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1. Pormeister, Kärt (2017). Informed consent to sensitive personal data processing for the performance of digital consumer contracts on the example of "23andMe". *Journal of European Consumer and Market Law*, 6 (1), 17–23.
2. Pormeister, Kärt (2017). The GDPR and Big Data: Leading the Way for Big Genetic Data? In: Schweighofer, E. et al. (Eds.). Privacy Technologies and Policy (3–18). Springer. (Lecture Notes in Computer Science).
3. Pormeister, Kärt (2017). Genetic data and the research exemption: is the GDPR going too far? *International Data Privacy Law*, 7 (2), 137–146, https://doi.org/10.1093/idpl/ipx006.
4. Pormeister, Kärt (2018). Genetic research and consent: on the crossroads of human and data research. *Bioethics*, 33(3), 347–356, https://doi.org/10.1111/bioe.12475.
5. Pormeister, Kärt. Regulatory environment for biobanking in Estonia. In: Slokenberga, S. et al. (Eds.). Individual rights, public interest and biobank research. Article 89 GDPR and European legal responses. Springer 2020 (to be published).

ANALYTICAL COMPENDIUM TO A CUMULATIVE DISSERTATION

I. INTRODUCTION

Transparency is one of the three core principles embedded into to the General Data Protection Regulation[1] (GDPR) of the European Union, requiring the use of any personal data to be carried out in a transparent manner in relation to the individual whose data is concerned. The transparency of, and the informed consent to, personal data processing and the purposes thereof have been regarded to be in the centre of the struggle to solve the conflict between individual privacy on the one hand, and commercial freedom on the other.[2] However, the need for transparency in regard to personal data processing and the scope of the principle of transparency are not limited to commercial uses of personal data. The requirement of transparency in relation to the individual (i.e. the data subject) applies whenever data processing activities fall under the scope of the GDPR.

In addition to data processing for commercial purposes, transparency regarding personal data usage is as crucial when it comes to the context of research as transparency is a vital component in ensuring public trust in, and thus support for, research.[3] Transparency becomes particularly relevant when it comes to the research use of personal data regarded as distinctly sensitive and inherently identifying as genetic data.[4]

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[1] Art. 5(1)(a), Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). OJ L119/1.

[2] J. Dickie (1999), p 55.

[3] T.P. van Staa et al. Big Health Data: The need to earn public trust. *BMJ* 2016; 354 doi: https://doi.org/10.1136/bmj.i3636 (Published 14 July 2016).

[4] Evidenced amongst many other sources in, e.g., the International Declaration on Human Genetic Data. UNESCO 2003. The declaration recognizes, "that human genetic data have a special status on account of their sensitive nature since they can be predictive of genetic predispositions concerning individuals and that the power of predictability can be stronger than assessed at the time of deriving the data; they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group; they may contain information the significance of which is not necessarily known at the time of the collection of biological samples; and they may have cultural significance for persons or groups".

The inherently identifying nature of genetic data has been recognized, inter alia, by the European Court of Human Rights, and can be argued based on the case-law of the Court of Justice of the European Union concerning fingerprints. See *S. and Marper v. The United Kingdom*, ECtHR [2008], Applications nos. 30562/04 and 30566/04, ECLI:CE:ECHR:2008: 1204JUD003056204; and Judgement of 17 October 2013, *Schwarz v. Bochum*, C-291/12, ECLI:EU:C:2013:670. See also K. Pormeister. Genetic research and consent: on the crossroads of human and data research. *Bioethics*, 33(3) (2019), 347–356, https://doi.org/10.1111/bioe.12475, 349.

1.1. The research problem

Transparency in relation to the individual participating in research has historically been facilitated via the notion of informed consent, i.e. via the process of providing information to potential research subjects before obtaining their consent to participation in a given research project. The requirement of informed consent for human subject research became a widely recognized part of research ethics with the adoption of the Nuremberg Code[5] in 1947.[6] Although informed consent is generally mainly seen as a vessel for enabling the exercise of autonomy-related rights, its key component is the provision of information prior to obtaining consent. The information provided to the individual should make all relevant nuances of the research project transparent to the potential participant (i.e. most notably, what is the aim of the project, what is required of the participant, and what are the potential risks and benefits involved).[7] Transparency in regard to the intentions of the researcher is what enables the (potential) participant to exercise autonomous decisions concerning participation in the research (e.g. whether to give, withhold, or withdraw consent).[8]

The basic principles of prior informed consent in research have largely remained the same as established in the Nuremberg Code, whilst transcending from ethics to the legal realm as well.[9] A potential participant of research must be informed of the nature, risks and purposes of the research to be undertaken, and participation is conditional on voluntary consent.[10] However, the historic understanding of informed consent in human subject research, and the nature of the information to be provided to a potential participant, is generally focused on the planned physical or psychological intervention to be carried out on the

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5 Full text available at https://history.nih.gov/research/downloads/nuremberg.pdf [Accessed 8 March 2018].

6 The Nuremberg Code "is generally seen as the first authoritative statement of consent requirements in biomedical ethics". N.C. Manson, O. O'neill (2007), p 2.

7 The role of informed consent in facilitating transparency has also been regarded from a broader perspective than transparency in relation to the research participant. For example, it has been suggested that in addition to informing participants, informed consents should be part of the documentation submitted to publicly available registries concerning clinical trials so that any interested parties, including the public, could review the original and any amendments thereafter. See Y. Yazici and H. Yazici. Informed consent: time for more transparency. *Arthritis Research & Therapy* 12(3) (2010), 121.

8 Guidelines on transparency under Regulation 2016/679. Article 29 Data Protection Working Party, 17/EN WP260 rev.01, p 5, para 4. Available at https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=622227 [Accessed 3 May 2019].

9 E.g. the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine ('Oviedo convention'). Oviedo, 4.IV.1997, ETS No. 164.

10 Ibid., Art. 16 Oviedo convention.

research subject.[11] Meanwhile, biomedical research has undergone a paradigm shift as "translational bioinformatics […] has become a key component of biomedical research in the era of precision medicine."[12] This, in turn, has created a reliance in research on the secondary use of biosamples and genetic data due to the high volumes of data needed.[13] This paradigm shift can be described as one from human subject research to human data research; effectively eliminating the need for the direct involvement of individuals.

In this shift from human subject research to human data research, transparency is challenged by increasing data processing and analysis capabilities as data can be easily replicated, transferred and used concurrently and repeatedly in multiple varying research projects anywhere in the world. In addition to general shifts in research stemming from developments in data analysis and transfer capabilities, the nature of genetic data in particular adds another level of complexity to the challenges regarding transparency in relation to individuals in the research context.

With the myriad of possibilities in regard to future and secondary research uses of genetic data, the question of transparency in relation to the individual essentially becomes one regarding the informedness of the individual – i.e. whether the individual can be informed to the extent that the possible future and secondary research uses of their genetic data are genuinely transparent to the individual. As G. Laurie has put it, "how can meaningful informed consent be obtained to future, yet-to-be-determined research?"[14] In addressing this dilemma, some have suggested anonymisation of data as an alternative to consent.[15] This 'binary approach' of consent or anonymise has been criticised[16] – particularly in regard to genomic data as it "serves as a marker unique to the individual" and "cannot, therefore, be completely anonymised"[17]. Furthermore, anonymity is context specific[18] and changes over time, depending on the availability of other data relating to the individual, but also depending on developments in technology and availability of such technology (i.e. the decrease in cost). If anonymity could be guaranteed, the data would be effectively detached from the individual

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[11] This is evident from, e.g., the comments on Arts. 5 and 16 in the Explanatory Report to the Oviedo convention. Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Oviedo, 4.IV.1997, ETS No. 164.

[12] J.D. Tenenbaum. Translational Bioinformatics: Past, Present, and Future. *Genomics Proteomics Bioinformatics* 14(1) (2016), pp 31–41.

[13] Ibid.

[14] G. Laurie (2002), p 292.

[15] I. Ellis, G. Mannion. Humanity versus Utility in the Ethics of Research on: 'Human Genetic Material'. *Genetics Law* 1(5) (2001), p 2.

[16] E.g. E.S. Dove, G. Laurie. Anonymising and sharing individual patient data. *British Medical Journal* 350:h1139 (2015).

[17] E.g. G. Laurie (2002), p 294.

[18] M. Taylor (2012), p 132.

and the question of transparency in relation to the individual would become obsolete. However, since anonymity cannot be guaranteed and, arguably, the concept of anonymous genetic data is an oxymoron, anonymity of genetic data cannot therefore be used as an argument for setting aside individual rights and interests, and the respective need for transparency in order to facilitate the exercise of such rights and interests.

Whilst the notion of prior informed consent still remains relevant today in conventional research scenarios in which physical or psychological interventions are carried out on human subjects, it does not play an equally significant role when it comes to human data research and the secondary uses of biosamples and genetic data retrieved therefrom. In cases where the requirement of informed consent does not apply in genetic research, the question of transparency becomes one of if and how transparency is facilitated in relation to data subjects if information is not provided as part of consent procedures.

Based on the above, this dissertation aims to address three research problems regarding transparency in relation to data subjects in genetic research. The first research problem pertains to the question of the applicability of consent requirements in genetic research and the resulting impact on the potential of informed consent for facilitating transparency. Namely, the issue to be first addressed is "The lack of clarity regarding when researchers need, and do not need, to obtain consent to use genetic data for research purposes".[19] This is a matter that could have been addressed during the reform of the personal data protection framework in the EU. However, the regulatory picture regarding the use of genetic data for research purposes remains fragmented and calls for clarification, particularly in regard to the requirement of consent and the legal possibilities of using genetic data in research without the consent of individuals. This research problem will be addressed from the perspective and on the example of Estonia.

The second research problem to be addressed – in scenarios where consent requirements still apply – is how effective can informed consent be as a vessel for facilitating transparency in relation to data subjects. On the one hand, the potential of informed consent for facilitating transparency faces the above addressed problem of uncertainty regarding the potential future research uses of genetic data. On the other hand, as there are legal alternatives to informed consent for using genetic data in research, the question is how such alternatives for data usage without consent impact the role of informed consent in facilitating transparency.

The third research problem relates to existing alternatives to informed consent in facilitating transparency in relation to data subjects. If informed consent of the individual is not required for the use of genetic data in research, the question is whether any and which legal modalities apply to facilitate transparency in relation to the individual and how effective they are as currently designed.

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[19] M. Taylor (2012), p 217.

1.2. Research objectives and questions

The aim of this dissertation is to critically analyse transparency in relation to the data subject in the context of genetic research in the post-GDPR era on the example of Estonia. As such, the first objective of the dissertation is to analyse and outline the current regulatory framework to determine the role of (informed) consent in research making use of genetic data. The exploration of applicable consent requirements will be accompanied by an analysis of the possible legal bases for the use of biosamples and genetic data in research without consent. This will enable to draw conclusions on how transparency in relation to the individual is affected by the interaction between consent as a legal basis for using genetic data in research on the one hand, and alternative legal bases on the other. Since the research use of both biosamples and genetic data derived therefrom is a matter not comprehensively addressed in international or EU law, Estonian law will be used as an example to outline the contradictions of the current regulatory system in regard to the requirements of consent, alternative legal bases for using genetic data in research, and their combined impact on transparency in relation to the individual. Whilst some have expressed concern that the GDPR might constitute an impediment to research and the re-use of data,[20] this dissertation will exemplify the opposite on the example of Estonia.

However, the problems regarding transparency in genetic research are not solved by and go beyond the notion of informed consent. Transparency becomes a challenge regardless of whether the use of genetic data in research is based on consent, or legal bases arising from national or other EU law. Thus the second objective of this dissertation is to critically evaluate the current normative framework as a whole in terms of transparency in relation to the individual by exploring alternative legal modalities for facilitating transparency in genetic research.

The described objectives of this dissertation are limited to the fundamental problems relating to transparency in relation to the individual in the context of genetic research. Although many of the issues raised and addressed in this dissertation can be applied mutatis mutandis to the research use of other types of personal data, the key differences are the inherently identifying nature of genetic data, and its vast informative and research potential.

This dissertation will not address the exercise of autonomy and other individual rights. In this dissertation, transparency is understood to be an essential prerequisite for the exercise of individual rights. There is little meaning to addressing individual rights in a regulatory context where the lack of transparency and informedness might effectively strip the individual of the basic knowledge in regard to the use of their biosamples and genetic data in the first place. Without knowledge on the part of the individual regarding the use of their biosamples and data, the invocation of individual rights becomes a mere

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[20] J. Krutzinna and L. Floridi (2019). Ethical Medical Data Donation: A Pressing Issue. In J. Krutzinna and L. Floridi (Eds.). *The Ethics of Medical Data Donation* (pp. 1–6). Springer Open, p 2.

theoretical exercise. Thus it is not the objective of this dissertation to address individual rights in research, but to focus on transparency as a fundamental requirement, which serves as an essential prerequisite for any potential exercise of such rights.

The scope of analysis and discussion in this dissertation in regard to transparency in relation to the individual will be limited to the individual, i.e. issues related to genetic data being 'data in common'[21] shared in part by blood relatives will not be discussed.

To achieve the research objectives laid out above, the main research questions to be addressed will be:

1. What are the legal modalities under the GDPR for facilitating transparency in relation to data subjects that apply in the research context?
2. How effective is informed consent in facilitating transparency in relation to the data subject in genetic research and what are its limits as a modality for transparency?
3. How does the correlation between informed consent and alternative legal bases for the use of genetic data in research impact transparency in relation to the data subject?
4. To what extent is the general obligation to inform applied in the research context and how does it impact transparency in relation to data subjects in genetic research?
5. What, if any, normative changes are necessary to effectively facilitate transparency in relation to the data subject in the context of genetic research?

1.3. Current status of research in the area

Regulatory approaches to genetic data, both in the general and in the research context, have been the subject of academic discourse for decades, with consent to biomedical research being one of the focal points of discussion.[22] The most extensive works in terms of genetic data and genetic privacy specifically include G. Laurie (2002)[23] and M. Taylor (2012)[24].

Laurie's work entails a comprehensive discussion and analysis of the concept of privacy in the health care setting[25], encompassing both informational and spatial privacy[26], with particular reference to genetic information. Laurie

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[21] M. Taylor (2012), pp 103 ff.

[22] E.g., N.C. Manson, O. O'neill. Rethinking Informed Consent in Bioethics. Cambridge University Press 2007; T. Murphy (ed.). New Technologies and Human Rights. Oxford University Press 2009; J. Candlish. Genetics, Molecular Biology and the Law. Wildy, Simmonds & Hill Publishing 2010; D. Price. Human Biosamples in Transplantation and Research. Cambridge University Press 2010.

[23] G. Laurie (2002).

[24] M. Taylor (2012).

[25] G. Laurie (2002), p 11.

[26] Ibid., p 64.

criticises consent as a means of protecting privacy and ensuring autonomy. One of the criticisms towards consent that Laurie puts forth is the fact that "there is no residual power once consent has been given unless further consent is required at some future point."[27] As such, according to Laurie, the power afforded by consent is somewhat illusory, as "the individual retains no continued relationship with the sample in either a factual or legal sense once consent has been obtained and the sample surrendered."[28] Laurie proposes to approach the issue of control regarding the use of genetic material through a 'property paradigm',[29] not as an alternative, but rather a supplement to the consent and other privacy models.[30] At the same time, Laurie admits that this approach is more difficult when it comes to the data derived from the samples.[31] Essentially, Laurie's proposal aims to provide individuals with bargaining power in regard to the use of their biospecimen through property rights. It does not entail (future) access to and (secondary) use of the data derived from the biosamples per se.

This dissertation addresses particularly the transparency of the use of genetic data in the research context through the lens of data protection. The arguments put forth by Laurie challenging the practical feasibility of prior informed consent in terms of failing to preserve a connection between the individual and their biosample can be mutatis mutandis applied here in terms of genetic data. Whereas regarding biosamples, transparency concerning the research use of genetic data through the data protection framework would concurrently affect biospecimen as well to the relevant extent, since although the physical sample itself is not data, it can be argued that from the moment that genetic data is retrieved from the sample, data protection rules come into play.[32] As such, the propositions made in this dissertation complement, and by no means challenge or substitute the property rights approach proposed by Laurie in regard to biosamples.

In his work, Laurie recognises an opt-out scheme in regard to research with genetic data as an "ethically justifiable public good"[33], and notes that the possibility to opt out ensures respect for individual autonomy[34]. Although this

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27 Ibid., p 312.

28 Ibid., p 312.

29 Ibid., p 315 ff.

30 Ibid., p 328.

31 Ibid., p 326.

32 Although it can also be argued that data protection rules apply to the biosamples as they contain DNA. D. Hallinan and P. De Hert argue that stating otherwise would be equal to suggesting "that handling a USB stick containing personal data was not subject to data protection law." See D. Hallinan and P. De Hert. Many Have It Wrong – Samples Do Contain Personal Data: The Data Protection Regulation as a Superior Framework to Protect Donor Interests in Biobanking and Genomic Research. In B. D. Mittelstadt and L. Floridi (Eds.). *The Ethics of Biomedical Big Data* (pp 119–138). Springer International Publishing Switzerland 2016.

