teavitada Andmekaitse Inspektsiooni, ei ole viimasel kohustust viia läbi projektide eelhindamist. Selle asemel peab Andmekaitse Inspektsioon vaid avaldama teabe uuringu läbiviimise kohta oma veebilehel.[385] Andmekaitse Inspektsioon võib teavet kasutada ka andmekaitsealase järelevalve eesmärgil, kuid see ei kujuta endast eetilist hindamist, mille käigus hinnataks projekti teaduslikku iseloomu ja vastavust avalikule huvile. Kuigi kavandatavad muudatused täpsustavad ka pseudonüümimise standardit,[386] on tegemist tehnilise kaitsemeetmega, mis ei asenda sisulist eetilist hindamist ega taga terviseandmete töötlemise õigustatust.

---

[381] Teadusuuring peab vastama ka metoodika- ja eetikastandarditele ja aitama kaasa avaliku huvi teenimisele. European Data Protection Board, 'Guidelines 05/2020 on Consent under Regulation 2016/679 (Version 1.1, Adopted on 4 May 2020)' (n 244) para 153; European Data Protection Supervisor (n 181) 11–12.

[382] Isikuandmete kaitse seaduse ning teadus- ja arendustegevuse ning innovatsiooni korralduse seaduse muutmise seaduse eelnõu (6. november 2025) <https://eelnoud.valitsus.ee/main/mount/docList/1461fdb4-9e8b-4860-a015-92a741384a90> vaadatud 5. veebruaril 2026.

[383] ibid.

[384] ibid, § 6(7).

[385] ibid, § 6(5).

[386] ibid, § 6(3), § 6^1(2).

Teise ohtliku ettepanekuna ei nõutaks kavandatud muudatuste kohaselt projekti eetilist hindamist, Andmekaitse Inspektsiooni teavitamist ega isegi andmete pseudonüümimist, kui vastutav töötleja töötleb andmeid ühes tema enda kontrolli all olevas andmekogus.[387] Ettepanekus ei täpsustata, millist tüüpi vastutavad töötlejad seda privileegi omavad või milliseid andmekogusid on mõeldud. Sätte sõnastuse põhjal võib iga vastutav töötleja töödelda oma kontrolli all olevaid terviseandmeid teadusuuringute eesmärgil ilma välise järelevalveta või vajaduseta andmeid pseudonüümida. Siiski on eelnõu autorid oma vastuskirjas selgitanud, et see säte on mõeldud ainult andmekogudele avaliku teabe seaduse tähenduses[388] ja nende vastutavatele töötlejatele.[389] Samas on ka avaliku teabe seaduses „andmekogu" mõiste väga lai, hõlmates suurt hulka avalikus sektoris kasutatavaid andmekogusid.[390] 1. märtsi 2022. aasta seisuga oli registreeritud 821 sellist andmekogu, kuid täpne arv on teadmata.[391] Kõnealune muudatusettepanek jätaks andmesubjektid ilma pseudonüümimisesega pakutavast kaitsest ning igasugusest välisest kontrollist selle üle, kas töötlemistegevus kujutab endast üldse teadusuuringut või vastab avalikule huvile. Selline olukord kujutaks tõsist ohtu andmesubjektide privaatsusele.

Seni on eetikakomitee hindamise nõue Eestis toiminud sõltumatu hindamismehhanismina, tagamaks, et kavandatavad uurimisprojektid kvalifitseeruvad tõeliseks teadusuuringuks ja vastavad avalikule huvile. See on sarnane nii Euroopa terviseandmeruumi kui ka Soome Findata lähenemisviisidega, mis hõlmavad sõltumatuid hindamismenetlusi andmeloa menetluste kaudu. Tuginedes sellele võrdlusele, ei oleks eetikakomitee nõude kaotamine Eestis, isegi kui see osati asendatakse tehniliste kaitsemeetmetega, kooskõlas kaasaegsete suundumustega digitaalsete terviseandmete töötlemisel Euroopa Liidus.[392] Euroopa terviseandmeruumi ja Soome Findata mehhanismides on kasutusel sõltumatud hindamismenetlused, hoolimata sellest, et teadlane saab andmetele juurdepääsu ainult pseudonüümitud vormis turvalises andmetöötluskeskkonnas.[393] Sellele võrdlusele tuginedes ei õigusta ka tehnilised kaitsemeetmed sõltumatute hindamismenetluste kaotamist.

---

[387] ibid, § 6(9).

[388] Avaliku teabe seadus (vastu võetud 15. novembril 2000) RT I 2000, 92, 597.

[389] Eesti Justiits- ja Digiministeeriumi e-kiri Autorile (13. jaanuar 2026).

[390] Avaliku teabe seaduse § 43^1 lõige 1: „Andmekogu on riigi, kohaliku omavalitsuse või muu avalik-õigusliku isiku või avalikke ülesandeid täitva eraõigusliku isiku infosüsteemis töödeldavate korrastatud andmete kogum, mis asutatakse ja mida kasutatakse seaduses, selle alusel antud õigusaktis või rahvusvahelises lepingus sätestatud ülesannete täitmiseks."

[391] Eesti Riigi Infosüsteemi Ameti e-kiri Autorile (26. veebruar 2026).

