

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

Citation

Kist, I. R. (2024, June 5). *A fair balance: health data protection and the promotion of health data use for clinical and research purposes*. Retrieved from https://hdl.handle.net/1887/3759726

Version: Publisher's Version

Licence agreement concerning inclusion of doctoral

License: thesis in the Institutional Repository of the University

of Leiden

Downloaded from: https://hdl.handle.net/1887/3759726

Note: To cite this publication please use the final published version (if applicable).

Irith Rolinka Kist

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

Issue date: 5 June 2024

"In my view, it is not straightforward to conclude from the GDPR that its objective is to grant data subjects control over their personal data as a right in itself, or that data subjects must have the greatest control possible over those data"

Opinion of Advocate General Campos Sánchez-Bordona of 6 October 2022 in case C-300/21, para 74

Cover image credits: cover design by Hettie Clements Print: ProefschriftMaken | www.proefschriftmaken.nl

ISBN: 978-94-6469-982-1

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

Proefschrift

ter verkrijging van de graad van doctor aan de Universiteit Leiden op gezag van de Rector Magnificus Prof. dr. ir. H. Bijl, volgens besluit van het College voor Promoties

te verdedigen op 5 juni 2024 klokke 10 uur

door Irith Rolinka Kist

Geboren te Broek in Waterland in 1972

Promotores:

Prof. dr. mr. G.J. Zwenne Prof. dr. ir. M.K. Schmidt

Promotiecommissie:

Prof. dr. mr. A. Berlee (Open Universiteit)

Prof. mr. dr. ir. B.H.M. Custers

Dr. mr. H.L. Janssen (Universiteit van Amsterdam)

Prof. dr. R.A. Verheij (Tilburg University)

Acknowledgments

This thesis is the fruit of research conducted from March 2020 to February 2023. The final revisions took place in February 2024. I express my sincere gratitude to my supervisors, prof. dr. mr. Gerrit-Jan Zwenne and prof. dr. ir. Marjanka Schmidt, for their excellent guidance and support during the entire process. I would like to thank Mrs. Renée Dekker with whom I wrote the final article, included in chapter 6 of this thesis. I am grateful to the Netherlands Cancer Institute – Antoni van Leeuwenhoek hospital in Amsterdam for the opportunity to combine my responsibilities as data protection officer with this thesis. I thank all my colleagues, both in the Netherlands and abroad, and both within the Netherlands Cancer Institute and beyond, for their valuable insights. Lastly, I am grateful to my family and friends for their inspiration and understanding.

This thesis is dedicated to the memory of my father Johannes Kist (1939 - 2023).

Contents

Acknowledgments	5
1. Introduction	11
1.1. Research questions	15
1.2. Scope of this thesis	16
1.3. Legal research methodology	17
1.3.1. Identification of the research field	18
1.3.2. Collection of the sources	20
1.3.3. Analysis of the sources	21
1.3.4. Interpretation of the sources	22
1.4. Legal framework of data protection and privacy	23
1.5. Concepts in data protection and health law relevant for this thesis	27
1.6. Design, structure and statement of authorship	42
2. The sustainability of consent by elderly persons developing dementia	49
2.1. Introduction	51
2.2. Legal framework	53
2.3. Dignity, self-determination, autonomy, and respect for one's privacy	54
2.4. Case study: Mr. X	56
2.5. Conclusion	58
3. Assessment of the Dutch rules on health data in the light of the GDPR	61
3.1. Introduction	63
3.1.1. Scope	63
3.1.2. Aim	64
3.2. EU legal framework	65
3.2.1. GDPR consent	66
3.2.2. Alternatives to consent for secondary health research in the GDPR	68
3.3. Legal framework in the Netherlands: consent and other lawful bases	70
3.3.1. Consent in Dutch law	71
3.3.2. Alternatives to consent for secondary health research in Dutch law	72
3.4. In search of the (most) appropriate lawful basis for secondary health	73
research: three examples	
3.5. Avenues for further exploration	76
3.6. Conclusion	78
4. The Dutch Code of Conduct for Health Research and the implementation	83
of the lawful basis of consent	
4.1. Introduction	85
4.1.1. Case study	87
4.1.2. The legal framework	87
4.1.3 The lawfulness of processing	89

4.2. Explicit consent as a point of departure in the Dutch Code of Conduct for Health Research	90
4.3. Consent modalities in the context of re-using health data for scientific research in the Dutch Code of Conduct	91
4.4. The relationship between consent in the WGBO, the draft Wzl, the GDPR and the UAVG with respect to the secondary use of health data for scientific research	93
4.5. Four other exceptions to the lawful basis of consent in the Dutch Code of Conduct	96
4.6. Conclusion	97
5. Proposal for a new data regime in the UK: an avenue to be explored by the EU	101
5.1. Introduction	103
5.2. UK GDPR – Limitations and deficiencies of scientific research	104
5.2.1. Barriers to responsible innovation and data flows	104
5.2.2. Barriers to scientific research	104
5.2.3. Rule-based regulatory compliance	106
5.3. Proposal for a UK GDPR amendment	106
5.3.1. Reducing barriers to responsible innovation and data flows	106
5.3.2. Reducing barriers to scientific research	107
5.3.3. Risk-based regulatory compliance	108
5.3.4. Analysis: the UK's changes to the retained EU law	109
5.4. Potential benefits of the UK GDPR amendment for scientific research: the example of the Netherlands	109
5.5. Conclusion	111
6. Closing the gaps in patients' data protection rights: a glance into the future with a Dutch case study	115
6.1. Introduction	117
6.1.1. Scope	119
6.1.2. Aim and research question	119
6.1.3. Legal research methodology	120
6.2. Legal background	121
6.2.1. Individual self-determination: the individual's autonomy	122
6.2.2. Informational self-determination: the individual's control over his data	123
6.2.3. Challenges to Individual and informational self-determination in the light of health innovations	126
6.2.4. Dutch case study: Mrs. Johnson's diagnosis	127
6.3. Health data protection: what has changed?	128
6.3.1. The changing relationship between the traditional care provider and the individual	129

6.3.2. The individual's health data and his position as a care receiver in a commercial context	130
6.4. Filling the gaps: data protection in health innovations	131
6.4.1. Filling the legislative gap: protecting the individual and his data by commercial companies	132
6.4.2. Filling the governance gap and overlap	133
6.5. Conclusion	137
7. Conclusions, recommendations and final considerations for future research	141
7.1. Answering the main research question	143
7.1.1. The legal framework	146
7.1.2. The legitimation for the use of health data	146
7.1.3. Individual rights or interests and the free flow of data	148
7.1.4. Monitoring compliance	148
7.2. Recommendations	149
7.3. Final considerations for future research	153
8. Bibliography	158
9. Index of cases	177
10. Opinions, Guidelines and Recommendations by the EDPB and EDPS	179
11. List of professional activities and affiliations	181
12. Curriculum Vitae	185
13. Summary	186
14. Summary in Dutch (Samenvatting)	194