33 G. Laurie (2002), p 291.

34 Ibid., p 288.

dissertation does not address autonomy rights in the context of genetic research, Laurie's work supports the underlying argument of this dissertation that providing individuals with the necessary knowledge regarding the use of their genetic data in research could mitigate the shortcomings of the current framework in which consent is either illusory (as noted by Laurie) when it is required, or has been forsaken entirely. Thus a common feature between the current work and the contribution of Laurie is that both are concerned with mechanisms to offer individuals whose biosamples or genetic data are being used in research a continuing connection with the samples or data derived from them.

M. Taylor (2012) has published a more recent comprehensive work on genetic privacy. Taylor analyses privacy protections specifically in the context of genetic research. He emphasises the need for clarity in regard to the application of consent requirements in terms of using genetic data in research, and, furthermore, has stressed the importance of this being co-ordinated consistently in Europe.[35] Taylor also points out the need to recognise biological samples in certain circumstances as personal data, thus suggesting a more logical and harmonised approach to genetic data and the biosamples carrying the said data.[36] In this regard, the approach in the hereby dissertation relies on the argument that the recognition of biospecimen as data is not necessary if genetic data in the meaning of DNA sequencing data is recognized as personal data regardless of additional identifiers or information, in which case the retrieval of genetic data from biosamples would trigger the application of the personal data protection framework – thereby alleviating the need to recognise biospecimen as data.

Though Taylor calls for a shift in the regulatory environment regarding the use of genetic data and biosamples in the research context, his work predates the GDPR, whereas this dissertation will analyse and lay out applicable consent requirements in genetic research in the current post-GDPR regulatory context on the Estonian example as a reference to relevant national rules. Whilst Taylor also calls for improvements in research infrastructure that could benefit both data subjects and researchers, his work does not entail specific suggestions in this regard.[37] Taylor does, however, underline a critique in regard to information disclosure to data subjects, which is central to this dissertation as well. Namely, Taylor points out in regard to Directive 95/46/EC[38] that, "the responsibility to provide information to a data subject on the purposes of processing, at least as required by the Directive, is not expressly an ongoing responsibility."[39] The same argument will be tested in this dissertation in terms of the GDPR and transparency in research in relation to data subjects. Another important remark made

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35 M. Taylor (2012), p 217.

36 Ibid., p 218–19.

37 Ibid.

38 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. 23.11.1995 OJ L281.

39 M. Taylor (2012), p 207.

by Taylor in regard to the notification of data subjects is the omission of the process of anonymisation of data from the concept of processing. Taylor deems this omission unjustifiable, and argues that this undermines the expectations of individuals in regard to the future uses of their data; especially in light of Taylor's argumentation regarding identifiability being context specific.[40] This dissertation will suggest the recognition of human DNA sequencing data as personal data regardless of additional identifiers or information, thus nullifying the anonymisation argument.

Concerning transparency in human data research, and the ongoing disclosure of information to data subjects, an earlier work of M. Taylor (2011)[41] is of particular relevance to this dissertation. In his article of 2011, Taylor specifically addresses the use of health data without consent, arguing that in the absence of consent an ongoing obligation to inform individuals of the research uses of their data would be needed to facilitate transparency on at least the minimal level. Taylor puts forth the same arguments in terms of ongoing informedness and anonymisation (as 'processing' within the meaning of the data protection framework) as referred to above. Taylor argues that, minimally, transparency "requires that people know when their expectations vis-a-vis their data are not met." As such, the core argument of this dissertation in regard to transparency of genetic data processing in the research context aligns with that made by Taylor in 2011. However, Taylor tackles the described issues from the UK perspective, taking into account Directive 95/46/EC, and in terms of health data of the National Health Service specifically.

In his doctoral thesis of 2018, D. Hallinan addresses the role of the GDPR in protecting genetic privacy in the context of biobanking.[42] In doing so, Hallinan also touches upon issues related to transparency, analysing whether the provisions of the GDPR are "technically unsuited for the broad analytical potential of genomic data", and "for the future uncertain analytical potential of genomic data", whereas arguing that the GDPR's "self-determination provisions rely on the effective function of transparency provisions".[43] The latter point regarding the relationship between transparency and individual rights under the GDPR forms an underlying argument put forth in this dissertation in regard to the essential importance of transparency. Namely, as Hallinan puts it, "[transparency] is a prerequisite for the effective function of other aspects of protection – for example self-determination provisions such as consent."[44] Like M. Taylor, Hallinan as well points out that the provision of information to data subjects

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40 Ibid., pp 213–216.

41 M. Taylor. Health research, data protection, and the public interest in notification. *Medical Law Review* 19(2) (2011), pp 267–303.

42 D. Hallinan. "Feeding Biobanks With Genetic Data: What role can the General Data Protection Regulation play in the protection of genetic privacy in research biobanking in the European Union?" (doctoral thesis) Vrije Unversiteit Brussel 2018.

43 Ibid., pp 376–380 and 426–431.

44 D. Hallinan (2018), p 427.

under the transparency clauses in the GDPR is a one-off communication.[45] However, unlike Hallinan's work, which analyses the impact of the GDPR on biobanks in general, this dissertation aims to address specifically transparency in relation to the data subject, and to do so based on the Estonian example as a reference to national law to offer a comprehensive analysis on the matter. Although Hallinan briefly refers to Estonian law as an example as well, he does so only in a context in which a biosample is obtained directly from an individual, and in regard to specifically the Estonian Biobank[46].[47]

In earlier works, D. Hallinan et al. (2013)[48] have discussed the regulation of genetic data under the then draft version of the GDPR more generally (i.e. not limited to particularly research, although including certain aspects of it), but their work precedes the final version of the GDPR, which makes a significant difference when it comes to the use of genetic data in research specifically (i.e. their earlier work contains references to clauses in the draft, which were omitted from the final version; e.g. reference to Articles 81 and 83, which, in the draft version, specifically concerned research regulations of health and other sensitive data)[49]. Furthermore, the referred work presents a broader approach of genetic data under the GDPR in general without specific focus on research (e.g. the issue of multiple data subject, anonymity, etc.).

A number of scholars have addressed the implications of the GDPR on scientific research in general.[50] For example, M. Shabani and P. Borry (2018)[51]

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[45] Ibid., p 376.

[46] The Estonian Biobank is a population-based biobank, currently operating as part of the Estonian Genome Center at the University of Tartu, containing samples and genetic data of more than a hundred fifty thousand Estonians. See the official website of the Estonian Biobank, available at https://www.geenivaramu.ee/en/about-us [Accessed 12 April 2019].

[47] Hallinan refers to certain paragraphs in the Estonian Penal Code arguing that there is a "general prohibition on scientific research without research subject consent." However, the relevant paragraphs in the Penal Code concern human subject research and obtaining biosamples from the individual directly. They do not concern secondary research uses of biosamples or human data research in which there are no human subjects. See D. Hallinan (2018), p 193.

[48] D. Hallinan et al. Genetic Data and the Data Protection Regulation: Anonymity, multiple subjects, sensitivity and a prohibitionary logic regarding genetic data? *Computer Law & Security Review* 29 (2013), pp 317–320.

[49] Ibid., p 325.

[50] E.g., G. Chassang. The impact of the EU general data protection regulation on scientific resesarch. *Ecancermedicalscience* 11:709 (2017); or J.M.M. Rumbold, B. Pierscionek. The effect of the General Data Protection Regulation on Medical Research. *Journal of Medical Internet Research* 19(2):e47 (2017); also N. Bertels. Scientific research under the GDPR: what will change? *KU Leuven Centre for IT & IP Law* 01.06.2016; available at https://www.law.kuleuven.be/citip/blog/scientific-research-under-gdpr-what-will-change/ [Accessed 12 March 2018].

[51] M. Shabani, P. Borry. Rules for processing genetic data for research purposes in view of the new EU General Data Protection Regulation. *European Journal of Human Genetics* 26 (2018), pp 149–156.

have analysed the rules for using genetic data under the GDPR, however, their work is more focused on issues of pseudonymisation, and the consent or anonymise approach. Furthermore, the author's analysis of genetic research under the GDPR[52] predates the relevant work of Shabani and Borry. More importantly, this dissertation aims to offer a comprehensive analysis of the research use of genetic data in the post-GDPR era, taking into account other applicable law as well (e.g. national law, other applicable EU law, and the legal rules applicable to biospecimen).

The particular challenges of health data research in a research environment increasingly reliant on big data analytics have more recently been addressed by E. Vayena and A. Blasimme (2018)[53]. In their article, Vayena and Blasimme propose "the implementation of a systemic oversight approach tailored to the features of the health data ecosystem." Though they support "more granual consent models" (i.e. essentially more specific), they recognize that general tendencies are leaning to the contrary (i.e. broad consent), and they further argue that it is not consent models that can bring along a more detailed oversight, but rather changes in the systematic approach to data oversight. In this regard, the underlying approach of this dissertation aligns with the arguments put forth by Vayena and Blasimme in terms of the limits of the concept of prior informed consent in regard to safeguarding the interests of individuals in terms of the use of their health (incl. genetic) data in research. This dissertation will address the same underlying concerns in regard to the possible implications of the shortcomings of the current system as laid out by Vayena and Blasimme:

"The combination of weakened consent and insufficient research oversight is potentially detrimental to health research in an evolving health data ecosystem. This state of affairs can result in direct harms to individuals and groups, and also risks damaging public trust in scientific research."[54]

The research undertaken for this dissertation serves the purpose of complimenting the existing literature in regard to regulations concerning the research use of genetic data.

1.4. Methods and resources

The objectives of this dissertation have been pursued through a qualitative systematic analysis of the relevant laws and associated documentation such as prior drafts, explanatory reports, etc. The principal research methods employed were analytical and teleological methods.

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[52] K. Pormeister. Genetic data and the research exemption: is the GDPR going too far? *International Data Privacy Law* 7(2) (2017), pp 137–146.

[53] E. Vayena and A. Blassime. Health Research with Big Data: Time for Systemic Oversight. *The Journal of Law, Medicine & Ethics* 46(1) (2018), pp 119–129.

[54] Ibid., p 123.

A systematic analysis of relevant legal acts was conducted in order to outline a possible supranational legal framework (or the lack thereof) for the use of genetic data in research in the European legal sphere[55]. The following legal instruments were determined to be of main importance to this dissertation: Directive 95/46/EC (until 25 May 2018); the GDPR (as of 25 May 2018); Regulation 536/2014 on clinical trials[56] (presumably as of 2020)[57]; the Oviedo convention[58]; and respective national laws implementing the discretionary clauses of the GDPR (of which Estonian law is referred to in this dissertation).

Though matters concerning health and health-related data, including cellular samples and DNA, are also covered by the European Convention on Human Rights (ECHR)[59] (most notably, by Art. 8 ECHR concerning the right to private life)[60], the ECHR does not contain any specific rules regarding research and there is currently no relevant case law from the European Court of Human Rights (ECtHR). Furthermore, presumably the ECHR would apply a case-by-case approach rather than determine the existence of any specific and uniformly applicable rules under Article 8 ECHR in regard to the research use of genetic

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[55] The European legal sphere within the meaning of this dissertation is to be understood as encompassing both the EU and the members of the Council of Europe.

[56] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. OJ L158/1.

[57] The entry into application of Regulation 536/2014 depends on the development of the EU portal and EU database for clinical trials (See Art. 80–82 and 99 of Regulation 536/2014). According to the European Commission, Regulation 536/2014 is currently estimated to come into application in 2020 (instead of 2018, as initially estimated). See the official website of the European Commission https://ec.europa.eu/health/human-use/clinical-trials/regulation_en [Accessed 22 April 2019].

[58] Supra n 9. The Oviedo convention has been ratified by the following countries: Bosnia & Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Greece, Hungary, Iceland, Latvia, Lithuania, Montenegro, Norway, Portugal, Republic of Moldova, Romania, San Marino, Serbia, Slovak Republic, Slovenia, Spain, Switzerland, The Former Yugoslav Republic of Macedonia, Turkey. For the chart of signatures and ratifications see official website of the Council of Europe at https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures [Accessed 14 March 2018].
Although it is important to emphasize that the ECtHR has referred to the Oviedo convention even in the absence of signature or ratification. See, e.g., *Glass v. The United Kingdom*, ECtHR [2004], Application no. 61827/00, ECLI:CE:ECHR:2004:0309JUD006182700.

[59] Convention for the Protection of Human Rights and Fundamental Freedoms. Rome, 4.XI.1950. ETS No. 005.

[60] For an overview regarding the case law of the ECtHR in matters regarding bioethics, See Research Report: Bioethics and the case-law of the Court. Council of Europe/European Court of Human Rights, 2016. Available at https://www.echr.coe.int/Documents/Research_report_bioethics_ENG.pdf [Accessed 2 May 2018].

data.[61] In addition, the ECtHR has given substance to Article 8 of the ECHR via reference to the Oviedo convention independent of whether the state party to the dispute has signed or ratified the Oviedo convention. For example, in *Glass v. the United Kingdom*[62], in assessing the UK's compliance with Article 8(2) ECHR, the ECtHR noted that it considered the UK's system consistent with the Oviedo convention. As F. Seatzu (2015) has put it, the Oviedo convention is a sort of tool used in the interpretation of the ECHR, and "the Oviedo Convention might be used interpretatively to specify and expand the scope of the provisions of ECHR, consistently with the unwritten rule that reference should be made to the source that provides the higher standards of protection of human health."[63] In this light, analysis concerning the ECHR is only briefly included in this dissertation due to the lack of specific rules regulating research or relevant case law, and due to the references to and reliance on the Oviedo convention in the case law of the ECtHR regardless of signature or ratification by the state party to the dispute.

For the purposes of establishing a systematic overview of supranational consent requirements (or lack thereof) in the context of genetic research, and taking into account that the latter might entail procurement of biosamples, but might also rely on already available biospecimen and genetic data, a systematic analysis of the GDPR, Regulation 536/2014 and the Oviedo convention was undertaken.

In regard to national law, in one prior publication reference was made to German data protection law as an example instead of Estonian law.[64] This is due to the fact that the new Estonian Personal Data Protection Act was not adopted until December 2018, and only came into force 15 January 2019.[65] Hence, the German Act to Adapt Data Protection Law[66] was referred to in order to illustrate possible approaches under national law (the German law was adopted already in June 2017, whereas the first draft version of the respective Estonian

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[61] See M. Taylor (2012), p 73.

[62] Supra n 58.

[63] F. Seatzu. The Experience of the European Court of Human Rights with the European Convention on Human Rights and Biomedicine. *Utrecht Journal of International and European Law* 31(810 (2015), pp 5–16.

[64] K. Pormeister. Genetic research and consent: on the crossroads of human and data research. *Bioethics*, 33(3) (2019), 347–356, https://doi.org/10.1111/bioe.12475.

[65] Estonian Personal Data Protection Act, RT I, 04.01.2019, 11. Available in English at https://www.riigiteataja.ee/en/eli/523012019001/consolide [Accessed 12 April 2019].

[66] German Act to Adapt Data Protection Law to Regulation (EU) 2016/679 and to Implement Directive (EU) 2016/680 (DSAnpUG-EU) of 30 June 2017. Available at https://www.bmi.bund.de/SharedDocs/downloads/EN/gesetztestexte/datenschutzanpassungsumsetzungsgesetz.html;jsessionid=309B1C7C94FA075EDF5837DFA525EAAE.1_cid295 [Accessed 14 March 2018].

law was not published until November 2017[67]). The analytical compendium will use the Estonian Data Protection Act of 2019 to provide an example of how the interaction between the GDPR and national data protection law – most importantly the dynamics between the research use of genetic data based on consent on the one hand, and without consent on the other – impact transparency in relation to the data subject.

The above-referred analysis in regard to applicable consent requirements in genetic research and the use of genetic data in research without consent is developed in five prior publications of the author:

Article I 'Informed consent to sensitive personal data processing for the performance of digital consumer contracts on the example of "23andMe"'[68] examines the processing of genetic data in the context of contractual relationships and analyses the intersection of data protection and contract law in this context. In terms of the use of genetic data in research, Article I opens up a specific dimension of genetic research left largely unnoticed by current regulatory frameworks. Namely, the fact that commercial genetic testing entities are accumulating vast collections of genetic data, and that genetic research is no longer in the exclusive realm of traditional research facilities. The fact that, once obtained (even if for commercial purposes), further research use of genetic data (by commercial entities) might not require additional consent, further emphasizes the need for transparency in relation to data subjects.

Article II 'The GDPR and Big Data: Leading the Way for Big Genetic Data?'[69] discusses the processing of genetic data under the GDPR from the perspective of big data, i.e. the fact that for purposes of research, genetic data is generally processed in high volumes, involving the data of a large number of data subjects. Article II analyses how this fact impacts rights and obligations under the GDPR. Most importantly, Article II contains an analysis of Article 14(5)(b) GDPR (which creates exceptions to the obligation to inform in regard to processing for, inter alia, research purposes) and discusses the impact of Article 11 GDPR in the context of genetic research. The interplay between Articles 14(5)(b) and 11 GDPR, and their combined impact on transparency in relation to data subjects, will be further elaborated upon in the analytical compendium.

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[67] The draft law of the new Estonian Personal Data Protection Act was published on 6 November 2017. Available only in Estonian at http://www.aki.ee/sites/www.aki.ee/files/elfinder/article_files/iks_en_9.11.17.pdf [Accessed 14 March 2018].