[392] Siin esitatud võrdlus Soomega on piiratud, sest käsitletakse üksnes Soome Findata andmetele juurdepääsu mehhanismi. Teatud riigiasutustel on olemas ka teised andmetele juurdepääsu võimalused, mis ei eelda Findata andmeloa taotlemist. Näiteks saab Soome Tervise ja Heaolu Instituut kasutada avaliku sektori andmebaaside terviseandmeid oma eriseaduse alusel, mille analüüs jääb käesoleva töö raamidest välja. Vt *Laki Terveyden ja hyvinvoinnin laitoksesta* 668/2008, § 2, § 5.

[393] EL terviseandmeruumi määrus, artiklid 66, 68, 73; *Laki sosiaali- ja terveystietojen toissijaisesta käytöstä* 552/2019, § 14, § 20, § 38.

4. Vastuväidete esitamise õigus ja loobumisõigus põhiõiguste tasakaalustajatena

IKÜM ei näe andmesubjektidele ette loobumisõigust (*opt-out*) ega tõhusat vastuväidete esitamise õigust takistamaks nende isikuandmete töötlemist teadusuuringus. Seetõttu ei taga IKÜM õiglast tasakaalu teadusuuringute vabaduse ja eraelu puutumatuse ning isikuandmete kaitse põhiõiguste vahel. Asjaolu, et IKÜM-s sätestatud vastuväidete esitamise õigus on nõrk ja praktikas mitmeti tõlgendatav, illustreerivad hästi Eesti ja Soome õigusaktid ja praktika. Eestis ei arvestata andmesubjektide vastuväiteid terviseinfosüsteemis sisalduvate terviseandmete töötlemisele teadusuuringute eesmärgil.[394] Seevastu Soomes arvestatakse andmesubjektide vastuväiteid Findata mehhanismis praktikas tingimusteta.[395] Vastuväidete tingimusteta arvestamisega kaasneb samas andmevalimi kallutatuse risk. Soomes tasakaalustab seda riski seaduses sätestatud erand, mis lubab konkreetsetes projektides kasutada andmeid sõltumata andmesubjektide esitatud vastuväidetest.[396] Üldreeglina loob andmesubjektide vastuväidete arvestamine, võimaldades samas teha erandeid konkreetsete projektide puhul, sobiva tasakaalu teadusuuringute vabaduse ning eraelu puutumatuse ja isikuandmete kaitse põhiõiguste vahel.

Euroopa terviseandmeruumi määrus näeb andmesubjektidele ette loobumisõiguse (*opt-out*), mis võimaldab andmesubjektidel igal ajal põhjusi nimetamata keelata oma andmete kasutamine Euroopa terviseandmeruumi mehhanismis.[397] Kuigi nimetatud loobumisõigus on üldiselt tingimusteta, on sellest võimalik teha ka erandeid ning andmesubjekti soove seega mitte arvestada.[398] Doktoritöö osaks olevas Publikatsioonis III selgitati riski, et erandeid loobumisõigusest võidakse tõlgendada liiga laialt. Juhul, kui Euroopa terviseandmeruumi määruses ette nähtud loobumisõigus ei rakendu, jääb IKÜM-s ette nähtud vastuväidete esitamise õigus siiski alles, kuid praktikas ei pruugi see andmesubjektide autonoomiat tõhusalt kaitsta. Seega, kuigi Euroopa terviseandmeruumi määrus näitab suundumust andmesubjektide autonoomia tugevama kaitse poole, sisaldab see ka erandeid, mis võivad jätta andmesubjektid tõhusate õigusteta. Samal ajal püsib Euroopa terviseandmeruumi mehhanismis ka oht, et loobumisõigust kasutatakse laialdaselt, vähendades selle mehhanismi kaudu kättesaadavate andmete väärtust. Nende riskide leevendamiseks on liikmesriikidel soovitatav kehtestada riigisisestes õigusaktides erand, mis võimaldab andmesubjektide loobumistega mitte arvestada, kui andmete töötlemine on vajalik teadusuuringuteks avaliku huviga seotud olulistel põhjustel.[399] IKÜM-s ette nähtud vastuväidete esitamise õiguse ja Euroopa terviseandmeruumi määruses ette nähtud loobumisõiguse vaheliste seoste keerukus

[394] TEHIK e-kiri Autorile (9. veebruar 2024).

[395] Findata e-kiri Autorile (21. veebruar 2024).

[396] *Tietosuojalaki* 1050/2018, § 31.

[397] Euroopa terviseandmeruumi määrus, artikkel 71.

[398] ibid, artiklid 1(7), 1(8), 71(4).

[399] ibid, artikkel 71(4).

tõi esile ka vajaduse luua keskne kanal, kus andmesubjektid saavad mõlemat õigust kasutada.

Doktoritöös analüüsitud mehhanismide võrdlusele tuginedes ei ole Eesti lähenemisviis vastuväidete esitamise õigusele kooskõlas kaasaegsete Euroopa Liidu suundumustega digitaalsete terviseandmete töötlemisel. Kui Euroopa terviseandmeruumi ja Findata andmete juurdepääsu mehhanismides on üldiselt olemas andmesubjekti tingimusteta loobumise või vastuväite esitamise õigus, siis Eesti terviseinfosüsteemi lähenemisviis on vastupidine. Eesti isikuandmete kaitse seaduse muudatusettepanekutes ei ole märke sellise lähenemise muutmisest. See on nii hoolimata asjaolust, et eetikakomitee kooskõlastuse saamise kohustust, mida kasutati vastuväidetega mittearvestamise õigustamiseks terviseinfosüsteemis,[400] on kavandatud piirata.[401]

5. Õiguste tasakaalustamise mudel

Tuginedes eelnevalt antud hinnangutele, pakutakse doktoritöös välja järgnev mudel, mis tasakaalustab teadusuuringute vabadust eraelu puutumatuse ja isikuandmete kaitse põhiõigustega.