[68] K. Pormeister. Informed consent to sensitive personal data processing for the performance of digital consumer contracts on the example of "23andMe". *Journal of European Consumer and Market Law* 6(1) (2017), pp 17–23.

[69] K. Pormeister. The GDPR and Big Data: Leading the Way for Big Genetic Data? In E. Schweighofer et al. (Eds.) *Privacy Technologies and Policy*. Springer 2017 (Lecture Notes in Computer Science), pp 3–18.

Article III 'Genetic data and the research exemption: is the GDPR going too far?'[70] establishes part of the core analysis regarding the research use of genetic data under the GDPR by outlining how genetic research is (and is not) regulated by the GDPR, and to which extent the matter is left to be regulated by Member State or other EU law. This publication will be relied upon in the analytical compendium in the analysis concerning applicable consent frameworks.

Article IV 'Genetic research and consent: on the crossroads of human and data research'[71] presents an analysis of consent requirements in terms of genetic research, taking into consideration the fact that genetic research might, and might not, entail procurement of biosamples, and how this might influence applicable consent requirements. Furthermore, Article IV outlines the parallel rules applying to biospecimen on the one hand, and genetic data derived therefrom on the other. The analytical compendium will refer to and elaborate upon these findings.

Article V 'Regulatory environment for biobanking in Estonia'[72] addresses both the specific national law concerning the Estonian Biobank, and general regulatory frameworks concerning the use of biospecimen and data derived therefrom in research (stemming in most part from data protection law). Most importantly, Article VI contains a comprehensive analysis of the rules for using personal (incl. genetic) data in research without consent under the 2019 Estonian Personal Data Protection Act. The analysis provided in Article V concerning Estonian data protection law will be relied upon in the analytical compendium.

The analysis regarding the impact of applicable consent frameworks on transparency in relation to data subjects, and the discussion concerning alternative modalities for facilitating transparency (and their efficacy in doing so), will be developed in this analytical compendium.

The choice to utilize Estonian law as an example is based first on the practicality of the author's familiarity and in-depth knowledge of this particular jurisdiction. The second reason for this choice is the fact that the health information of the whole population is available in electronic state databases, and can be accessed fur purposes of research. Furthermore, part of the strategical vision of the Estonian e-Health system is to eventually include genetic data into electronic health records.[73] Thus Estonia provides for a unique setting in which

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[70] K. Pormeister. Genetic data and the research exemption: is the GDPR going too far? Supra n 52.

[71] K. Pormeister. Genetic research and consent: on the crossroads of human and data research. Supra n 64.

[72] K. Pormeister. Regulatory environment for biobanking in Estonia. In: Slokenberga, S. et al. (Eds.). Individual rights, public interest and biobank research. Article 89 GDPR and European legal responses. Springer 2019/2020 (to be published).

[73] E-Health vision 2025. E-Health strategic development plan 2020. (*E-tervise visioon 2025. E-tervise strateegiline arengukava 2020*). Estonian Health Strategy 2020. Government Office, 29–31. Available in Estonian. https://www.sm.ee/sites/default/files/content-editors/eesmargid_ja_tegevused/Eesti_e_tervise_strateegia/e-tervise_strateegia_2020.pdf. Accessed 28 March 2018.

the regulatory framework must be approached and understood from the perspective that potentially the health and genetic data of the whole population will be readily available for secondary use in research.

The methods of using the Estonian example are two-fold. In the first part of the analytical compendium, Estonian national law will be used as an example to comprehensively outline the main aspects of consent requirements applicable to genetic research, and how this impacts transparency. In the second part of the compendium, the Estonian e-Health system will be used as a practical example of demonstrating shortcomings regarding, and potential for, transparency in relation to data subjects within the current system.

1.5. Definitions

Before the commencement of the substantive discussion of the analytical compendium, some key definitions must be addressed first in order to clarify the meanings attached to them in this dissertation.

Genetic data. For the purposes of this dissertation, the term 'genetic data' is to be understood as human DNA sequencing data (incl., but not limited to, whole-genome sequencing data). This is due to two reasons. First, DNA sequencing data cannot be fully anonymised, as it is unique to the individual and constant, thus carrying particular privacy implications.[74] As the ECtHR has observed, "[DNA] profiles contain substantial amounts of unique personal data."[75] The ECtHR's conclusions on the privacy implications associated with the retention of genetic data are "not affected by the fact that, since the information is in coded form, it is intelligible only with the use of computer technology and capable of being interpreted only by a limited number of persons."[76]

Second, it is the essentially boundless informational potential[77] that sets this particular type of sensitive data apart from possible broader interpretations of the term 'genetic data', and from other types of sensitive data (e.g. other categories of health-related data). Thus resulting in equally boundless potential for its various uses in (future) research.

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[74] G. Laurie (2002), pp 109, 115.

[75] *S. and Marper v. The United Kingdom*, ECtHR [2008], Applications nos. 30562/04 and 30566/04, ECLI:CE:ECHR:2008:1204JUD003056204, § 75.

[76] Ibid.

[77] Or *interpretive potential* as Taylor puts it, to indicate that it is possible to recognise future potential to interpret certain data before such interpretation is even possible. See M. Taylor (2012), p 41. In the context of genetic data, it refers to the fact that the data itself that is available today (e.g. one's DNA sequence, or a biosamples from which the DNA sequence can be derived) can yield information, the quality and quantity of which is relative to technological and scientific advancements. In other words, the ability to interpret genetic data, and thus the meaning of the data can (and, in fact, will) change over time.

Some of the arguments made in this dissertation can mutatis mutandis be applied to the research use of other (special) categories of personal data as well, however, due to the heightened potential privacy implications of particularly human DNA sequencing data, this dissertation focuses specifically on genetic data.

Genetic research. In accordance with the definition assigned to 'genetic data', 'genetic research' within the meaning of this dissertation shall be understood as research making use of human DNA sequencing data. Generally, genetic research could be defined much more broadly, e.g. including research making use of family medical history in order to determine inheritable patterns.[78] However, the focal interest of this dissertation lies on human DNA sequencing data because of the ongoing possibility of re-identification, and due to the privacy implications associated particularly with the informative potential of this type of data. Furthermore, as noted, human DNA sequencing data provides for essentially boundless research possibilities in the search for "correlations within extensive multi-parametric datasets".[79] In order to find possible correlations between DNA and other factors, this type of research will in most cases require additional personal data to be processed (most importantly health and medical data, but also other types of personal data). This is not to assert that some arguments made in this dissertation could not be applied vis-à-vis other types of research as well.

As defined in this dissertation 'genetic research' might – but need not – entail the procurement of biospecimen and genetic data. It shall cover both scenarios in which individuals are directly involved in order to procure biosamples, and those in which the biosamples and/or genetic data derived therefrom have already been obtained and stored. The necessary biospecimen and data might already be available from previous research projects. They might also have been accumulated into clinical or health databases, or commercial databases, which have obtained the data for respectively purposes of clinical care, or provision of commercial services (e.g. direct-to-consumer genetic testing).

The notion of 'scientific research' in general, as emphasized in Recital 159 GDPR, should be interpreted in a broad manner, and not defined through an institutional prism. Research within the meaning of this dissertation should be understood as it is under the GDPR, i.e. as not being confined to traditional research settings or institutions, but defined through the activity itself as being "a research project set up in accordance with relevant sector-related methodo-

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[78] Regarding the importance of family history in genetics, see, e.g., Understanding Genetics: A New York, Mid-Atlantic Guide for Patients and Health Professionals. Genetic Alliance; The New York-Mid-Atlantic Consortium for Genetic and Newborn Screening Services 2009. Available at https://www.ncbi.nlm.nih.gov/books/NBK115563/ [Accessed 2 May 2018].

[79] E. Vayena and A. Blassime. Health Research with Big Data: Time for Systemic Oversight. Supra n 53, p 121.

logical and ethical standards, in conformity with good practice."[80] This may also include privately funded research and research carried out by private companies with commercial interests.

Secondary use of genetic data. 'Secondary use' is understood as referring to the use of biosamples or genetic data for purposes other than which they were initially collected for.[81] In a research context this might, on the one hand, refer to the use of biosamples and/or data that was initially collected for a different research purpose. On the other hand, the term 'secondary use' might also refer to a scenario in which the biosample and/or data was originally collected in an entirely different context and for a purpose other than research, i.e. for purposes of clinical care or commercial genetic testing services.

Data controller and third party controller. In terms of transparency and the data controller's obligation to provide information, it is important to clarify the concepts of 'data controller' and 'third party (data) controller'. The GDPR defines 'data controller' in Article 4(7) as the party that "determines the purposes and means of the processing of personal data". Whereas according to Article 4(8) GDPR 'processor' refers to the party that "processes personal data on behalf of the controller".

The GDPR defines 'third party' in Article 4(10) as "a natural or legal person, public authority, agency or body other than the data subject, controller, processor and persons who, under the direct authority of the controller or processor, are authorised to process personal data". However, this is not to be confused with 'third party (data) controller'. The Article 29 Data Protection Working Party (WP29) have, in their guidelines regarding transparency under the GDPR, referred to 'third party data controllers' in a scenario where data is obtained not from the data subjects directly, but from another data controller (who might have obtained said data from the data subject, but also, in turn, from another data controller).[82] 'Third party controller' could vice versa be used to refer not to the controller from whom the data was obtained, but to the controller who obtains the data for further processing (i.e. rendering the receiving party a new controller, rather than just a 'recipient' within the meaning of Art. 4(9) GDPR).

To exemplify the above, when a researcher acquires health data from research participants directly, the researcher is the data controller as he determines the

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[80] Article 29 Working Party Guidelines on Consent under Regulation 2016/679. Adopted on 28 November 2017. As last revised and adopted on 10 April 2018. Article 29 Data Protection Working Party, 17/EN WP 259 rev.01, p 28. Available at https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051 [Accessed 3 May 2019].

[81] See, e.g., International Review of Secondary Use of Personal Health Information. Health Information and Quality Authority (Ireland), January 2012. Available at https://www.hiqa.ie/system/files/Review-Secondary-Use-Health-Info.pdf [Accessed 19 March 2018].

[82] Guidelines on transparency under Regulation 2016/679. Article 29 Data Protection Working Party, 17/EN WP260 rev.01, supra n 8, p 15, para 26.

purpose and means of processing. If the researcher then shares the data with another researcher, the latter could become a data controller in terms of the same (duplicated) data depending on the terms on which the data is transferred to him (i.e. whether the receiving researcher can conduct further research with the data on his own terms). If the second researcher is free to use this data in his research at his own discretion, i.e. to determine the (research) purposes and means of processing, then the second researcher could be referred to as a third party controller.

In this dissertation, the phrase 'third party controller' will be used in this simplistic manner as referring to the exchange of personal data between two parties who both can be deemed data controllers within the meaning of the GDPR, with the receiving party becoming the third party controller.

1.6. Structure of the analytical compendium

The analytical compendium is structured into three substantive chapters. Chapter II will analyse the meaning and role of research transparency under the personal data protection framework, and analyse existing legal modalities under the GDPR for facilitating transparency in relation to data subjects. These legal modalities will then be subject to in-depth analysis in Chapters III and IV. Chapter III will explore the role of informed consent and its impact on transparency in genetic research, using Estonia as a reference to national law. Chapter IV will analyse the general obligation to inform under the GDPR as a modality of transparency in genetic research. Chapter V will follow with conclusions and normative propositions.

II. TRANSPARENCY UNDER THE PERSONAL DATA PROTECTION FRAMEWORK

Under the GDPR, transparency in relation to data subjects is one of the three core principles of data protection alongside lawfulness and fairness.[83] Transparency has been regarded as a new obligation arising from the GPDR,[84] given that, unlike the GDPR, Directive 95/46/EC did not include transparency as a core principle of processing, and only indicated to it in a single recital.[85] Transparency within the meaning of the GDPR is seen by the WP29 as an overarching obligation concerning three central areas: provision of information to data subjects; how data controllers communicate with individuals regarding their rights under the GDPR; how controllers facilitate the exercise of the referred rights.[86] This dissertation is concerned with the first of the three areas of transparency distinguished by the WP29 – provision of information to data subjects – as it serves as a prerequisite for the latter two dimensions of transparency under the GDPR.

This chapter will first explore the meaning and role of transparency in research from the perspective of the personal data protection framework (2.1.). This will be followed by a compendious analysis of the existing legal modalities for facilitating transparency under the GDPR (2.2.).

2.1. Transparency as a procedural prerequisite for substantive values

In data protection law, the principle of transparency is established in relation to the data subject[87] and is thus approached from the perspective of individuals whose personal data is being processed.[88] The WP29 have referred to transparency within the meaning of the GDPR as being "user-centric rather than legalistic".[89]

Transparency in research, however, has historically carried a different meaning – one focused on the internal workings of the research community, rather

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83 Art. 5(1)(a) GDPR, supra n 1.

84 Guidelines on transparency under Regulation 2016/679. Article 29 Data Protection Working Party, 17/EN WP260 rev.01, supra n 8, p 4, para 1.

85 Art. 6(1)(a) and Recital 38 of Directive 95/46/EC, supra n 38.

86 Guidelines on transparency under Regulation 2016/679. Article 29 Data Protection Working Party, 17/EN WP260 rev.01, supra n 8, p 4, para 1.

87 An identified or identifiable natural person as defined in Art. 4(1) GDPR, supra n 1.

88 Art. 5(1)(a) GDPR, supra n 1.

89 Guidelines on transparency under Regulation 2016/679. Article 29 Data Protection Working Party, 17/EN WP260 rev.01, supra n 8, p 5, para 4.

than being geared towards research participants.[90] Transparency in the research context is often addressed from the perspective of the research community as a means of ultimately ensuring the validity of research.[91] Given that data protection law applies to personal data processing in research,[92] the principle of transparency in the research context must therefore be seen as twofold. On the one hand, research transparency can indicate to ethical or legal standards that are aimed towards transparency within the research community. On the other hand, research transparency from the perspective of data protection law and within the meaning of the GDPR must be understood as being directed at individuals (participating in and/or having their personal data used in research). This dissertation is concerned with the latter aspect of transparency in genetic research, i.e. transparency within the meaning of the personal data protection framework.

As noted, in the personal data protection framework transparency is one of the three core principles alongside lawfulness and fairness. Recital 39 GDPR elaborates on the importance and meaning of transparency by stating that the principle of transparency "concerns, in particular, information to the data subjects on the identity of the controller and the purposes of the processing […]". According to the referred recital, this information relayed to the data subject must be "easily accessible and easy to understand". Recital 58 GDPR reiterates the same notions in regard to the principle of transparency. Essentially, as explained in Recital 60 GDPR, "The principles of fair and transparent processing require that the data subject be informed of the existence of the processing operation and its purposes." Hence, the principle of transparency in data protection requires, at the very least, for the individual to be informed about the fact and the purposes of the processing of their personal data, and the identity of the data controller in charge of such processing.

The WP29 have described transparency as being "about engendering trust in the processes which affect the citizen by enabling them to understand, and if necessary, challenge those processes."[93] Referring to an Opinion of Advocate General Cruz Villalon[94], the WP29 note that,

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[90] See, e.g., The European Code of Conduct for Research Integrity (Revised edition). ALLEA – All European Academies 2017. Available at https://ec.europa.eu/research/participants/ data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf [Accessed 2 May 2019].

[91] See, e.g., A. Moravcsik. Transparency: The Revolution in Qualitative Research. Symposium, *American Political Science Association* (2014). Available at https://www.princeton.edu/~amoravcs/library/transparency.pdf [Accessed 7 May 2018].

[92] Recital 159 GDPR: "Where personal data are processed for scientific research purposes, this Regulation should also apply to that processing." Supra n 1.

[93] Guidelines on transparency under Regulation 2016/679. Article 29 Data Protection Working Party, 17/EN WP260 rev.01, supra n 8, p 4, para 2.

[94] Case C-201/14 *Smaranda Bara and Others v Președintele Casei Naţionale de Asigurări de Sănătate, Casa Naţională de Asigurări de Sănătate, Agenţia Naţională de Administrare Fiscală (ANAF)* [2015] Opinion of Advocate General Cruz Villalon (9 July 2015), ECLI:EU:C:2015:461.

> "Transparency, when adhered to by data controllers, empowers data subjects to hold data controllers and processors accountable and to exercise control over their personal data by, for example, providing or withdrawing informed consent and actioning their data subject rights."[95]

Thus, the core importance of transparency in the data protection framework can be most simply expressed by the following: an essential precondition for the exercise of any rights is transparency within the context in which these rights are to be exercised. In other words, without knowledge regarding the use of their data, an individual cannot exercise any rights in terms of the data and the specific use.[96] Hence, the lack of transparency in relation to individuals would essentially render all rights afforded to them under the GDPR practically meaningless.

However, the crucial role of transparency in the data protection framework should not be seen as being limited to protecting solely the private interests of data subjects. To the contrary, transparency serves as an essential cornerstone in safeguarding the interests of all stakeholders in research. On the one hand, transparency is necessary to enable the effective exercise of autonomy and privacy[97] related individual rights. On the other hand, transparency is equally important in protecting public interests[98] and those of the research community. A lack of transparency can endanger trust in the research being in the public interest, which can have a debilitating effect on the willingness to participate in and the acceptance of research activities; which, in turn, can ultimately hamper research. As M. Taylor (2011) has put it in regard to the use of health data in research, "The maintenance of trust in the decision-making system requires transparency, accountability, and proportionality."[99]

Thus transparency is not just a prerequisite for safeguarding individual private interests related to autonomy and privacy, but it is also crucial in protecting the interests of the public and the research community, thereby serving as a procedural foundation for safeguarding substantive values at stake in research. Schematically, the role of transparency in relation to the individual in the research context can be expressed as follows:

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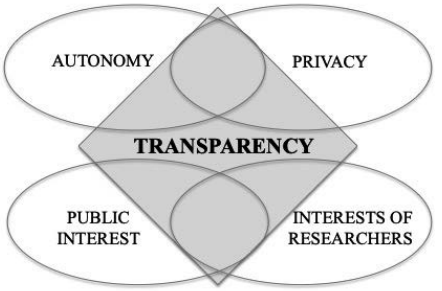
[95] Guidelines on transparency under Regulation 2016/679. Article 29 Data Protection Working Party, 17/EN WP260 rev.01, supra n 8, p 5, para 4.

[96] K. Pormeister. The GDPR and Big Data: Leading the Way for Big Genetic Data? Supra n 69, p 18.

[97] This dissertation does not aim to add to the already extensive discourse and literature on the definitions of and relationship between autonomy and privacy in (genetic) research, as both are recognized substantive values in data protection and research, and data protection in the research context. See, e.g., G. Laurie (2002), pp 182 ff; M. Taylor (2012), pp 14 ff.

[98] The understanding of 'public interest' within this dissertation follows M. Taylor's (2011) approach of using a 'thin' concept of public interest, "founded upon the every-day observation that there are common (individual) interests within any community." M. Taylor. Health research, data protection, and the public interest in notification. Supra n 41, p 272.

[99] Ibid., p 301.



The importance of transparency in building trust in research, and getting the public invested, has been demonstrated, for example, by a 2007 study of the UK Medical Research Council on the use of personal health information in medical research.[100] Focusing specifically on the secondary use of health information, the study showed that,

> "If the public feels in control of their information and its potential uses, then they are likely to be more inclined to allow their personal health information to be used for medical research purposes."[101]

Furthermore, the findings of the referred study indicate that though few people are aware of the very notion of the secondary use of personal health information in research, "if the public is informed about what medical research entails, they are generally positive towards it."[102] The main findings of the study include the conclusion that,

> "The key factor that might make people more inclined to allow their personal health information to be used for medical research is information. If the public had more information specifically about the purposes of medical research, they would be more inclined to allow their personal health information to be used for that purpose."[103]

Similar findings were established in regard to the Estonian Biobank[104]. A survey with 917 participants found that an overwhelming majority (95%) considered "it most important to be informed about what kind of research will be done

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[100] Medical Research Council. The Use of Personal Health Information in Medical Research: General Public Consultation. Final Report. June 2007. Available at https://www.mrc.ac.uk/documents/pdf/the-use-of-personal-health-information-in-medical-research-june-2007/ [Accessed 22 March 2018].

[101] Ibid., p 7.

[102] Ibid., p 8.

[103] Ibid., p 9.

[104] Supra n 46.

using their gene data."[105] A notable 81% were in favour of renewed consent being sought before conducting new research on existing samples.[106]

The importance of keeping individuals informed about the use of their genetic data has been recognized on an international level as well. The importance of transparency in regard to genetic data specifically has been underlined, for example, in UNESCO's International Declaration on Human Genetic Data[107], which, in Article 6(a), stresses the importance of transparency in regard to the collection, processing, use and storage of genetic data. As another example, in their 1997 recommendation regarding the protection of medical data (incl. genetic data),[108] the Committee of Ministers of the Council of Europe[109] put forward in Principle 5.2. that, "when medical data are not collected from the data subject, the latter should be notified of the collection as soon as possible […], unless this is clearly unreasonable or impracticable, or unless the data subject has already received the information." The recommendation adds in Principle 5.3. that information should be given to each data subject individually. The explanatory memorandum[110] to the recommendation states that each member state should determine the ways and means to supply the information.

Based on the above, the author asserts that transparency of personal data processing in research is an important precondition not just for the exercise of the rights of the data subject, but a tool for engaging the public in discourse regarding research and enhancing public trust in research. By enhancing public trust in research, transparency in relation to individuals concurrently serves the interests of the public and the research community.

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[105] K. Korts. Estonia. In M. Häyry et al. (Eds.). "The Ethics and Governance of Human Genetic Databases: European Perspectives." Cambridge University Press (2007), pp 47–52, 51.

[106] Ibid.

[107] International Declaration on Human Genetic Data. UNESCO, 2004. Available at http://unesdoc.unesco.org/images/0013/001361/136112e.pdf [Accessed 27 March 2018].

[108] Council of Europe, Committee of Ministers, Recommendation No. R (97) 5 on the Protection of Medical Data (Feb. 13, 1997). Accessible at https://rm.coe.int/16804f0ed0 [Accessed 22 March 2018].

[109] The Committee of Ministers is the Council of Europe's statutory decision-making body, which is made up of the Ministers for Foreign Affairs of member States. See official website of the CoE at https://www.coe.int/en/web/cm/home [Accessed 22 March 2018].

[110] Explanatory Memorandum of Recommendation No.R (97) 5 of the Committee of Ministers to Member States on the protection of medical data (Adopted by the Committee of Ministers on 13 February 1997 at the 584th meeting of the Ministers' Deputies). Available at https://rm.coe.int/16806846cb [Accessed 22 March 2018].

2.2. Modalities of transparency under the GDPR

As defined above, the core of the principle of transparency under the GDPR is the provision of information to data subjects concerning the fact of processing of their data, the purposes of the processing, and the identity of the controller. This core is complemented with further layers of transparency such as certain additional information to be communicated, and the precision and clarity of the information to be provided (as required under Article 12 GDPR); thus concerning more than the mere fact of communication, but the quality of it. As noted in the introductory part of this chapter, the WP29 have as well considered the facilitation of the exercise of data subjects' rights as part of the "overarching obligation of transparency under the GDPR".[111]

Though the manner in which information is provided to data subjects, and the facilitation of the exercise of individual rights and communication relevant thereto, can as well be regarded to form integral parts of the principle of transparency in data protection, on the very primary level, it is the provision of elementary information like the fact and purposes of processing that is a prerequisite for any more precise communication or activity to follow, or for the quality and clarity of the information provided to even become relevant. This dissertation focuses on the fundamental aspect of transparency as the provision of information to data subjects regarding (at least) the fact and purposes of the processing of their data, and the identity of the data controller. In the author's opinion, the described fundamental aspect of providing basic information to individuals must be regarded as the primary means of facilitating transparency in relation to data subjects, upon which further layers of transparency can then be built.

The general obligation to provide information to data subjects is stipulated in Articles 13 and 14 GDPR. Whereas Article 13 GDPR concerns scenarios in which data has been obtained directly from the individual, Article 14 GDPR concerns scenarios where data has been obtained from other sources. The obligation to inform established under the referred articles is independent of the legal basis used for processing the data (i.e. whether processing is based on informed consent of the individual, or alternative legal grounds).

Particularly in the research context, the provision of information to the individual might be part of consent procedures. If the use of personal data in research is based on consent as a legal basis for processing, the provision of information to the individual is part of the process of obtaining consent, as consent to data processing needs to be informed (Art. 4(11) GDPR). As explained in Recital 42 GDPR, "For consent to be informed, the data subject should be aware at least of the identity of the controller and the purposes of the processing for which the personal data are intended." Thus the provision of information prior to obtaining consent can be seen as a modality of transparency as its

[111] Guidelines on transparency under Regulation 2016/679. Article 29 Data Protection Working Party, 17/EN WP260 rev.01, supra n 8, p 4, para 1.

purpose aligns with the requirements stemming from the principle of transparency in data protection: for the individual to be informed about at least the fact of the processing of their data, the identity of the controller, and the purposes for which the data is processed.

In addition to the provision of information to data subjects, the 'purpose limitation', embedded in Article 5(1)(b) GDPR, can be regarded as a modality of transparency. The purpose limitation establishes a general rule that personal data may only be "collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes" – thus making the purposes of processing transparent to the extent of excluding processing for purposes other than for which the data was collected. As such, the purpose limitation has been seen as serving primarily the principle of transparency, providing predictability, and thus strengthening the data subjects' autonomy, "as they can be confident that their data are processed only for purposes for which they were collected."[112]

However, there is an explicit exception to the purpose limitation in Article 5(1)(b) GDPR when it comes to further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. This means that personal data can be further processed for research purposes regardless of the initial purposes for which the data was collected, as long as this is done in accordance with Article 89(1) GDPR. The latter, however, merely refers to vague 'appropriate safeguards' that should be adopted.[113] It is important to emphasize that such further research use of personal data would still require an appropriate legal basis for the processing of the data. The exception from the purpose limitation allows for available personal data to be further used in research if an appropriate legal basis for such use of the data can be invoked. If this legal basis were informed consent, the data subject would be informed of the new processing purposes during consent procedures. If such further processing for research purposes would be based on alternative legal grounds (i.e. based on law), the question is whether the new purposes would be communicated to the data subject.

Thus, from the three primary modalities of transparency under the GDPR outlined above, two remain applicable in the research context: the provision of information to data subjects prior to obtaining consent, and the general obligation to inform (regardless of the legal basis for processing). The efficacy of these modalities in providing transparency in relation to the data subject in genetic research shall be analyzed in the following chapters.

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[112] The Data Protection Commissioner of Hessen as Chair of the Conference of the Data Protection Commissioners of the Federation and of the States. The General Data Protection Regulation requires substantial improvement in crucial points! 26 August 2015, p 2. Available at https://www.baden-wuerttemberg.datenschutz.de/wp-content/uploads/2015/08/2015-08-26_Press_Release_DSK.pdf [Accessed 8 May 2019].

[113] For criticism regarding Art. 89(1) GDPR, See, e.g., K. Pormeister. Genetic data and the research exemption: is the GDPR going too far? Supra n 52, p 140.

III. INFORMED CONSENT AS A MODALITY OF TRANSPARENCY IN GENETIC RESEARCH

In the previous chapter, the provision of information prior to obtaining consent for personal data processing was identified as one of the modalities of transparency under the GDPR. The aim of this chapter is to analyse applicable consent requirements in genetic research in order to determine the role and impact of informed consent in regard to transparency in relation to the data subject in the context of genetic research.

The need to regulate the research use of genetic data consistently across the EU has been called for by scholars[114], however the relevant regulatory picture remains fragmented.[115] Although the GDPR was meant to harmonize personal data protection rules across the EU, and in terms of its scope, the GDPR clearly governs the use of genetic data in research, relevant substantive rules within the GDPR are scarce, and major aspects – such as conditions for processing data without consent for research purposes, and most of the derogations from the rights of data subjects[116] – have been left to be regulated in national or other EU law.[117] Furthermore, in terms of genetic research, the GDPR is concerned with data but not with the physical biosamples from which the data is derived. To formulate a comprehensive understanding of applicable consent requirements in genetic research, however, relevant rules in regard to biosamples must be taken into account as well.

Considering the aim of this chapter, and the fragmented nature of consent frameworks in genetic research, this chapter will, first, address genetic research scenarios in which biosamples are procured from individuals (3.1.). This will be followed by a respective analysis regarding research making use of already available biosamples or genetic data (3.2.). A separate analysis will follow regarding genetic data and research in the context of clinical trials as these are subject to

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[114] Taylor's (2012) suggestions in this regard predate the GDPR. Taylor proposes that the questions regarding consent in genetic research could be best addressed "through reform of the Directive." He adds that the question of how to interpret the relationship between consent and the research use of genetic data in terms of the Directive "would ideally be co-ordinated so as to be consistent across Europe." See M. Taylor (2012), p 217.

[115] What is more, within this fragmented legal framework, the matter of intra-EU applicable law in the research context has been overlooked entirely. See K. Pormeister. Genetic research and applicable law: the intra-EU conflict of laws as a regulatory challenge to cross-border genetic research. *Journal of Law and the Biosciences*, 5(3), 706–723.

[116] Some derogations are embedded into the GDPR in regard to personal data processing for research purposes. For example, Art. 17(3)(d) creates an exception from the right to be forgotten when it comes to researches uses of personal data, provided that the invocation of this right "is likely to render impossible or seriously impair the achievement of the objectives of that processing". For an analysis concerning derogations from data subjects' rights in the GDPR in regard to personal data processing for research purposes, See K. Pormeister. Genetic data and the research exemption: is the GDPR going too far? Supra n 52.

[117] Ibid.

specialized EU law (3.3.). Thereafter, the previously made conclusions will be put into context on the example of Estonia in order to offer a comprehensive analysis on consent requirements (or lack thereof) in genetic research based on the example of one Member State (3.4.). Finally, the chapter will close with conclusive remarks on informed consent as a modality of transparency in genetic research (3.5.).

3.1. Consent in genetic research entailing procurement of biosamples

3.1.1. Consent to participation in human subject research

Following World War II, the concept of free and informed consent became "a cardinal principle governing scientific research with human subjects."[118] It reflects the basic rule that one has "the right to protect one's bodily integrity from unauthorized intrusions"[119]; i.e. no one can be forced to participate in research against their will nor can biosamples be retrieved from an individual for research purposes without their consent.

In addition to being an ethical principle, the notion of informed consent in medicine and research is also embedded in international law. The general principle of informed consent in medicine and biology is as well reflected in the Charter of Fundamental Rights of the EU,[120] however, EU law does not regulate human subject research as such, other than in the case of clinical trials,[121] which shall be addressed separately.

Research that entails a physical intervention for procuring biosamples from an individual falls under the definition of biomedical research within the

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[118] G. Mazur (2011), p vii.

[119] R.R. Faden and T.L. Beauchamp (1986), p 121.

[120] Art. 3 of the Charter of Fundamental Rights of the European Union. Although the Charter applies to institutions and bodies of the EU, it only applies to Member States when they are implementing EU law. Since human subject research as such is not regulated by EU law (other than clinical trials), it remains debatable whether the Charter could be referenced as establishing a general rule of informed consent in the context of human subject research in general (when this is not regulated by EU law). See Art. 51, Charter of Fundamental Rights of the European Union (2000/C 364/01), 18.12.2000. OJ C364/1.

[121] Although there is EU law concerning the quality and safety for the procurement of human biosamples, this is limited to biosamples intended for human application, i.e. not research – unless the human application of the biosamples is part of research, i.e. in vivo research on humans. In terms of in vivo research on humans, the referred directive does not regulate research as such, but the safety of the procedures associated with the retrieval, storage and distribution of human biosamples. See Recital 11 and Arts. 1 and 2(1), Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human biosampless and cells. OJ L102/48.

meaning of, and is thus governed by, the Oviedo convention of the Council of Europe.[122] The latter establishes a general requirement of prior informed consent in human subject research under Articles 16(v) and 5. This consent concerns primarily the physical or psychological intervention that the participant is to be subject to; i.e. in the case of genetic research the procurement process of the necessary biosamples (e.g. blood withdrawal or the obtaining of a saliva or other tissue sample). The information to be provided prior to obtaining consent concerns "the purpose, nature and consequences of the intervention and the risks involved."[123] In other words, this type of consent is not the same as informed consent within the meaning of the GDPR – consent to human subject research is primarily concerned with the physical or psychological dimensions of participating in a given research project, whereas consent to data processing within the meaning of the GDPR[124] concerns the use of personal data obtained from participants during the research. Consent to data processing shall be addressed in the following section.

In terms of consent to participation in human subject research, even in regard to countries in the European legal sphere that have not ratified the Oviedo convention, the same basic principle of informed consent in human subject research would arise from the right to respect for private lifer under Article 8[125], and in more extreme cases even from the prohibition of torture under Article 3[126] of the European Convention on Human Rights (ECHR)[127]. Furthermore, as explained in Section 1.4. of this analytical compendium, the ECtHR has referenced the

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[122] Estonia ratified the Oviedo convention in 2002. For full list of signatures and ratifications See the official website of the Council of Europe https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures [Accessed 18 April 2019].

[123] Explanatory Report to the Oviedo convention, supra n 11, p 7, para 35.

[124] The GDPR defines the concept of 'informed consent' through the lens of data protection by limiting it to an individual's agreement for their personal data to be processed. See Art. 4(11) GDPR, supra n 1.

[125] The scope of Art. 8 ECHR covers the right to physical, moral and psychological integrity. See, e.g., European Court of Human Rights. Guide on Article 8 of the European Convention on Human Rights: Right to respect for private and family life, home and correspondence. Updated on 31 December 2018. Council of Europe. Available at https://www.echr.coe.int/documents/guide_art_8_eng.pdf [Accessed 25 April 2019].

[126] Regarding human subject research and the prohibiton of torture under Art. 3 ECHR, the ECtHR has deemed it unacceptable "that a program of scientific research with new drugs be implemented without the consent of the subject submitted to the experimentation. Accordingly, the Court considers that the treatment to which the applicant was subjected against his will amounted to inhuman and degrading treatment within the meaning of Article 3 of the Convention". See §§ 88–91, *Case of Bataliny v. Russia*, EctHR [2015], Application no. 10060/07, ECLI:CE:ECHR:2015:0723JUD001006007.

[127] Supra n 59.