1. Enne terviseandmetele juurdepääsu andmist tuleb teadusprojekti teaduslikku iseloomu ja vastavust avalikule huvile hinnata sõltumatu hindamismenetluse käigus. Sellest nõudest ei või teha erandeid ka juhul, kui andmeid töötlevad riigiasutused või kui need on kaitstud tehniliste kaitsemeetmetega. Euroopa terviseandmeruumi mehhanismi kontekstis tähendab see andmeloa menetlust. Riigisiseste andmetele juurdepääsu mehhanismide kontekstis võib see tähendada eetikakomitee hindamist või andmeloa menetlust.
2. Selleks et kontrollida, kas kavandatav projekt on teadusuuring, tuleb tugineda Frascati käsiraamatule ning Euroopa Andmekaitsenõukogu ja Euroopa Andmekaitseinspektori väljatöötatud kriteeriumitele. Nende kohaselt peab teadusuuring olema 1) uudne; 2) loominguline; 3) ettemääramatu tulemusega; 4) süstemaatiline; ja 5) ülekantav ja/või korratav[402] ning vastama metoodika- ja eetikastandarditele ja aitama kaasa avaliku huvi teenimisele.[403] Seejuures asjaolu, et teadusuuring on lisaks ka erahuvides, ei välista avalikes huvides olekut. Arvestades tehnoloogia ja uurimismeetodite, sealhulgas tehisintellekti kiiret arengut, on Euroopa Liidu tasandil vaja täiendavaid kaasaegseid suuniseid, et selgitada teadusuuringute piire.

---

400 TEHIK e-kiri autorile (9. veebruar 2024).

401 Isikuandmete kaitse seaduse ning teadus- ja arendustegevuse ning innovatsiooni korralduse seaduse muutmise seaduse eelnõu (6. november 2025) (n 382).

402 OECD (n 77) 45.

403 European Data Protection Board, 'Guidelines 05/2020 on Consent under Regulation 2016/679' (Version 1.1, Adopted on 4 May 2020)' (n 244) para 153; European Data Protection Supervisor (n 181) 11–12.

3. Vajalik on välja töötada suunised koos praktiliste näidetega selle kohta, mida tähendab avalik huvi teadusuuringute kontekstis. Riigisiseste andmetele juurdepääsu mehhanismide puhul võib nendes suunistes arvestada liikmesriigi kultuurilist tausta ja eetilisi väärtusi. Vastavad suunised võib välja töötada koostöös eetikakomiteede ning teadlaste ja andmesubjektide esindajatega. Suunised selle kohta, millised teadusuuringud on Euroopa terviseandmeruumi mehhanismis lubatud, tuleb välja töötada liikmesriikide üleselt. EL terviseandmeruumi määrusega hõlmamata eetiliste väärtuste kaitse tagamiseks peavad liikmesriigid kehtestama eetilise hindamise nõude.[404]
4. Avaliku huvi hindamisel tuleb arvestada teadusprojektiga kaasnevate riskide ja kasu suhet. Mida suurem on teadusprojekti väärtus ühiskonnale, seda enam on õigustatud privaatsuse ja isikuandmete kaitsega seotud riskid. Projektid, millel puudub või on väga vähene ühiskondlik väärtus, ei õigusta selliste riskide võtmist.
5. Riigisisestes andmetele juurdepääsu mehhanismides tuleb kehtestada nõue avalikustada uurimistulemused, nähes samas ette mõistliku ooteperioodi õigustatud konkurentsihuvi kaitsmiseks.[405]
6. Üldjuhul tuleb andmesubjektide vastuväiteid ja loobumisi aktsepteerida nii riigisisestes andmetele juurdepääsu mehhanismides kui ka Euroopa terviseandmeruumi mehhanismis. Erandid sellest peavad olema võimalikud tingimusel, et sellise erandi vajadust on sõltumatult hinnatud, kaaludes ka erandi tegemise riske ja kasu.[406] Ka nende teadusprojektide puhul, kus on üldreeglina põhjendatud vastuväidetega ja loobumistega mitte arvestada, peab andmesubjektide vastuväiteid kaaluma.
7. Liikmesriigid peavad looma kanali (nt veebiportaali kaudu) Euroopa terviseandmeruumi määrusest tuleneva loobumisõiguse kasutamiseks ja IKÜM-s sätestatud vastuväite esitamise õiguse kasutamiseks ning nende õiguste kohta teabe saamiseks.

6. Tuleviku väljavaated

Võrreldes praeguste Eesti ja Soome riigisiseste mehhanismidega ei ole Euroopa terviseandmeruumi mehhanismis oodata suuri muudatusi avaliku huvi hindamises ega teadusuuringu mõiste tõlgendamises.[407] Võrreldes Eesti riigisisese regulat-

[404] Euroopa terviseandmeruumi määrus, artikkel 55(2).

[405] Euroopa terviseandmeruumi mehhanismis on see nõue juba olemas (Euroopa terviseandmeruumi määruse artikkel 61(4)).