Oviedo convention and used it to give substance to Article 8 ECHR even in cases where the state party had not been a party to the Oviedo convention.[128]

Hence, when it comes to obtaining biosamples necessary for genetic research from individuals directly for research purposes, this constitutes 'human (subject) research' within the meaning of the Oviedo convention,[129] and thus prior informed consent is clearly required by the convention. If, however, the biosamples have been obtained for purposes independent of research, this general requirement of consent to research within the meaning of the Oviedo convention no longer applies.[130] It follows that whilst the procurement of biosamples from individuals for research purposes requires informed consent of the individual under the Oviedo convention, the research rules of the Oviedo convention do not apply where biosamples have been obtained independent of research (e.g. in the course of clinical care) and might later be used in research.

Although the Oviedo convention establishes quite clear rules on informed consent for participation in human subject research, as an instrument of international law it does presume in Article 1 the adoption of relevant national laws by the state parties in order to give effect to the rules established under the convention. Hence informed consent in regard to participation in genetic research in the form of human subject research, i.e. as in including the collection of biosamples from individuals, shall be revisited in Section 3.4. of this chapter on the example of Estonia.

3.1.2. Consent to data processing in genetic research

Genetic research entailing the procurement of biosamples directly from individuals would, of course, at the same time entail the processing of genetic data. The very purpose of obtaining biosamples for research purposes is, in most

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[128] See supra n 58 and n 63.

[129] The act of obtaining biosamples for research purposes constitutes a physical intervention within the meaning of Art. 5 of the Oviedo convetion, and thus triggers the consent requirement in research as stipulated in Art. 16(v) of the convention, which refers back to consent rules under Art. 5.

[130] This is evidenced in the explanatory report to the additional protocol of the Oviedo convention regarding biomedical research. The explanatory report to the additional protocol on biomedical research emphasizes that the definition and scope of 'biomedical research' does not encompass scenarios in which biosamples or personal data are obtained in the course of medical interventions independent of a research project, even when they might be later used in biomedical research. See Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research. Strasbourg, 25.I.2005. CETS No. 195, p 4, para 17.

See also K. Pormeister. Genetic research and consent: on the crossroads of human and data research. Supra n 64, p 350.

cases, the data they can provide.[131] This means that the personal data protection framework becomes applicable parallel to the rules regarding participation in human subject research.

In terms of genetic data, the GDPR sets out general rules in terms of processing special categories of personal data. The only specific reference in the GDPR to genetic data remains that in Article 9(4), which affords additional discretion to Member Sates for adopting "further conditions, including limitations," when it comes to genetic, health or biometric data. Thus, discrepancies between national laws in terms of rules concerning any processing of genetic data (incl. for research purposes) might arise from Article 9(4) GDPR. In the research context specifically, discrepancies are likely to arise since Article 9(2)(j) GDPR leaves the research use of special categories of personal data to be regulated in other EU law or Member State law. Aside from a few clauses in the GDPR concerning research specifically (e.g. Art. 14(5)(b), Art. 17(3)(d) and Art. 89), the research use of genetic data will be subject to national or other EU law.

In terms of genetic data and the rules stemming directly from the GDPR, the general prohibition of processing in Article 9(1) GDPR applies. This means that one of the exceptions permitting processing, listed in Article 9(2) GDPR, has to be applied in order for any processing of genetic data to be in compliance with the GDPR. One of these exceptions is the explicit and informed consent of the individual for specific data processing purposes. It is important to emphasize that the GDPR does not explicitly establish a requirement of consent when it comes to the research use of any of the special categories of personal data, including genetic data.[132]

The general legal basis for processing genetic data based on consent is established in Article 9(2)(a) GDPR. The latter requires for the consent to set out the specific purpose(s) for which the data will be processed. In the context of research, this should be understood as setting out specific research projects in which the data will be used.[133] In this regard, Recital 33 GDPR recognizes the need for more lax consent requirements in the research context by setting out that "data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research" (as opposed to "for one or more specified purposes" as stipulated in Art. 9(2)(a) GDPR). The answer to the question of how specific the processing purposes must be within the consent will impact how efficiently consent can provide for transparency in relation to the data subject, i.e. whether

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[131] In certain cases, e.g. *in vivo* research on humans involving transplantion of tissue, cells or organs, the physical biosamples might be of interest rather than the data contained within them (e.g. research involving stem cell transplants).

[132] See K. Pormeister. Genetic data and the research exemption: is the GDPR going too far? Supra n 52, pp 138–140; and K. Pormeister. Genetic research and consent: on the crossroads of human and data research. Supra n 64, p 353.

[133] K. Pormeister. Genetic research and consent: on the crossroads of human and data research. Supra n 64, p 353.

the information provided to the data subject prior to obtaining consent will make it transparent to the data subject what purposes the data will be processed for.

Presumably, a recital cannot alter a rule in the regulation itself. Recitals have been seen as interpretive tools, sometimes performing "a supplementary normative role".[134] Recitals, however, do not have an autonomous legal effect.[135] As made clear by the Court of Justice of the EU (CJEU), "[…] the preamble to a Community act has no binding legal force and cannot be relied on as a ground for derogating from the actual provisions of the act in question."[136]

Based on this role attributed to recitals in EU law by the CJEU, a possible broader consent notion for research purposes, as described in Recital 33 GDPR, is something that could be addressed in national or other EU law, as indicated in Article 9(2)(j) GDPR. The latter enables Member States and the EU to establish legal grounds for the processing of special categories of data for research purposes, with these legal grounds being independent of the strict requirements regarding consent under Article 9(2)(a) GDPR.[137] Hence, Recital 33 GDPR can be seen as setting limits to the discretion provided under Article 9(2)(j) GDPR in terms of regulating consent in research. However, the WP29 seem to have taken the opposite approach towards Recital 33 GDPR.

In an opinion of 2017 regarding consent under the GDPR (in November 2017, the opinion was adopted, but still to be finalized)[138], the WP29 maintained that,

> "First, it should be noted that Recital 33 does not disapply the obligations with regard to the requirement of specific consent. This means that, in principle, scientific research projects can only include personal data on the basis of consent if they have a well-described purpose. Where purposes are unclear at the start of a scientific research programme, controllers will have difficulty to pursue the programme in compliance with the GDPR."[139]

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[134] R. Baratta. Complexity of EU law in the domestic implementing process. 19th Quality of Legislation Seminar 'EU Legislative Drafting: Views from those applying EU law in the Member States'. 3 July 2014. Available at http://ec.europa.eu/dgs/legal_service/seminars/20140703_baratta_speech.pdf [Accessed 8 May 2019].

[135] Ibid.

[136] Judgement of 19 November 1998, *Nilsson and Others*, C-162/97, ECLI:EU:C:1998:554, paragraph 54.

[137] See K. Pormeister. Genetic data and the research exemption: is the GDPR going too far? Supra n 52, pp 138–140.

[138] Guidelines on Consent under Regulation 2016/679 (as of 24 January 2018). Adopted on 28 November 2017. Article 29 Data Protection Working Party, 17/EN WP259. Available at http://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=615239 [Accessed 19 March 2018].

[139] Ibid., p 27.

These guidelines were revised in 2018, and in the revised version the WP29 had somewhat modified its stance on Recital 33, by altering the last sentence in the quotation above to the following,

> "For the cases where purposes for data processing within a scientific research project cannot be specified at the outset, Recital 33 allows **as an exception** that the purpose may be described at a more general level."[140] (emphasis added by the author)

From this last reference it appears that the WP29 see Recital 33 GDPR as creating an exception to the general rules of specificity of consent. In the author's opinion, this approach is in conflict with the case law of the CJEU concerning the legal status of recitals referred to above. Although recitals can be used to interpret legal clauses, they cannot create outright exceptions to rules established in the substantive clauses themselves.

In the 2017 version of the guidelines, the WP29 then goes on to explain that Recital 33 GDPR will allow describing the research purpose on "a more general level", but should be interpreted more strictly when it comes to special categories of personal data.[141] They further add that if the purposes of the research cannot be "fully specified", the controller can ask for consent for a purpose in "more general terms".[142] In the 2018 version of the guidelines, the WP29 refers to the fact that Article 9 GDPR sets strict conditions for the processing of special categories of data, and so "applying the flexible approach of Recital 33 will be subject to a stricter interpretation and requires a high degree of scrutiny."[143]

Essentially, according to the WP29 it seems that in terms of special categories of data such as genetic data, the specificity requirement of consent is to be seen as laying somewhere in-between the strict rules established in Article 9(2)(a) GDPR and the more lax principles expressed in Recital 33 GDPR. From this it follows that, on the one hand, the WP29 are trying to maintain a strict approach to consent to (sensitive) data processing in research. On the other hand, the WP29 seem to indicate that the approach to research consent reflected in Recital 33 GDPR is directly applicable, i.e. it need not be regulated under Member State or other EU law (unlike previously presumed by the author). Although the WP29 maintain that "Recital 33 does not disapply the obligations with regard to the requirement of specific consent", at the same time they assert that the purpose of processing "may be described at a more general level". In other words, according to the WP29 the level of specification of purposes within the consent

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[140] Article 29 Working Party Guidelines on Consent under Regulation 2016/679, supra n 80, p 28.

[141] Guidelines on Consent under Regulation 2016/679 (as of 24 January 2018), supra n 138, p 28.

[142] Ibid.

[143] Article 29 Working Party Guidelines on Consent under Regulation 2016/679, supra n 80, p 28.

is different in research due to Recital 33 GDPR, compared to other scenarios of processing based on consent and the general rule under Article 9(2)(a) GDPR. With this, essentially the WP29 are stating that at Recital 33 does alter the specificity requirements regarding consent when it comes to consent to data processing in the research context. This makes their opinion somewhat contradictory.

What is more, the WP29 do not touch upon the question of how broadly "certain areas of scientific research" within the meaning of Recital 33 GDPR should be interpreted in practice. They emphasize that "future research" as a purpose is not specific enough.[144] However, they do not bring any explicit examples as to which level of specification would be appropriate in a research context, other than referring to "more general terms" or "more general level" in regard to the applicability of the principles expressed in Recital 33 GDPR, as referenced above.

Even if one were to agree with the WP29 in terms of the direct applicability of the principles in Recital 33 GDPR, it remains arguable how liberally one should interpret the concept of "certain areas of scientific research". In other words, it is unclear how broad the consent to use special categories of personal data in research could be – whether applied directly or established in national or other EU law. In this regard, two comparators can be used. First, in the 2013 amendment proposals to the draft version of the GDPR, Amendment 191 set out to establish in Article 81(1b) that "for the processing of medical data [incl. genetic data] exclusively for public health purposes of scientific research, the consent may be given for one or more specific and similar researches."[145] The specific rules for the use of health data (incl. genetic data) in research did not make it into the final draft of the GDPR assumedly because of opposition from the medical and research sector.[146] However, the wording used in the proposed Article 81(1b) ("one or more specific and similar researches") would have been more restrictive compared to the phrase used in Recital 33 of the final version

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[144] Article 29 Data Protection Working Party. Opinion 03/2013 on purpose limitation. Adopted on 2 April 2013. 00569/13/EN WP 203, p 16. Available at https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2013/wp203_en.pdf [Accessed 24 April 2019].

[145] Amendment 191, Proposal for a regulation, Article 81. Report on the proposal for a regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) (COM(2012)0011 – C7-0025/2012 – 2012/0011(COD)). 22 November 2013, Committee on Civil Liberties, Justice and Home Affairs. Available at http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A7-2013-0402+0+DOC+XML+V0//EN# [Accessed 19 March 2018].

[146] See, e.g., P.G. Casali on behalf of the European Society for Medical Oncology (ESMO) Switzerland. Risks of the new EU Data protection regulation: an ESMO position paper endorsed by the European oncology community. *Annals of Oncology* 25(8) (2014), pp 1458–1461.

("certain areas of scientific research").[147] The former indicates to 'researches' as in (one or multiple) research projects, whereas the latter concerns whole areas of research.[148]

In terms of genetic research this leaves the question whether 'genetic research' as such could be considered a "certain scientific area of research" within the meaning of Recital 33 GDPR? Or would 'genetic research' be too vague and general? Considering that genetic research could theoretically constitute an inquiry into the association between DNA and essentially anything and everything, and put in the light of the strict interpretation called for by the WP29 in regard to special categories of personal data, the raised questions should be answered in the negative.

To conclude, in the opinion of the author, and based on relevant case law of the CJEU, Recital 33 GDPR cannot create an exception to the requirement in Article 9(2)(a) GDPR of setting out specific purpose(s) in the consent. As established in Article 9(2)(j) GDPR, the research use of special categories of data is to be regulated in national or other EU law – including rules on consent to data processing for research purposes (within the limits indicated in Recital 33 GDPR).

3.1.3. Conclusions on consent in genetic research entailing the procurement of biosamples

To sum up the matter of consent in genetic research entailing the procurement of biosamples, two things can be concluded. First, from a legal theoretical perspective such research entails parallel procedures in regard to consent – in practical terms this should not be understood as inherently separate processes resulting in two consent forms[149], but to be taken as entailing two types of consent with different focuses and applicable rules. One for participation in the research project, and the other for the processing of the personal data obtained during the research project.

The procedure for the procurement of the biosamples as a physical intervention on the human body is subject to consent requirements stemming from rules regarding human subject research, like those in Articles 16(v) and 5 of the Oviedo convention, unless respective (more specific) rules are embedded in

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[147] K. Pormeister. Genetic research and consent: on the crossroads of human and data research. Supra n 64, p 353.

[148] Ibid.

[149] In practical terms, Art. 7(2) GDPR provides the relevant rules for incorporating informed consent to data processing into documentation concerning other matters as well. Consent to participation in human subject research (i.e. the physical or psychological intervention) might constitute such 'other matters'. Thus, if consent to data processing is incorporated into one consent form with the participation consent, under Art. 7(2) GDPR the consent to data processing must "be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language."

national law (in which case national law should be referred to). This consent primarily focuses on the risks associated with the intervention on the human subject, such as the risks of infection or bruising related to taking blood samples. This type of informed consent is not focused on or concerned with the possible (future) uses of the data obtained from the biosample.

In terms of the use of the genetic data derived from such samples, general consent requirements for special categories of personal data under the GDPR apply. Based on the consent guidelines of the WP29, one might conclude that Recital 33 GDPR creates a directly applicable exception for research when it comes to the question of how specific the purposes of processing need to be in the informed consent – i.e. whether consent needs to be limited to certain research projects, as it would be under the general rule in Article 9(2)(a), or whether consent can be obtained for the use of the data in 'certain areas of scientific research'. In the opinion of the author, this is something to be addressed in national or other EU law, as Article 9(2)(j) GDPR clearly leaves the research use of special categories of personal data to be regulated in either Member State or other EU law.

Furthermore, the author deems the guidelines on consent of the WP29 somewhat contradictory and problematic in terms of the breadth of research consent and the practical meaning of Recital 33 GDPR. Whilst the WP29 assert that Recital 33 does not disapply the specificity requirement of consent, at the same time they state that Recital 33 GDPR (directly, i.e. without national or other EU law implementing such principles) enables for processing purposes to be described on a more general level when it comes to research. Thus, essentially the WP29 are saying that Recital 33 GDPR at the very least alters or modifies (even if it does not entirely disapply) the rules of specificity of consent under the GDPR. In fact, the WP29 even refer to Recital 33 GDPR as creating an exception, which a recital – according to CJEU case law – cannot do. The author concludes that instead of creating a directly applicable exception to the specificity requirement of consent in research, Recital 33 GDPR should be seen as limiting the discretion provided in Article 9(2)(j) GDPR to EU and national lawmakers in regulating the research use of special categories of personal data.

3.2. Genetic research entailing secondary use of biosamples and data

As established in the introductory chapter of the analytical compendium, the phrase 'secondary use' is understood as referring to the use of biosamples or data for purposes other than which they were initially collected for.[150] As opposed to the above analysed research scenario, in which biosamples are obtained from

[150] See, e.g., International Review of Secondary Use of Personal Health Information. Health Information and Quality Authority (Ireland), January 2012. Available at https://www.hiqa.ie/system/files/Review-Secondary-Use-Health-Info.pdf [Accessed 19 March 2018].

research participants directly, research based on secondary use entails the utilization of already available biosamples and/or genetic data derived therefrom, and does therefor not directly involve the individuals whose samples and/or genetic data are concerned.

This might, on the one hand, refer to the use of biosamples or data that was initially collected for a different research purpose. On the other hand, the term 'secondary use' might also refer to a scenario, in which the biosamples or data were originally collected for an entirely different purpose than research, i.e. clinical care or commercial genetic testing services.

In the 'secondary use' scenario, necessary DNA sequencing data might already be available for research, and thus further analysis of biosamples might not be necessary. However, biosamples might still be involved if the available data is not sufficient or if DNA has not yet been sequenced from the samples. Because genetic research might rely on the secondary use of both biosamples and genetic data, and these are subject to different sets of rules, they will be subject to separate analysis.

3.2.1. Secondary use of biosamples in research

In the European legal sphere, the only supranational legal rule governing the further use of human biosamples in research stems from Article 22 of the Oviedo convention.[151] The latter establishes that,

> "When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures."

Article 22 does not in and of itself establish any such procedures. The referred 'appropriate information and consent procedures' are a matter of national law (Art. 1 Oviedo convention).[152] The threshold set in Article 22 does not require prior *informed* consent, nor does it necessarily require consent at all.[153] As laid out in the explanatory report to the Oviedo convention,

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[151] Although, in the EU, there is Directive 2004/23/EC and directives of the Commission implementing the former, these govern human cells and biosamples only in regard to their use for human application, but not research, other than their application in the context of in vivo human research. See supra n 121.

See also K. Pormeister. Genetic research and consent: on the crossroads of human and data research. Supra n 64, p 354.

[152] See also Section 3.1.1. of this chapter.

[153] K. Pormeister. Genetic research and consent: on the crossroads of human and data research. Supra n 64, p 354.

> "The information and consent arrangements may vary according to the circumstances, thus allowing for flexibility since the express consent of an individual to the use of parts of his body is not systematically needed. Thus, sometimes, it will not be possible, or very difficult, to find the persons concerned again in order to ask for their consent. In some cases, it will be sufficient for a patient or his or her representative, who have been duly informed (for instance, by means of leaflets handed to the persons concerned at the hospital), not to express their opposition. In other cases, depending on the nature of the use to which the removed parts are to be put, express and specific consent will be necessary, in particular where sensitive information is collected about identifiable individuals."[154]

What is clear from the above is that the minimum threshold established by Article 22 of the Oviedo convention is due notification that would enable the expression of opposition. The latter essentially constitutes a pre-emptive opt-out approach to the secondary use of biosamples. As noted, the specific requirements are subject to national law, with the minimum requirements being expressed in Article 22 of the Oviedo convention. For this reason, the secondary use of biosamples for research will be further elaborated upon in Section 3.4. of this chapter on the Estonian example.

To conclude, on a supranational level in the European legal sphere, Article 22 of the Oviedo convention seems to be the only rule to govern the secondary use of biosamples in research. This rule establishes a minimum threshold of due notification of the individuals from whom the samples were taken (or their representatives) to enable the expression of opposition. More stringent requirements – like that of prior (informed) consent – may arise from national laws.

3.2.2. Secondary use of genetic data in research

As previously noted, the secondary use of genetic data in research might occur when the data was initially obtained and used in a research context based on the consent of the individual, but with the research purposes being limited in the consent. The research purposes in this initial consent might either be limited to specific projects, or possibly to a "certain area of scientific research" as set out by Recital 33 GDPR (if one were to accept the stance of the WP29 regarding the direct applicability of Recital 33 GDPR). The purposes of processing laid out in the initial consent would then refer to the primary use of the data, and possible future research purposes falling outside of the scope of the initial consent would thereby constitute secondary use. However, like in the case of the biosamples, secondary use of genetic data in research might also occur if the

[154] Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Supra n 11, p 21, para 137.

genetic data was initially obtained for and used in an entirely different context, e.g. for purposes of clinical care or commercial genetic testing services.

As to the health care sector, the transition to electronic health records has made extensive research based on health record databases a practicable reality. Although the GDPR does not explicitly refer to the secondary use of data, it does in Recital 157 address research based on data retrieved from registries, i.e. existing databases. However, Recital 157 GDPR merely points out that such research should be "subject to appropriate conditions and safeguards set out in Union or Member State law." That is as far as the GDPR goes in regard to differentiating between research scenarios.[155]

There is no question that secondary use of genetic data could be based on new consent obtained from the data subject. This would mean that researchers would have to reach out to and obtain new consent from all individuals whose data is already available and of interest to the researchers. However, and particularly in genetic research, this is more often than not considered impracticable, disproportionally cumbersome, or even impossible, as genetic research might require the use of data from thousands or even tens of thousands of people.[156]

Under Articles 5(1)(b) and (e) GDPR, the purpose and storage limitations do not apply when it comes to the storage and further use of data for, inter alia, scientific research purposes. This means that regardless of in what context and for what purposes genetic data was initially obtained, it can be put to further use in research regardless of possible limitations in the initial consent or context (i.e. data might also be initially obtained not based on consent, but based on law, e.g., in the health care sector, but specifically for the provision of health care services). There might be discrepancies in this regard across the EU if a Member State has opted to maintain or introduce further conditions, including limitations, in regard to genetic, health or biometric data, as allowed by Article 9(4) GDPR for specifically these three categories of data.

Such further processing of already obtained data for research purposes would still require a legal basis. However, obtaining (new) consent is not the only alternative for a legal basis for the secondary use of data in research, as the GDPR does not explicitly require consent for the processing of special categories of personal data for research purposes.[157] Though Article 9(2)(a) GDPR establishes consent as one possible legal basis for such use, alternative legal bases might arise from national or other EU law, as Article 9(2)(j) GDPR provides for legal grounds for processing to be established in Member State or other EU law – legal grounds, that are independent of the consent requirement

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[155] K. Pormeister. Genetic research and consent: on the crossroads of human and data research. Supra n 64, p 348.

[156] See, e.g., E.P. Hong, J.W. Park. Sample Size and Statistical Power Calculation in Genetic Association Studies. *Genomics & Informatics* 10(2) (2012), p 117–122. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3480678/# [Accessed 20 March 2018].

[157] Article 29 Working Party Guidelines on Consent under Regulation 2016/679, supra n 80, p 28.

in Article 9(2)(a) GDPR.[158] Thus, reference must be made to national laws to further analyse the scenario of secondary use of genetic data in research. This will be done in Section 3.4. of this chapter on the example of Estonia.

To conclude, though secondary processing of genetic data can be undertaken by obtaining new consent from data subjects, secondary processing is also possible without consent if Member State or EU law provide for grounds for data processing without consent for research purposes.[159]

3.3. Genetic research in the context of clinical trials

One scenario regarding genetic research that needs to be addressed separately is that of genetic research entailing the secondary use of genetic data obtained during clinical trials. This is due to the fact that unlike other types of human subject research, clinical trials are regulated by EU law – namely, by the upcoming Regulation 536/2014 (estimated to come into application in 2020[160]).

3.3.1. Primary research use of genetic data in clinical trials

In regard to clinical trials on medicinal products for human use, according to Recital 161 GDPR, Regulation 536/2014 will regulate consent procedures regarding participation in such trials. In terms of the referred consent procedures under Regulation 536/2014, the WP29 have noted, "In the context of data protection law, the latter form of consent could be considered as an additional safeguard."[161] Informed consent to participation in a clinical trial is not to be confused with informed consent to data processing within the meaning of the GDPR.[162] Much like in the case of the general requirements for informed consent in human subject research previously analysed in this chapter, the consent for participation in clinical trials is not concerned with data protection, but responds

[158] K. Pormeister. Genetic data and the research exemption: is the GDPR going too far? Supra n 52, p 139.

[159] Article 29 Working Party Guidelines on Consent under Regulation 2016/679, supra n 80, p 28.

[160] See supra n 57.

[161] Article 29 Working Party Guidelines on Consent under Regulation 2016/679, supra n 80, p 28.

[162] European Data Protection Board (EDPB). Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)). Adopted on 23 January 2019, para 15. Available at https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_opinionctrq_a_final_en.pdf [Accessed 22 April 2019].

> "[…] primarily to core ethical requirements of research projects involving humans deriving from the Helsinki Declaration. The obligation to obtain the informed consent of participants in a clinical trial is primarily a measure to ensure the protection of the right to human dignity and the right to integrity of individuals under Article 1 and 3 of the Charter of Fundamental Rights of the EU; it is not conceived as an instrument for data protection compliance."[163]

However, in terms of the legal basis for the primary research use of personal data in clinical trials, the European Data Protection Board (EDPB) is of the opinion that in most cases informed consent within the meaning of the GDPR would not be the appropriate legal basis.[164] The EDPB argues this based on the "clear situation of imbalance of powers between the participant and the sponsor/ investigator", which "will imply that the consent is not 'freely given' in the meaning of the GDPR." This imbalance, they claim, might be due to the health condition of the potential participant, socio-economic status or "any situation of hierarchical dependency".[165] According to the EDPB, informed consent within the meaning of the GDPR might be the legal basis for the primary use of personal data in clinical trials, however only in cases in which the sponsor can show compliance with all the conditions set for informed consent under the GDPR.[166]

According to the EDPB, as far as special categories of personal data are concerned, the legal basis for the primary use of such data in research could be either Article 6(1)(e) or (f) GDPR (i.e. respectively public interest or legitimate interests pursued by the controller), however only where a specific derogation under Article 9(2) GDPR can be relied upon. The EDPB suggests both Articles 9(2)(i) and (j) as possible appropriate derogations.[167]

Thus, the EDPB concludes that the primary research use of special categories of personal data in clinical trials could be based on three alternative legal grounds: (1) informed consent within the meaning of Articles 6(1)(a) and 9(2)(a) GDPR (only in limited cases); (2) relying on the public interest clause in Article 6(1)(e) along with Article 9(2)(i) or (j) GDPR; or (3) based on Article 6(1)(f) and the legitimate interests of the controller along with Article 9(2)(j)

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[163] Ibid., para 16.

[164] In its opinion on the interplay between the CTR and the GDPR, the EDPB distinguishes two different phases of clinical trials in regard to determining possible legal bases for the processing of personal data. One phase concerns "Processing operations related purely to research activities". The other concerns "Processing operations related to reliability and safety purposes". In the latter case, concerning special categories of personal data, the adequate legal basis for processing in the opinion of the EDPB is Art. 9(2)(i) GDPR, and for other types of personal data it is Art. 6(1)(c). Ibid.

[165] EDPB Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)), supra n 162, para 20.

[166] Ibid., para 17.

[167] Ibid., paras 25 and 28.

GDPR.[168] The same conclusions are recognized by the Directorate-General for Health and Food Safety of the European Commission.[169]

The author is in disagreement with the position taken by the EDPB and the Commission in regard to the claim that in most cases informed consent would not be the appropriate legal basis for personal data processing in clinical trials in the research phase due to the voluntariness requirement of consent.[170] The arguments of the EDPB rely heavily on a presumed "imbalance of powers" between the potential trial participant and the sponsor of the trial. The core problem with this line of argumentation is that the same rationale would then have to be mutatis mutandis applied to the consent for participation in the clinical trial, as Regulation 536/2014 defines 'informed consent' as a "free and voluntary expression" (Art. 2(2)(21) Regulation 536/2014) – as does the GDPR, which requires consent to be freely given (Art. 4(11) GDPR). In other words, if the supposed imbalance of powers between a potential participant and the sponsor of a clinical trial negates the possibility of consent within the meaning of the GDPR to be freely given, it would then also have to have the same impact on the voluntariness of the consent to participation in the trial within the meaning of Regulation 536/2014.

In turn, based on the logic relied upon by the EDPB, it would follow that participation in clinical trials in most cases could not be based on informed consent since consent could not be considered 'freely given' due to the presumed imbalance of powers – which would be a ludicrous conclusion, as the exact opposite principle applies. As a general rule, participation in clinical trials is subject to informed consent.[171] Regarding consent to participation in a clinical trial, the possibility of the imbalance of powers and its impact on the voluntariness of consent is addressed in Regulation 536/2014, which sets out in Recital 31 that,

> "In order to certify that informed consent is given freely, the investigator should take into account all relevant circumstances which might influence the decision of a potential subject to participate in a clinical trial, in particular whether the potential subject belongs to an economically or socially disadvantaged group or is in a situation of institutional or hierarchical

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[168] Ibid., para 34.

[169] European Commission. Directorate-General for Health and Food Safety. Health Systems and Products. Medical products – quality, safety and innovation. Question and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation. Updated 10 April 2019. Available at https://ec.europa.eu/health/sites/health/files/files/documents/qa_clinicaltrials_gdpr_en.pdf [Accessed 23 April 2019].

[170] The author does not dispute the positions of the EDPB in regard to the legal bases for data processing in clinical trials related to reliability and safety (as opposed to processing related to research activities). See also supra n 164.

[171] Arts. 1 and 3, Charter of Fundamental Rights of the EU, supra n 120; Recital 27 of Regulation 536/2014, supra n 56.

> dependency that could inappropriately influence her or his decision to participate."

This means that an imbalance of powers excluding the voluntariness of consent would rule out participation in the trial. Vice versa, if consent to participation in the trial can be deemed freely given, the same conclusion must be made in terms of the consent to data processing, since the latter is obtained in the context of the same relationship (i.e. between the potential participant and the sponsor).

Exceptions do apply to the general requirement of consent to participation in a clinical trial, and certain circumstances can justify incorporating individuals into clinical trials without or prior to obtaining consent.[172] In the opinion of the author, it is specifically these cases in which trial participation is based on legal grounds other than consent in which data processing needs to rely on alternative bases as well.

What is more, in stating that consent would not be the appropriate legal basis for data processing for the primary research purposes in clinical trials, both the EDPB and the Commission refer to the opinion of the WP29 regarding consent under the GDPR in a misleading manner.[173] The EDPB and the Commission make a general reference to the opinion of the WP29 in stating that, "as explained in the Guidelines on consent of the Working Party 29, consent will not be the appropriate legal basis in most cases, and other legal bases than consent must be relied upon".[174] However, the WP29 do not make this statement in regard to the research context specifically. In fact, in their guidelines on consent, in regard to research the WP29 make no reference to any alternative suitable legal bases for data processing for research purposes.[175] In these guidelines the WP29 address the imbalance of powers and the resulting difficulties of using consent as a legal basis for data processing in the context of processing by public authorities and in employment.[176] In terms of the appropriateness of consent as a legal basis for data processing the WP29 note that consent is an appropriate option "if a data subject is offered control and is offered a genuine choice with regard to accepting

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[172] See Art. 35 and Recital 36 of Regulation 536/2014, which refer to emergency situations like a patient having "suffered a sudden life-threatening medical condition due to multiple traumas, strokes or heart attacks, necessitating immediate medical intervention. For such cases, intervention within an ongoing clinical trial, which has already been approved, may be pertinent. However, in certain emergency situations, it is not possible to obtain informed consent prior to the intervention." Supra n 56.

[173] Article 29 Working Party Guidelines on Consent under Regulation 2016/679, supra n 80.

[174] European Data Protection Board (EDPB). Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)), supra n 162, para 20; European Commission. Question and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation, supra n 169, p 6.

[175] Article 29 Working Party Guidelines on Consent under Regulation 2016/679, supra n 80, pp 27–30.

[176] Ibid., pp 6–7.

or declining the terms offered or declining them without detriment."[177] As emphasized above, the very same rationale applies to consent in regard to participation in clinical trials (or any human subject research for that matter).

To conclude, unlike the EDPB and the Commission, the author is of the opinion that the primary research use of personal (incl. genetic) data in clinical trials can and should, in most cases, be based on informed consent within the meaning of the GDPR. The counterarguments to this position used by the EDPB and the Commission are illogical given that consent to participation in the trial needs to be freely given as well – and if consent to participation in the trial can be freely given by the potential participant, the voluntariness of the consent for data processing within that same relationship between the participant and trial sponsor cannot be negated.

3.3.2. Secondary use of genetic data obtained during clinical trials

Regulation 536/2014 contains a specific clause regarding the secondary use of the personal data obtained during clinical trials. Article 28(2) of Regulation 536/2014 sets out that,

> "Without prejudice to Directive 95/46/EC, the sponsor may ask the subject or, where the subject is not able to give informed consent, his or her legally designated representative at the time when the subject or the legally designated representative gives his or her informed consent to participate in the clinical trial to consent to the use of his or her data outside the protocol of the clinical trial exclusively for scientific purposes. That consent may be withdrawn at any time by the subject or his or her legally designated representative.
>
> The scientific research making use of the data outside the protocol of the clinical trial shall be conducted in accordance with the applicable law on data protection."

The EDPB and the Commission have dismissed the consent referred to in Article 28(2) of Regulation 536/2014 as a possible legal basis for data processing. Both argue that in order to utilize the possibility referred to in Article 28(2) of Regulation 536/2014, the sponsor of the clinical trial would need a specific legal basis for data processing – whereas the Commission refers to Article 6 GDPR in stating so.[178] The EDPB emphasizes that consent within the meaning of Article 28(2) of Regulation 536/2014 "is not the same consent referred to in

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[177] Ibid., p 3.

[178] European Data Protection Board (EDPB). Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)), supra n 162, para 30; European Commission. Question and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation, supra n 169, pp 7–8.

the GDPR as one of the legal basis for the processing of personal data".[179] Both the EDPB and the Commission are of the opinion that the concept of 'informed consent' in its entirety within the meaning of Regulation 536/2014 and its Chapter V is to be distinguished from the consent for data processing within the meaning of the GDPR.[180] The Commission explains that informed consent within the meaning of Regulation 536/2014 "serves as an ethical standard and procedural obligation", and "is the fundamental condition under which a person can be included into a clinical trial. It is not conceived as an instrument for data processing compliance."[181]

The author concurs with the general notion that the consent to participation in clinical trials within the meaning of Regulation 536/2014 (and human subject research as such) is to be distinguished from consent to data processing within the meaning of the GDPR. However, in the author's opinion the one exception to this general approach in regard to consent under Regulation 536/2014 is precisely that embedded into Article 28(2). There are three arguments to support this dissenting position of the author.