[406] Euroopa terviseandmeruumi mehhanismis tähendab see, et liikmesriigid peavad ette nägema erandi loobumisõigusest olulistel avaliku huviga seotud põhjustel, nagu lubab määruse artikkel 71 lg 4.

[407] Ehkki Eesti ja Soome õigusaktides ei nõuta, et teadusuuringud peavad kõikidel juhtudel olema avalikes huvides, hinnatakse andmetele juurdepääsu menetlemisel vähemalt osaliselt avaliku huvi olemasolu, nagu on täpsemalt selgitatud doktoritöö osaks olevas Publikat-

siooniga on oodata siiski olulist muudatust seoses loobumisõiguse (*opt-out*) lisandumisega Euroopa terviseandmeruumi mehhanismis, mis tähistab nihet andmesubjektide autonoomia ja enesemääramisõiguse kaitsmise suunas. Kuigi doktoritöö osaks olevas Publikatsioonis III hoiatatakse, et on oht, et liikmesriigid võivad sellest loobumisõigusest ette näha laiaulatuslikke erandeid, on Euroopa terviseandmeruumi määruse üldine suundumus siiski andmesubjekti autonoomia suurem kaitse.

Eesti ja Soome mehhanismide võrdlus võimaldab hinnata ka piiriülese teaduskoostöö jaoks vajalikku reeglite sarnasust. Doktoritöö tulemused ei anna põhjust arvata, et avaliku huvi nõue või teadusuuringu mõiste sisustamine õiguslikus aluses takistaks piiriülest teaduskoostööd Eesti ja Soome vahel. Pigem viitab asjaolu, et nii Eestis kui ka Soomes on võimalik teadusuuringute õiguslikul alusel teha arendus- ja innovatsioonitegevusi, sarnasele laiale tõlgendusele.[408] Kuigi Eesti terviseinfosüsteemi ja Soome Findata lähenemisviisid vastuväidete esitamise õigusele erinevad radikaalselt, ei takista see tingimata piiriülest teaduskoostööd. Findata mehhanismis oli 2025. aasta seisuga vastuväidete arv ligikaudu 2000,[409] mis tähendab ~0,035% elanikkonnast, mis ei pruugi ohustada andmete esinduslikkust või võrreldavust. Lisaks on Soomes erandkorras võimalik andmetele juurdepääs ka sõltumata esitatud vastuväidetest.[410] Seega ei takista doktoritöös analüüsitud õiguslikud piirangud piiriülest teaduskoostööd kahe liikmesriigi vahel. Samas võivad piiriülest teadustööd takistada muud aspektid, näiteks Soome õigusaktides sisalduv nõue kasutada konkreetsetele nõuetele vastavaid turvalisi andmetöötluskeskkondi. Piiriülese koostöö edendamiseks on selle nõude osas vastu võetud paindlikkust suurendavad muudatused, mis jõustuvad 1. mail 2026.[411]

Järgnevatel aastatel peavad andmetöötlejad ja andmesubjektid tegutsema pidevalt muutuvas õiguslikus keskkonnas. Tulevikus on vaja analüüsida, millal on pseudonüümitud terviseandmed teadusuuringutes käsitatavad isikuandmetena, võttes arvesse Euroopa Kohtu praktikat ja IKÜM-s sisalduva isikuandmete mõiste muutmise ettepanekuid.[412] Lisaks on Euroopa komisjon teinud ettepaneku defineerida teadusuuringu mõiste IKÜM-s, mis võib õigusraamistikku veelgi ümber kujundada.[413] Soomes jõustuvad terviseandmete teisest kasutust reguleeriva

---

sioonis I. Kuigi Euroopa terviseandmeruumi määrus sätestab teadusuuringutele kriteeriumid, mida võib käsitada avalikku huvi nõuetena, ei ole need kriteeriumid liiga ranged, nagu on selgitatud katusepeatüki punktis 3.3.1.

408 Täpsem analüüs on esitatud doktoritöö osaks olevas Publikatsioonis II.

409 *Hallituksen esitys HE 87/2025 vp* (n 109), p 4.2.7.4.

410 *Tietosuojalaki* 1050/2018, § 31.

411 Hallituksen esitys HE 87/2025 vp (n 109), p 7.1, § 51c; *Laki sosiaali- ja terveystietojen toissijaisesta käytöstä annetun lain muuttamisesta* 1159/2025, § 51c.

412 Kohtuasi C-413/23 P *EDPS v SRB* (CJEU 4 September 2025); Commission, 'Digital Omnibus' (n 112), art 3(1)(a). Vt sel teemal Euroopa Kohtu praktikat laiemalt hõlmavat aruetlu: Line Lundström and Santa Slokenberga, 'Evolution of Personal Data in the Court of Justice's Case Law and Implications for Scientific Research' (2026) 9 Nordic Journal of European Law 25 <https://doi.org/10.36969/njel.v9i1.28394>.

413 Commission, 'Digital Omnibus' (n 112), art 3(1)(b).

seaduse muudatused 1. mail 2026.[414] Eestis on doktoritöö kirjutamise lõpufaasis tehtud ettepanekud isikuandmete kaitse seaduse ulatuslikuks muutmiseks teadusuuringuid puudutavas osas.[415] Kuna need muudatused ei puuduta Euroopa terviseandmeruumi rakendamist, on tulevikus oodata veel olulisi muudatusi.

Teadusuuringute vabadust ning eraelu puutumatust ja isikuandmete kaitse põhiõigusi on võimalik optimaalselt tasakaalustada doktoritöös välja töötatud mudeli abil, mis on asjakohane nii praeguste kui ka tulevaste andmetele juurdepääsu mehhanismide puhul. Doktoritöös esitatud mudel annab liikmesriikidele praktilise raamistiku riigisiseste andmetele juurdepääsu mehhanismide täiustamiseks ja Euroopa terviseandmeruumi määruse rakendamiseks. Kombineerides sõltumatud hindamismenetlused, selged kriteeriumid teadusuuringute mõiste tõlgendamiseks, praktilised juhised avaliku huvi nõude kohta ja andmesubjektide proportsionaalsed sekkumise õigused, täidab doktoritöös esitatud mudel IKÜM ja Euroopa terviseandmeruumi määruse poolt jäetud lüngad.

[414] *Laki sosiaali- ja terveystietojen toissijaisesta käytöstä annetun lain muuttamisesta* 1159/2025, § 60.

[415] Isikuandmete kaitse seaduse ning teadus- ja arendustegevuse ning innovatsiooni korralduse seaduse muutmise seaduse eelnõu (6. november 2025) (n 382).

PUBLICATIONS

CURRICULUM VITAE

Name Maret Kruus
Date of birth 16.10.1989
E-mail maret.kruus@gmail.com

Career

2024–	Law firm WALLESS, attorney-at-law
2021–	University of Tartu, School of Law, PhD Student
2018–2024	Law firm NOVE, attorney-at-law
17.04.2023–16.05.2023	University of Helsinki, visiting researcher
2014–2018	Law firm Ellex Raidla, lawyer, attorney

Education

2013–2014	University of Sheffield, Faculty of Law, visiting student
2011–2014	University of Tartu, Faculty of Law, Master's degree (cum laude)
2008–2011	University of Tartu, Faculty of Law, baccalaureus

Publications

Kruus, Maret (2025). Opting Out of Scientific Research with Health Data: The Limits of the EHDS and the GDPR. European Journal of Health Law, 32 (2), 165–189. DOI: 10.1163/15718093-BJA10141.

Kruus, Maret (2023). The Public Interest Requirement in the Secondary Use of Health Data in Scientific Research: The Examples of Estonia and Finland. Juridica International, 32, 64–73. DOI: 10.12697/JI.2023.32.06.

Kruus, M. (2023). Development and Innovation Activities with Health Data: On What Legal Basis? Examples of Estonia, Finland, and the EHDS Proposal. European Health & Pharmaceutical Law Review, 7 (3), 97–108. DOI: 10.21552/ehpl/2023/3/4.

Kruus, Maret; Matjus, Mari (2020). Arsti kohustused Eesti kohtupraktikas [Physician's Legal Obligations according to Estonian Case-law]. Lege Artis, February.

Kruus, Maret; Int, Rainis; Nõmper, Ants (2018). The Patient's Will – Why and for Whom? Forms, Formalisation, and Implementation Issues. Juridica International, 27, 158–169. DOI: 10.12697/JI.2018.27.14.

Kruus, Maret; Nõmper, Ants (2018). Riigi kohustused tervise kaitse tagamiseks: vaktsineeritute osakaalu suurendamine õiguslike meetmetega [The State's Obligations in Ensuring the Protection of Health: Increasing the Vaccination Rate Using Legal Measures]. Juridica, 3, 159–168.

Kruus, Maret; Nõmper, Ants (2018). Meditsiiniõiguslik tagasivaade 2017. aastale – vaktsineerimist soodustavad meetmed [Review of 2017 from Medical Law perspective – Measures for Increasing the Vaccination Rate]. Eesti Arst, 97 (3), 166–169. DOI: 10.15157/ea.v0i0.14077.

ELULOOKIRJELDUS

Nimi Maret Kruus
Sünniaeg 16.10.1989
E-post maret.kruus@gmail.com

Teenistuskäik

2024– Advokaadibüroo WALLESS, vandeadvokaat
2021– Tartu Ülikool, õigusteaduskond, doktorant
2018–2024 Advokaadibüroo NOVE, vandeadvokaat
17.04.2023–16.05.2023
Helsingi Ülikool, doktorantuuri välislähetus
2014–2018 Advokaadibüroo Ellex Raidla, jurist, advokaat

Haridustee

2013–2014 Sheffieldi Ülikool, õigusteaduskond (vahetusaasta)
2011–2014 Tartu Ülikool, õigusteaduskond, magistrikraad (cum laude)
2008–2011 Tartu Ülikool, õigusteaduskond, bakalaureusekraad

Publikatsioonid

Kruus, Maret (2025). Opting Out of Scientific Research with Health Data: The Limits of the EHDS and the GDPR. European Journal of Health Law, 32 (2), 165–189. DOI: 10.1163/15718093-BJA10141.

Kruus, Maret (2023). The Public Interest Requirement in the Secondary Use of Health Data in Scientific Research: The Examples of Estonia and Finland. Juridica International, 32, 64–73. DOI: 10.12697/JI.2023.32.06.

Kruus, M. (2023). Development and Innovation Activities with Health Data: On What Legal Basis? Examples of Estonia, Finland, and the EHDS Proposal. European Health & Pharmaceutical Law Review, 7 (3), 97–108. DOI: 10.21552/ehpl/2023/3/4.

Kruus, Maret; Matjus, Mari (2020). Arsti kohustused Eesti kohtupraktikas. Lege Artis, February.