First, from the text and wording of Article 28(2) of Regulation 536/2014 it is apparent that the consent established in the referred clause is not concerned with participation in the trial as it refers solely to the future use of data. Consent under Article 28(2) concerns the secondary use of the data obtained during the trial outside of the trial (i.e. for different research purposes). It thus constitutes a parallel procedure to obtaining participation consent and does not impact participation in trial. This means that the overarching approach to the meaning of 'informed consent' under Regulation 536/2014 as being focused solely on participation in clinical trials (and not data processing) is not applicable to the consent referred to in Article 28(2).

Second, and closely connected to the previous point, the argument that the consent referred to in Article 28(2) is one designed as a legal basis for data processing, is further indicated in Recital 29 of Regulation 536/2014. The latter explains that the aim of this consent is to enable researchers to use the data collected during trials "for future scientific research, for example for medical, natural or social sciences research purposes." Thus the aim of the consent referred to in Article 28(2) of Regulation 536/2014 is precisely to enable *data processing* for future projects, provided that this is done "exclusively for scientific purposes".

Third, the assertion that Article 28(2) of Regulation 536/2014 does not establish a separate notion of consent for future processing of the data obtained during clinical trials begs the question of why this clause exists in Regulation

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[179] European Data Protection Board (EDPB). Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)), supra n 162, para 29.

[180] Ibid.; European Commission. Question and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation, supra n 169, p 6.

[181] Ibid.

536/2014 in the first place. The GDPR does not exclude the possibility for other EU law to regulate the research use of personal data. To the contrary, concerning the research use of special categories of data, Article 9(2)(j) GDPR refers to this as being a matter to be regulated in Member State or other EU law. Following the rationale of the EDPB and the Commission, however, Article 28(2) of Regulation 536/2014 would serve no actual purpose. The trial sponsor could always obtain consent in accordance with the GDPR in order to use the data outside of the clinical trial, but would then also be limited by the condition of having to set out specific purposes in the consent as required by Article 9(2)(a) GDPR (though according to the WP29 this is modified to a less strict standard by Recital 33 GDPR). This is, in fact, exactly what the Commission argues as they refer to Recital 33 GDPR.[182]

Since the author disagrees with the Commission and the EDPB in regard to the meaning of Article 28(2) of Regulation 536/2014 and the nature of the consent referred to therein, it also brings about a disagreement in regard to the specificity and acceptable breadth of consent in this context. Unlike Article 9(2)(a) and Recital 33 GDPR, Article 28(2) of Regulation 536/2014 sets no apparent limits to the breadth of this type of consent other than the use of the data "exclusively for scientific purposes". As noted above, Recital 29 of Regulation 536/2014 further explains that this type of consent will enable "data from clinical trials to be used for future scientific research, for example for medical, natural or social sciences research purposes" (i.e. essentially any future research purposes). Because the EDPB and the Commission are of the opinion that Article 28(2) of Regulation 536/2014 does not establish a broader type of consent for data processing, and solely refer to the GDPR in terms of consent and its requirements, they also conclude that the limits set in Recital 33 GDPR still apply (though in the author's opinion it would then have to be the limits set by Art. 9(2)(a) GDPR, unless national or other EU law provides for a broader research consent). However, if one were to accept the author's arguments in regard to the independent nature of the consent in Article 28(2) of Regulation 536/2014 as a legal basis for data processing, one could negate the applicability of the limits in the GDPR in regard to the breadth of consent, and conclude that Article 28(2) of Regulation 536/2014 allows for a type of open research consent for the future use of the data obtained during trials.[183]

Other aspects of the collection, storage and further use of the data obtained during clinical trials are still subject to the GDPR, as is evidenced by the last sentence of Article 28(2) Regulation 536/2014.

To conclude, the author is of the opinion that the primary use of genetic data in clinical trials (i.e. genetic research as part of clinical trials) should, in most cases, be based on informed consent as a legal basis for the processing. This is in

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[182] Ibid., pp 8–9.

[183] See K. Pormeister. Genetic research and consent: on the crossroads of human and data research. Supra n 64, pp 354–355.

contrast to the positions expressed by the EDPB and Commission. However, their reasoning against consent as a primary legal basis for data processing for research purposes in clinical trials collides with simple logic: if voluntariness of the consent to data processing is under question due to the presumed imbalance of powers between the potential participant and the sponsor of the trial, this same imbalance would exclude the voluntariness of the consent to participation in the trial, which, in turn, would exclude participation from the trial in the first place (hence nullifying any dilemma regarding the voluntariness of the consent to data processing).

Furthermore, the author also disagrees with the EDPB and the Commission regarding the secondary use of genetic data obtained during clinical trials. Consent under Article 28(2) of Regulation 536/2014 does not concern or in any way affect participation in the trial. Its sole aim is to enable the future research use of the data obtained during a clinical trial, i.e. it is designed as a form of consent for data processing.

3.4. Consent frameworks put into context on the Estonian example

The aim of this Section is to put all the above into context on the example of one national legal system with the purpose of establishing a comprehensive analysis and overview of applicable consent requirements (or lack thereof) in genetic research. This will be done on the example of Estonia.

3.4.1. Consent to genetic research entailing procurement of biosamples

Estonian national legal acts do not entail an explicit general rule of consent when it comes to participation in human subject research. Of course, this general principle can be derived from fundamental rights protected by the Constitution of Estonia, like the right to liberty and security of person[184] and the right to the inviolability of private and family life.[185] However, due to the lack of respective specific legal clauses in Estonian national law, and based on relevant Supreme Court case law, the author is of the opinion that the rules in the Oviedo

[184] "Security of person" is a direct translation and should be understood as integrity of person, which in health care and research is reflected in the notion of free and informed consent. See commentary to § 20, *Eesti Vabariigi Põhiseadus. Kommenteeritud väljaanne* (2017).

[185] § 20 and § 26 of the Constitution of the Republic of Estonia, RT 1992, 26, 349. Available in English at https://www.riigiteataja.ee/en/eli/521052015001/consolide [Accessed 18 April 2019].

convention concerning consent to participation in human subject research can be directly applied in Estonia.[186]

Thus, generally, informed consent is required for participation in human research,[187] and the physical intervention of obtaining biosamples from individuals cannot be performed without prior consent. This is also clearly evidenced in Estonian penal law, as the latter criminalizes conducting human research on individuals who have not provided consent pursuant to law or have not been informed of significant risks associated with the research.[188] Estonian penal law also criminalizes forcing or inducing someone to donate biosamples, organs or cells,[189] and obtaining organs or biosamples for transplantation purposes if the individual was not informed of associated significant risks, or if the person removing the organ or biosamples knew that the donor is to receive payment for the organ or biosamples[190].

In regard to the primary research use of the genetic data derived from the biosamples, in addition to the GDPR, the national data protection law applies. On 15 January 2019, the new Estonian Personal Data Protection Act[191] (DP Act) came into force, elaborating upon and supplementing the GDPR, and implementing the directive on data processing in law enforcement[192]. However the Estonian DP Act does not regulate consent to data processing in the research

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[186] § 123(2) of the Estonian Constituion establishes that "When laws or other legislation of Estonia are in conflict with an international treaty ratified by the *Riigikogu*, provisions of the international treaty apply." The Constitution of the Republic of Estonia, ibid.

Referring to § 123(3) of the Constitution, the Estonian Supreme Court has established in its case law that a legal rule contained in an international treaty can be directly applied if there is no respective legal rule under national law. The direct applicability of an international treaty presumes that the rule in the treaty is aimed at regulating national relationships, and that the rule is specific enough in order not to need clarification in national law. Judgment no 3-3-1-58-02 of 20 December 2002 of the Estonian Supreme Court.

[187] There are exceptions, as enshrined in, e.g., Article 17 of the Oviedo convention that addresses research on individuals not able to consent. In rare cases and under certain circumstances, research without consent on individuals not able to give consent can be justified. See also Recital 36 and Art. 35 of Regulation 536/2014 on clinical trials, supra n 56.

[188] § 138 of the Estonian Penal Code, RT I, 13.03.2019, 77. Available in English at https://www.riigiteataja.ee/en/eli/501042019020/consolide [Accessed 18 April 2019].

[189] 'Forcing' is to be understood as removing organs, biosamples or cells if such removal is "performed through deprivation of liberty, violence, deceit, threatening to cause damage, by taking advantage of dependence on another person, helpless situation or vulnerable situation of the person". See § 138^1 and § 140 of the Estonian Penal Code, ibid.

[190] Note that this only applies if the organ or biosamples are meant for transplantation purposes, i.e. not research. § 139 of the Estonian Penal Code, ibid.

[191] Supra n 65.

[192] Directive (EU) 2016/680 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 by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA. OJ L119/89.

context. This means that in regard to informed consent for genetic data processing for research purposes, the GDPR must be referred to. Consent to data processing in research under the GDPR was addressed in Section 3.1.2. of this chapter. It was concluded that whilst informed consent is an appropriate legal basis for the primary research use of genetic data, it remains arguable how broad this consent can be, i.e. how specific the purposes listed within the consent have to be. This is a notably crucial practical question in genetic research due to the vast research potential of genetic data. It is clear that the breadth of research consent – at least as far as special categories of data within the meaning of Article 9 GDPR are concerned – cannot go beyond Recital 33 GDPR ("certain areas of scientific research").

One instance in which Estonian law does regulate consent to the research use of genetic data is the specific case of the Estonian Biobank. Consent to participation in the Estonian Biobank project is established under the Human Genes Research Act[193] (HGRA). Under § 12(1) HGRA consent is given for the purposes of "genetic research, assessment of personal health risks and prevention of diseases, public health research and statistical purposes." This consent concerns the use of the tissue, the genetic data derived therefrom, and all health data stored in state databases.

The issue of the practical application of Recital 33 GDPR in Estonia remains unclear in two aspects. First, there is the question of how to determine how broadly "certain areas of scientific research" should be interpreted in practice. For example, one could question whether the above-referred consent to participation in the Estonian Biobank is specific enough (i.e. can 'genetic research' as such be considered 'a certain area of research'?). Second, unlike the WP29, the author is not convinced that Recital 33 GDPR can be directly applied without respective national laws implementing this type of broader research consent. As argued in Section 3.1.2. of this chapter, although in EU law recitals might have interpretive value, the rules on consent regarding the processing of special categories of data (incl. genetic data) are very clear under Article 9(2)(a) GDPR: consent can be given for "one or more specified purposes". For example, in Estonian law, § 12(1) HGRA could be regarded as an exercise of the discretion granted to Member States under Article 9(2)(j) GDPR for regulating the research use of special categories of personal data – though, as noted, it remains arguable whether the breadth of consent under the HGRA exceeds the limits set in Recital 33 GDPR.

Based on the above, and in light of the fact that the Estonian DP Act does not address consent for data processing for research purposes, the author concludes that informed consent in research for the use of genetic data should adhere to the specificity requirements under Article 9(2)(a) GDPR (with the exception of the consent of the Estonian Biobank established under § 12(1) HGRA). The author does not argue this to be necessarily the best suited approach from the

[193] Estonian Human Genes Research Act, RT I 2000, 104, 685. Available in English at https://www.riigiteataja.ee/en/eli/508042019001/consolide [Accessed 2 August 2019].

perspective of data subjects, however, it is how the law currently stands in the opinion of the author.

Thus, in terms of genetic research entailing the procurement of biosamples in order to use the genetic data derived from the samples for research purposes, two types of consent requirements apply. First those concerning the physical act of the procurement of the biosamples, and, second, those regarding consent to data processing under the GDPR. As prescribed in Article 9(2)(a) GDPR, the latter consent can be obtained for specific research purposes.

3.4.2. Research entailing secondary use of biosamples and/or genetic data derived therefrom

As noted earlier in this chapter, the concept of human subject research within the meaning of the Oviedo convention would not cover a scenario in which biosamples have been obtained for purposes outside of a research project. For example, if blood of a patient was withdrawn in the course of their clinical care, and this blood would later be used in research, this would not constitute human subject research.[194] However, the Oviedo convention does contain in Article 22 a rule regarding the reuse of a removed part of the human body. The referred article establishes a minimum threshold of due notification to enable objection, with possible further conditions – such as a requirement of (informed) consent – to be established in national laws.[195]

Under Estonian law, there is no general rule of consent regarding the secondary research use of already obtained biosamples. There is a respective legal rule for the secondary use of blood withdrawn from patients in the course of clinical care and from blood donors. The Estonian Blood Act[196] sets out in § 10(1) that secondary use of donors' blood and blood components in research requires written consent. Whereas under § 10(2) of the Blood Act, patients' blood and blood components that were obtained for the purposes of clinical care may be used for commercial or research purposes subject to written consent. In either case, there is no requirement for the consent to be 'informed', but simply in writing.[197]

However, the Blood Act would not apply to other types of tissue, e.g., saliva or other samples that can as well be used in order to sequence DNA.[198] The only

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[194] See supra n 130. See also K. Pormeister. Genetic research and consent: on the crossroads of human and data research. Supra n 64, p 350.

[195] Ibid., p 354.

[196] Estonian Blood Act, RT I 2005, 13, 63. Available in English at https://www.riigiteataja.ee/en/eli/510042015002/consolide [Accessed 20 March 2018].

[197] K. Pormeister. Regulatory environment for biobanking in Estonia. Supra n 72.

[198] See, e.g., U.G. Poehls et al. Saliva samples as a source of DNA for high throughput genotyping: an acceptable and sufficient means in improvement of risk estimation throughout mammographic diagnostics. *European Journal of Medical Research* 23:20 (2018), doi: 10.1186/s40001-018-0318-9.

general national law governing the procurement, handling and transplantation of cells, tissues and organs does not govern their use for research purposes,[199] as the law implements Directive 2004/23/EC, which only concerns human application, but not the research use of cells, biosamples and organs.[200] Hence the only governing rule in terms of the secondary use of biosamples in research in the Estonian context remains Article 22 of the Oviedo convention.

Thus, where Estonian law does not require consent for the further use of biosamples – such as is the case with blood in particular – the minimum threshold of due notification established under Article 22 of the Oviedo convention applies. This means that in terms of genetic research, biosamples other than blood, e.g. saliva samples obtained by direct-to-consumer genetic testing companies, could be further used for research purposes without the need to obtain consent from the individual. Article 22 of the Oviedo convention would minimally require due notification in order to enable objections.

Of course, in regard to either scenario – whether (informed) consent is required or not for the secondary use of any type of biosample – in the context of genetic research it would not be the physical tissue that is of core interest, but the genetic data contained therein. In terms of the use of genetic data in research, informed consent could be used as a legal basis for data processing. However, the Estonian DP Act[201] offers an alternative for the use of the data in research without the need to obtain consent.

3.4.3. Research use of genetic data without consent of the data subject

The Estonian DP Act does not distinguish between different types of data in terms of the substantive requirements for the use of personal data in research without consent. It does distinguish between two scenarios: one where pseudonymised data is used, and another where personal data is processed in research with direct identifiers.[202]

As to the first scenario, § 6(1) of the DP Act allows for personal data to be used in research without consent in pseudonymised form or in a form, which provides an equivalent level of protection. The DP Acts establishes no substantive requirements or applicable safeguards other than pseudonymisation. In regard to safeguards required under Article 89(1) GDPR, the latter mentions pseudonymisation as an example of possible safeguarding measures in the context of research. However, under § 6(2) of the DP Act, de-pseudonymisation is permitted for additional research use of the data. What this means in practice, will

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[199] § 1(3)(4) of the Estonian Procurement, Handling and Transplantation of Cells, Biosampless and Organs Act, RT I, 26.02.2015, 1. Available in English at https://www.riigiteataja.ee/en/eli/520032017006/consolide [Accessed 20 March 2018].

[200] See supra n 121.

[201] Supra n 65.

[202] See also K. Pormeister. Regulatory environment for biobanking in Estonia. Supra n 72.

depend on the exact research scenario. For example, whether a researcher receives the data already in pseudonymised form from another controller who holds the key-code for de-pseudonymisation, or whether it is the researcher who pseudonymises the data and holds the key-code himself.

In regard to the second scenario referred to above, § 6(3) of the DP Act also allows for personal data to be used in research without consent and with direct identifiers, i.e. in a form, which enables direct identification of the data subject. In this case, three substantive requirements apply: (1) the purposes of processing cannot be achieved after removal of the data enabling identification or it would be unreasonably difficult to achieve these purposes; (2) there is an "overriding public interest" in the given research project in the opinion of the researcher; (3) no obligations will be put on data subjects nor will their rights be "excessively damaged in any other manner".

The first requirement of the three is unambiguous – there needs to be good reason for access to and use of data with direct identifiers in research. In practice, particularly in the Estonian context, a common argument would be the need to accumulate data on the same individual from different (state) databases. In order to do this, names and/or personal identification codes would be needed. However, the other two conditions are more ambiguous. The "overriding public interest" requirement is, first, to be determined by the researchers themselves. Second, scientific research is not a linear journey, thus – and specifically in the case of genetic and health-related research – it would be extremely difficult to draw a line between 'public interest' and 'overriding public interest'. Regrettably, the explanatory note to the DP Act does not comment on or elaborate upon the requirement of "overriding public interest" in the context of research.[203] As to the third condition regarding the non-impact on the obligations and rights of data subjects, it would be difficult if not impossible to prove a negative. Hence the latter condition would have to be deemed as met by way of confirmation on behalf of the researcher.