Kruus, Maret; Int, Rainis; Nõmper, Ants (2018). The Patient's Will – Why and for Whom? Forms, Formalisation, and Implementation Issues. Juridica International, 27, 158–169. DOI: 10.12697/JI.2018.27.14.

Kruus, Maret; Nõmper, Ants (2018). Riigi kohustused tervise kaitse tagamiseks: vaktsineeritute osakaalu suurendamine õiguslike meetmetega. Juridica, 3, 159–168.

Kruus, Maret; Nõmper, Ants (2018). Meditsiiniõiguslik tagasivaade 2017. aastale – vaktsineerimist soodustavad meetmed. Eesti Arst, 97 (3), 166–169. DOI: 10.15157/ea.v0i0.14077.

DISSERTATIONES IURIDICAE UNIVERSITATIS TARTUENSIS

1. **Херберт Линдмяэ**. Управление проведением судебных экспертиз и его эффективность в уголовном судопроизводстве. Тарту, 1991.
2. **Peep Pruks**. Strafprozesse: Wissenschaftliche “Lügendetektion”. (Instrumentaldiagnostik der emotionalen Spannung und ihre Anwendungsmöglichkeiten in Strafprozess). Tartu, 1991.
3 **Marju Luts**. Juhuslik ja isamaaline: F. G. v. Bunge provintsiaalõigusteadus. Tartu, 2000.
4. **Gaabriel Tavits**. Tööõiguse rakendusala määratlemine töötaja, tööandja ja töölepingu mõistete abil. Tartu, 2001.
5. **Merle Muda**. Töötajate õiguste kaitse tööandja tegevuse ümberkorraldamisel. Tartu, 2001.
6. **Margus Kingisepp**. Kahjuhüvitis postmodernses deliktiõiguses. Tartu, 2002.
7. **Vallo Olle**. Kohaliku omavalitsuse teostamine vahetu demokraatia vormis: kohalik rahvaalgatus ja rahvahääletus. Tartu, 2002.
8. **Irene Kull**. Hea usu põhimõte kaasaegses lepinguõiguses. Tartu, 2002.
9. **Jüri Saar**. Õigusvastane käitumine alaealisena ja kriminaalsed karjäärid (Eesti 1985–1999 longituuduurimuse andmetel). Tartu, 2003.
10. **Julia Laffranque**. Kohtuniku eriarvamus. Selle võimalikkus ja vajalikkus Eesti Vabariigi Riigikohtus ja Euroopa Kohtus. Tartu, 2003.
11. **Hannes Veinla**. Ettevaatusprintsiip keskkonnaõiguses. Tartu, 2004.
12. **Kalev Saare**. Eraõigusliku juriidilise isiku õigussubjektsuse piiritlemine. Tartu, 2004.
13. **Meris Sillaots**. Kokkuleppemenetlus kriminaalmenetluses. Tartu, 2004.
14. **Mario Rosentau**. Õiguse olemus: sotsiaalse käitumise funktsionaalne programm. Tartu, 2004.
15. **Ants Nõmper**. Open consent – a new form of informed consent for population genetic databases. Tartu, 2005.
16. **Janno Lahe**. Süü deliktiõiguses. Tartu, 2005.
17. **Priit Pikamäe**. Tahtluse struktuur. Tahtlus kui koosseisupäraste asjaolude teadmine. Tartu, 2006.
18. **Ivo Pilving**. Haldusakti siduvus. Uurimus kehtiva haldusakti õiguslikust tähendusest rõhuasetusega avalik-õiguslikel lubadel. Tartu, 2006.
19. **Karin Sein**. Ettenähtavus ja rikutud kohustuse eesmärk kui lepingulise kahjuhüvitise piiramise alused. Tartu, 2007.
20. **Mart Susi**. Õigus tõhusale menetlusele enda kaitseks – Euroopa Inimõiguste ja Põhivabaduste Kaitse Konventsiooni artikkel 13 Euroopa Inimõiguste Kohtu dünaamilises käsitluses. Tartu, 2008.
21. **Carri Ginter**. Application of principles of European Law in the supreme court of Estonia. Tartu, 2008.
22. **Villu Kõve**. Varaliste tehingute süsteem Eestis. Tartu, 2009.

23. **Katri Paas**. Implications of Smallness of an Economy on Merger Control. Tartu, 2009.
24. **Anneli Alekand**. Proportsionaalsuse printsiip põhiõiguste riive mõõdupuuna täitemenetluses. Tartu, 2009.
25. **Aleksei Kelli**. Developments of the Estonian Intellectual Property System to Meet the Challenges of the Knowledge-based Economy. Tartu, 2009.
26. **Merike Ristikivi**. Latin terms in the Estonian legal language: form, meaning and influences. Tartu, 2009.
27. **Mari Ann Simovart**. Lepinguvabaduse piirid riigihankes: Euroopa Liidu hankeõiguse mõju Eesti eraõigusele. Tartu, 2010.
28. **Priidu Pärna**. Korteriomanike ühisus: piiritlemine, õigusvõime, vastutus. Tartu, 2010.
29. **René Värk**. Riikide enesekaitse ja kollektiivse julgeolekusüsteemi võimalikkusest mitteriiklike terroristlike rühmituste kontekstis. Tartu, 2011.
30. **Paavo Randma**. Organisatsiooniline teovalitsemine – *täideviija täideviija taga* kontseptsioon teoorias ja selle rakendamine praktikas. Tartu, 2011.
31. **Urmas Volens**. Usaldusvastutus kui iseseisev vastutussüsteem ja selle avaldumisvormid. Tartu, 2011.
32. **Margit Vutt**. Aktsionäri derivatiivnõue kui õiguskaitsevahend ja ühingujuhtimise abinõu. Tartu, 2011.
33. **Hesi Siimets-Gross**. Das „Liv-, Est- und Curlaendische Privatrecht" (1864/65) und das römische Recht im Baltikum. Tartu, 2011.
34. **Andres Vutt**. Legal capital rules as a measure for creditor and shareholder protection. Tartu, 2011.
35. **Eneken Tikk**. Comprehensive legal approach to cyber security. Tartu, 2011.
36. **Silvia Kaugia**. Õigusteadvuse olemus ja arengudeterminandid. Tartu, 2011.
37. **Kadri Siibak**. Pangandussüsteemi usaldusväärsuse tagamine ja teabekohustuste määratlemine finantsteenuste lepingutes. Tartu, 2011.
38. **Signe Viimsalu**. The meaning and functioning of secondary insolvency proceedings. Tartu, 2011.
39. **Ingrid Ulst**. Balancing the rights of consumers and service providers in electronic retail lending in Estonia. Tartu, 2011.
40. **Priit Manavald**. Maksejõuetusõigusliku regulatsiooni valikuvõimaluste majanduslik põhjendamine. Tartu, 2011, 193 lk.
41. **Anneli Soo**. Remedies against ineffectiveness of defense counsel. Judicial supervision over the performance of defense counsel in Estonian criminal proceedings. Tartu, 2011, 282 p.
42. **Arnold Sinisalu**. Mõjutustegevuse piirid rahvusvahelises õiguses. Tartu, 2012, 277 lk.
43. **Kaspar Lind**. Käibemaksupettused ja nende tõkestamine. Tartu, 2012, 155 lk.
44. **Berit Aaviksoo**. Riigi otsustusruumi ahenemine: kodakondsus nüüdisaegses Euroopas. Tartu, 2013, 368 lk.
45. **Kai Kullerkupp**. Vallasomandi üleandmine. Õigusdogmaatiline raamistik ja kujundusvõimalused. Tartu, 2013, 398 lk.

46. **Iko Nõmm**. Käibekohustuse rikkumisel põhinev deliktiõiguslik vastutus. Tartu, 2013, 212 lk.
47. **Piia Kalamees**. Hinna alandamine õiguskaitsevahendite süsteemis. Tartu, 2013, 232 lk.
48. **Irina Nossova**. Russia's international legal claims in its adjacent seas: the realm of sea as extension of Sovereignty. Tartu, 2013, 205 p.
49. **Age Värv**. Kulutuste kondiktsioon: teise isiku esemele tehtud kulutuste hüvitamine alusetu rikastumise õiguses. Tartu, 2013, 273 lk.
50. **Elise Vasamäe**. Autoriõiguste ja autoriõigusega kaasnevate õiguste jätkusuutlik kollektiivne teostamine. Tartu, 2014, 308 lk.
51. **Marko Kairjak**. Keerukuse redutseerimine Eesti õiguses karistusseadustiku § 217^2 objektiivse koosseisu relatiivsete õigusmõistete sisustamise näitel. Tartu, 2015, 179 lk.
52. **Kadi Pärnits**. Kollektiivlepingu roll ja regulatsioon nüüdisaegsetes töösuhetes. Tartu, 2015, 179 lk.
53. **Leonid Tolstov**. Tort liability of the director to company's creditors. Tartu, 2015, 169 p.
54. **Janar Jäätma**. Ohutõrjeõigus politsei- ja korrakaitseõiguses: kooskõla põhiseadusega. Tartu, 2015, 242 lk.
55. **Katre Luhamaa**. Universal Human Rights in National Contexts: Application of International Rights of the Child in Estonia, Finland and Russia. Tartu, 2015, 217 p.
56. **Mait Laaring**. Eesti korrakaitseõigus ohuennetusõigusena. Tartu, 2015, 267 lk.
57. **Priit Kama**. Valduse ja kohtuliku registri kande publitsiteet Eesti eraõiguses. Tartu, 2016, 194 lk.
58. **Kristel Degener**. Abikaasade vara juurdekasvu tasaarvestuse varasuhe. Tartu, 2016, 242 lk.
59. **Olavi-Jüri Luik**. The application of principles of European insurance contract law to policyholders of the Baltic states: A measure for the protection of policyholders. Tartu, 2016, 228 p.
60. **Kaido Künnapas**. Maksukohustuse täitmise preventiivne tagamine enne maksukohustuse tuvastamist: ettevaatuspõhimõte maksumenetluses.Tartu, 2016, 388 lk.
61. **Eve Fink**. Õiguspärase ootuse kaitse põhimõtte eeldused ja piirid Euroopa liidu õiguses. Tartu, 2016, 245 lk.
62. **Arsi Pavelts**. Kahju hüvitamise nõue täitmise asemel ostja õiguste näitel. Tartu, 2017, 414 lk.
63. **Anna-Maria Osula**. Remote search and seizure of extraterritorial data. Tartu, 2017, 219 p.
64. **Alexander Lott**. The Estonian straits. Exceptions to the strait regime of innocent or transit passage. Tartu, 2017, 259 p.
65. **Dina Sõritsa**. The Health-care Provider's Civil Liability in Cases of Prenatal Damages. Tartu, 2017, 365 p.

66. **Einar Vene**. Ajaline faktor halduskohtumenetluses tühistamis- ja kohustamiskaebuse lahendamist ning rahuldamist mõjutava tegurina. Tartu, 2017, 294 lk.
67. **Laura Feldmanis**. Süüteokatsest loobumise instituudi põhjendus ja kohaldatavuse piirid kuritegelikule eeltegevusele. Tartu, 2017, 292 lk.
68. **Margit Piirman**. Inimese pluripotentsete tüvirakkudega seotud leiutiste patentimise piirangud vastuolu tõttu avaliku korra ja moraaliga (Eesti patendiõiguse näitel). Tartu, 2018, 246 lk.
69. **Kerttu Mäger**. The Taming of the Shrew: Understanding the Impact of the Council of Europe's Human Rights Standards on the State Practice of Russia. Tartu, 2018, 305 p.
70. **Tambet Grauberg**. Õiguse kuritarvitamise keelamise põhimõte: Euroopa Kohtu seisukohtade mõju liikmesriigi maksuõigusele. Tartu, 2018, 277 lk.
71. **Maarja Torga**. The Conflict of Conflict Rules – the Relationship between European Regulations on Private International Law and Estonian Legal Assistance Treaties Concluded with Third States. Tartu, 2019, 252 p.
72. **Liina Reisberg**. Semiotic model for the interpretation of undefined legal concepts and filling legal gaps. Tartu, 2019, 232 p.
73. **Mari Schihalejev**. Debtor-Related Creditors' Claims in Insolvency Proceedings. Tartu, 2019, 137 p.
74. **Ragne Piir**. Mandatory Norms in the Context of Estonian and European International Contract Law: The Examples of Consumers and Posted Workers. Tartu, 2019, 117 p.
75. **Madis Ernits**. Constitution as a system. Tartu, 2019, 201 p.
76. **Kärt Pormeister**. Transparency in relation to the data subject in genetic research – an analysis on the example of Estonia. Tartu, 2019, 184 p.
77. **Annika Talmar**. Ensuring respect for International Humanitarian Law 70 years after the adoption of the Geneva Conventions of 1949. Tartu, 2020, 286 p.
78. **Liliia Oprysk**. Reconciling the Material and Immaterial Dissemination Rights in the Light of the Developments under the EU Copyright *Acquis*. Tartu, 2020, 397 p.
79. **Katrin Sepp**. Legal Arrangements in Estonian Law Similar to Family Trusts. Tartu, 2020, 163 p.
80. **Taivo Liivak**. Tort Liability for Damage Caused by Self-driving Vehicles under Estonian Law. Tartu, 2020, 206 p.
81. **Anne Veerpalu**. Regulatory challenges to the use of distributed ledger technology: Analysis of the compliance of existing regulation with the principles of technology neutrality and functional equivalence. Tartu, 2021, 365 p.
82. **Maren Krimmer**. Protecting Property Rights through International Treaties but With Constitutional Brakes: The Case of Contemporary Russia. Tartu, 2021, 153 p.
83. **Seili Suder**. Protection of employee privacy in the digital workplace. Tartu, 2021, 247 p.

84. **Tiina Mikk**. Päritavuse kriteeriumid ja päritavuse välistamise võimalused digitaalse pärandi kontekstis e-konto näitel. Tartu, 2021, 387 lk.
85. **Märt Maarand**. Credit institution's limited rights for appealing the recovery and resolution measures in the European Union laws. Tartu, 2022, 159 p.
86. **Pierre Thévenin**. Soviet and Russian Approach to the Law of the Sea: Liberalism and Local Resistance. Tartu, 2022, 296 p.
87. **Annemari Õunpuu**. Kommertspant ettevõtja vallasvarale. Tartu, 2023, 495 lk.
88. **Kadri Härginen**. Due Diligence Obligations of a Contracting Authority Under the EU Public Procurement Law. Tartu, 2023, 180 p.
89. **Artur Simonyan**. Regional International Law in Eurasia. Tartu, 2024, 307 p.
90. **Sevanna Poghosyan**. Soviet and Russian approaches to democracy in international law. Tartu, 2024, 221 p.
91. **Maris Vutt**. Legal Opportunities for Using Digital Solutions in Decision-Making for a Limited Liability Company. Tartu, 2024, 180 p.
92. **Liva Rudzite-Celmina**. Creations Involving Artificial Intelligence Under the European Patent Convention: Legal Implications and Potential Solutions. Tartu, 2025, 254 p.
93. **Hannes Vallikivi**. Eesti Vabariik kui õigusriik. Poliitiliste põhivabaduste õiguslik kaitse 1918–1940. Tartu, 2025, 390 p.
94. **Susann Liin**. Varaühisus ja ühisvara valitsemine. Tartu, 2025, 574 p.
95. **Anna Markina**. Operationalising ISRD Evidence for Youth Justice in Estonia: A Child-Rights Framework for Proportionate, Least-Restrictive Responses. Tartu, 2025, 245 p.
96. **Triinu Rennu**. Maakorraldusõigus kui riigi maapoliitika vahend maaõiguslike suhete korrastamisel ja maakasutuse moderniseerimisel Eesti Vabariigis (1918–1940). Tartu, 2026, 296 p.