Generally, as emphasized in the explanatory note to the DP Act, the system of the research use of personal data without consent of data subjects in Estonia relies on self-monitoring by researchers.[204] Only where research is based on special categories of data (e.g. genetic data) does § 6(4) of the DP Act require an ethics review (alternatively, a review by the Data Protection Inspectorate, where there is no ethics committee in a respective area of research). The text of the law clearly triggers the review requirement whenever research is based on special categories of data. Whereas the explanatory note aims to significantly limit the review requirement.[205] According to the explanatory note, the ethics review is required only where special categories of data are to be processed with direct

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[203] *Seletuskiri isikuandmete kaitse seaduse eelnõu juurde* (Explanatory note to the DP Act). Available only in Estonian at https://www.riigikogu.ee/tegevus/eelnoud/eelnou/5c9f8086-b465-4067-841e-41e7df3b95af [Accessed 27 April 2019].

[204] § 6 of the explanatory note to the DP Act, ibid.

[205] K. Pormeister. Regulatory environment for biobanking in Estonia. Supra n 72.

identifiers (the above-referred scenario under § 6(3) of the DP Act). The explanatory note goes even further in stating that a review is only required if special categories of data are to be used in research with direct identifiers continuously throughout the analysis of the data. The latter statement is dubious at best. First, the statement is clearly at odds with the law itself. Second, in practical terms, generally data analysis in research does not require the processing of direct identifiers such as names or identity codes; making the referred statement in the explanatory note highly questionable.[206]

It is important to understand that – and this is clearly stated in the explanatory note to the DP Act – under the described Estonian approach, i.e. in this system reliant on self-compliance of researchers, if the researcher demonstrates compliance with the requirements under § 6 of the DP Act, the researcher must be provided access to the requested personal data (available in, e.g., state databases).

Thus the Estonian example demonstrates that informed consent might not necessarily be a legal requirement for the use of genetic data in research (even where direct identifiers are attached). Though the physical procurement of biosamples is clearly subject to informed consent, the later secondary use of the biosamples might not be (e.g. further use of patient or donor blood is subject to written consent, whereas further use of saliva samples is subject to a requirement of due notification). When it comes to genetic data, though use of the data in research might rely on informed consent as a legal basis, the consent can only be for limited purposes – according to the WP29 consent could be given on a more general level as described in Recital 33 GDPR regardless of national law, though in their opinion this exception should still be interpreted strictly; thus leaving it entirely unclear, what it means in practice. However, under Estonian law, genetic data can as well be used in research without consent based on § 6 of the Estonian DP Act. Processing genetic data for research purposes without consent might be conditional on an ethics review (or, alternatively, a review by the Data Protection Inspectorate), however the substantive requirements to do so would not be difficult to meet. In fact, there is at least one case in the practice of the Research Ethics Committee of the University of Tartu in which the committee approved of DNA being sequenced from biosamples obtained for research where the informed consent of participants did not explicitly mention the sequencing of DNA from the samples or the use of particularly genetic data. Due to the confidentiality of the ethics review proceedings and decisions, the author is not able to cite the decision.[207]

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[206] Ibid.

[207] The author was a member of the Research Ethics Committee of the University of Tartu in 2016–2019.

3.5. Conclusive remarks on the role of informed consent as a modality of and its impact on transparency

Whilst consent and the required provision of information to individuals is still an integral part of genetic research that entails procurement of biosamples from individuals directly, it seems to have lost its prominence in the transition of research towards reliance on secondary uses of both biosamples and the genetic data derived therefrom.

The research use of biosamples and genetic data is subject to different sets of rules. Whereas the use of the genetic data is subject to the GDPR, the use of the biosamples depends in most part on national law. The Estonian example illustrates how this might create issues with transparency in relation to individuals. Whilst Estonian law would require written consent for the secondary research use of patient and donor blood, it does not require this consent to be informed. This consent would thus not have to specify whether DNA might later be sequenced from the blood for research purposes. Furthermore, for other types of biosamples like saliva, due notification would suffice. Of course, in regard to the genetic data, data protection law would apply. As evidenced by the Estonian example, however, national data protection law might allow for genetic data to be used in research without consent (even with direct identifiers, though then subject to review requirements). Thus, in sum, by giving consent for (or not objecting to) biosamples to be used in research the individual might ultimately and effectively allow their genetic data to be used in research without being aware of doing so.

However, even where genetic data are obtained for and used in research on the basis of informed consent, two problems in regard to transparency in relation to the data subject arise. First, it remains unclear how broadly the purposes of processing in a research context may be communicated to individuals prior to obtaining consent. The author argues that the strict rules under Article 9(2)(a) GDPR in terms of the specificity of consent should apply in genetic research, unless national or other EU law allows for broader research consent; whereas the WP29 have seen Recital 33 GDPR as creating a direct exception to the strictness of the referred clause. Regrettably, it remains unclear what the position of the WP29 means in practice in the context of genetic research. The general rule under Article 9(2)(a) GDPR would require specificity on the level of research projects to be communicated to the individual. If national or other EU law were to facilitate broader research consent, as set out in Recital 33 GDPR, then guidelines to the practical application of this type of broader consent in research should accompany such provisions. However, if the principles in Recital 33 GDPR are directly applicable, as argued by the WP29, such guidelines in regard to the practical application of the principles expressed in Recital 33 GDPR should be issued by the EDPB.

Second, whether informed consent to data processing in research is limited to specific research projects or more broadly defined areas of research, the data

could still be later used in different research without the consent of the individual. Since the storage and purpose limitations do not apply as far as the research use of data is concerned, the limits of the initial consent would not rule out the later use of the same data on alternative legal grounds, such as those established in national law and embedded in § 6 of the Estonian DP Act.

In sum, even in cases where requirements of informed consent (and the respective prior provision of information) apply in genetic research, these do not limit the further research use of the genetic data. Hence, informed consent to data processing cannot be seen as an effective modality of transparency for two reasons. First, defining specific processing purposes prior to obtaining consent would be difficult in genetic research, whereas defining the purposes more broadly would render future processing of the data non-transparent to the data subject. Second, the processing purposes listed in the consent and the provision of information prior to obtaining consent do not limit the use of the data for future research purposes that were not communicated to the data subject prior to obtaining consent. Thus, in the context of genetic research, informed consent cannot adequately facilitate transparency in relation to the data subject within the meaning of the GDPR.

IV. THE GENERAL OBLIGATION TO INFORM AS MODALITY OF TRANSPARENCY IN GENETIC RESEARCH

Regardless of the legal basis for data processing – whether it is informed consent of the individual or an alternative legal ground – the GDPR obliges data controllers to provide information to data subjects concerning the processing of their data. Thus, where information is not provided to the individual as part of consent procedures, the general obligation to provide information to the data subject regarding the processing of their data applies.

The general obligation to inform is not novel in the data protection framework as it was already part of the obligations put on data controllers under Directive 95/46/EC.[208] Although unlike its predecessor, the GDPR is directly applicable and lays out this obligation more extensively and in more detail, it remains problematic in terms of effectively facilitating transparency, at least as far as the research context is concerned.

The author concluded in the previous chapter that the provision of information in the context of consent procedures does not adequately facilitate transparency in relation to the data subject in genetic research. The aim of this chapter is to analyse the general obligation to inform as a modality of transparency in order to determine whether transparency in genetic research in relation to individuals can be effectively facilitated via this obligation of data controllers. In this chapter, arguments will be presented to demonstrate that the design of the general obligation to inform is flawed as far as the research use of personal data is concerned; rendering it ineffective for purposes of facilitating transparency in relation to the data subject in genetic research.

This chapter will first present an analysis on the general obligation to inform under the GDPR (4.1.) and, in particular, the exceptions applicable to this obligation when personal data is being processed for research purposes (4.2.). Thereafter the author will address the design flaws rendering the obligation to inform ineffective as a modality of providing transparency in relation to the data subject in genetic research (4.3.). Finally, the author shall avail a practical example from Estonia in order to critically examine existing practical modalities and their potential for effectively facilitating transparency in relation to data subjects in the context of research use of personal data (4.4.).

4.1. The general obligation to inform under the GDPR

Articles 13 and 14 GDPR oblige data controllers to provide information to data subjects regarding the processing of their data – with the former article regulating scenarios where data has been obtained from the data subject directly, and the latter regarding scenarios where data has been obtained from other sources (e.g.

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[208] Arts. 10 and 11 of Directive 95/46/EC, supra n 38.

another data subject or controller). Amongst the information to be provided to individuals regarding the use of their personal data are, most importantly, the identity and contact details of the controller, and the purposes of and legal basis for the processing.

Both articles are essentially identical, albeit a few minor, and some major differences. As to minor differences, Article 13 GDPR obliges controllers to provide individuals the required information at the time of obtaining the data, whereas Article 14(3)(a) GDPR, as a general rule, mandates this to be done within a reasonable period, but the latest within one month after obtaining the data. Unlike Article 13, Article 14(1)(d) GDPR also requires the categories of personal data concerned to be communicated to the individual. Both described discrepancies are due to the scope of the respective articles – since Article 13 GDPR concerns scenarios where data is obtained directly from individuals, there is no need to communicate the categories of personal data concerned, as the individual will be the one providing the data.[209] The same rationale applies to the timing of the provision of the required information as in this scenario there is direct contact with individuals enabling immediate communication of the information.

The major difference between Articles 13 and 14 GDPR is the fact that the latter establishes a list of exceptions to the obligation to provide information to data subjects. The only exception in Article 13 GDPR is established in paragraph 4 according to which the obligation to inform does not apply "insofar as the data subject already has the information."[210] The same notion is also reflected in the list of exceptions under Article 14 GDPR. In terms of this approach to the exceptions to the obligation to inform, ironically, from the perspective of data subjects, it would be of equal (if not greater) importance to be informed of processing activities precisely in cases in which the data has been obtained from sources other than the data subject.

The list of exceptions in Article 14 GDPR includes a specific exception for the research context. Hence, where data has been obtained from sources other than the individual (e.g. health information databases), exceptions to the obligation to inform might apply, particularly if the data is to be used for research purposes. As noted above, in scenarios falling under Article 13 GDPR there are no respective exceptions to the obligation to inform. M. Taylor (2012) has criticized this discrepancy in terms of Directive 95/46/EC and its Articles 10 and 11 – however, the underlying argument remains the same and as relevant under the GDPR. Taylor argues that the primary controller who obtained the data from

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[209] Or, as put by the WP29, "This information is required in an Article 14 scenario because the personal data has not been obtained from the data subject, who therefore lacks an awareness of which categories of their personal data the data controller has obtained." Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, Annex, p 36.

[210] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, p 27, para 56.

the individual should as well be afforded some leniency in terms of the obligation to inform.[211] Taylor goes on to explain that even where data has been obtained directly from the data subject, the data might still later find use in research, whilst (re)contacting the concerned individuals might be impossible or involve a disproportionate effort (just as it might for a processor who has not obtained the data directly from the data subject).

In terms of Taylor's criticism, one example could be health care providers. The latter obtain personal data from individuals for the purposes of clinical care from individuals directly (for purposes of simplification, the author excludes from this example prior medical records that might be accessed without direct involvement of the data subject). Article 13 GDPR applies in terms of the provision of information to the individual, which means that no exceptions apply and the patients should be re-contacted to provide information on further processing of their data for research purposes. However, there is a nuance to this, which arises under Article 13 GDPR. Although like Article 10 of Directive 95/46/EC criticised by Taylor in regard to the lack of exceptions, Article 13 GDPR does not specifically or explicitly provide an exception to the obligation to inform in this scenario, it does address secondary processing needs. Namely, Article 13(3) GDPR obliges the controller to inform individuals of intentions regarding further processing of the data for purposes other than for which the data was collected. The same rule is embedded into Article 14(4) GDPR. Thus, if a health care provider has intentions to further use patient data obtained for clinical care for research purposes, and if these intentions already exist at the time of obtaining the data from the patients, the health care provider could fulfil the obligation to inform in regard to such further research processing when obtaining the data from the patient (e.g. during the visit during which the medical data is obtained for purposes of clinical care). Hence, under Article 13 GDPR, the primary controller's secondary processing needs and the accompanying possible need for exceptions from the obligation to inform are not addressed via per se exceptions to the obligation to inform, but rather by the possibility provided under Article 13(3) GDPR to fulfil the obligation to inform in regard to secondary processing already during the provision of information regarding primary processing – thereby eliminating the need to re-contact individuals. Of course, this presumes that the controller already has known intentions for possible secondary uses of the data (which may be the case in terms of health care providers later utilising the data for research purposes; particularly if the given health care provider is, e.g., a hospital associated with a university).

However, the practical meaning of Article 13(3) GDPR will largely depend on how broadly secondary processing purposes need to be defined. If defined broadly, the provision of information regarding secondary processing purposes could be limited to a one-off communication.

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[211] M. Taylor (2012), p 89.

Another nuance to the applicability of the obligation to inform in scenarios where data has been obtained from data subjects directly, are the impact of the principle of data minimisation under Article 5(1)(c) GDPR and the principle expressed in Article 11(1) GDPR. The former article sets out that no more personal data shall be processed than is necessary for the purposes for which the data is processed. Article 11(1) GDPR lays out that,

> "If the purposes for which a controller processes personal data do not or do no longer require the identification of a data subject *by the controller*, the controller 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 this Regulation." (emphasis added by the author)

Applying the rationale of the above-referred principles to scenarios where a controller has no need or no longer needs to identify data subjects, identifying information (incl. contact information) should not be obtained and should be discarded if not needed for the particular processing purposes, and should not be processed for the sole purposes of complying with the GDPR (incl. the obligation to inform). Not obtaining or discarding contact information would render the fulfilment of the obligation to provide information on secondary processing purposes impossible regardless of the lack of a respective exception under Article 13 GDPR. This would likely not be the case in the above-described example of a health care provider using patient data for research purposes, however, it could be the case were the data was initially obtained from data subjects for other purposes, which do not require obtaining or maintaining contact or other identifying information of data subjects. For example, if the data was obtained for research purposes as primary processing purposes with no need to further contact the data subjects, information enabling contact should not be obtained or maintained, and provision of information on secondary processing purposes would then be de facto impossible.

To conclude, although in scenarios where data has been obtained from data subjects directly, Article 13 GDPR does not establish exceptions to the obligation to inform, this obligation might be nullified in regard to secondary processing by the principle of data minimisation and Article 11(1) GDPR where a given controller does not or no longer needs to identify data subjects and does not obtain or discards contact information (thus rendering it impossible to provide information on secondary processing). Furthermore, even where the obligation to inform regarding secondary processing purposes can be fulfilled in scenarios falling under Article 13 GDPR, the provision of information might be limited to a one-off communication depending on how broadly secondary processing purposes are communicated.

The problem of the obligation to inform being limited to a one-off communication shall be elaborated upon further below. However, first, the research exceptions to the obligation to inform under Article 14 GDPR scenarios shall be addressed.

4.2. The research exceptions to the obligation to inform

As noted, under Article 14 GDPR concerning scenarios where data has been obtained from sources other than the data subject (e.g. third party data controllers, public sources, data brokers, or other data subjects)[212], a list of exceptions apply in regard to the controllers' obligation to inform; one of which concerns inter alia expressly the research context. Namely, Article 14(5)(b) GDPR establishes that the obligation to inform does not apply if,

> "the provision of such information proves impossible or would involve a disproportionate effort, in particular for processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, subject to the conditions and safeguards referred to in Article 89(1) or in so far as the obligation referred to in paragraph 1 of this Article is likely to render impossible or seriously impair the achievement of the objectives of that processing. In such cases the controller shall take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available".

The WP29 have interpreted Article 14(5)(b) GDPR as establishing essentially three different exceptions: (1) the provision of information proves impossible (particularly for processing for archiving, research or statistical purposes); (2) the provision of information would involve a disproportionate effort (particularly for processing for archiving, research or statistical purposes); (3) the provision of information would make the achievement of the objectives of the processing impossible or seriously impair them.[213] Thus, two of the three scenarios addressed under Article 14(5)(b) give particular consideration for the research context. The author will address the two exceptions separately and argue that they are likely to apply in the context of genetic research.

4.2.1. Impossibility of providing information in the research context

In terms of the provision of information proving impossible, the WP29 have considered that, "In practice, there will be very few situations in which a data controller can demonstrate that it is actually impossible to provide the information to data subjects."[214] The WP29 then go on to offer an example in which a data controller has no means to directly contact individuals due to a lack of valid contact information.

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[212] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, p 15, para 26.

[213] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, p 28, para 58.

[214] Ibid., p 29, para 59.

The impossibility of providing information must be considered taking into account the GDPR as a whole, whilst simultaneously looking at it from the research perspective specifically. Two important factors come into play that were already commented upon earlier: the principle of data minimisation under Article 5(1)(c) GDPR and Article 11(1) GDPR. The principle of data minimisation would require that a party interested in using personal data in research would not request or obtain any more data than is necessary for fulfilling the particular research purpose. As noted earlier, Article 11(1) GDPR adds to this that personal data should not be acquired or maintained for the sole purposes of complying with the GDPR if a given controller does not or no longer need to identify data subjects.

From this it follows that unless contact information is relevant to and necessary for fulfilling certain research objectives, such data should not be obtained or maintained for the sole purpose of complying with the GDPR (incl. the obligation to inform). Without information enabling the controller to contact the individuals, the provision of information would be rendered impossible.

Furthermore, in a research context, though re-identification of and re-contacting specific individuals might be necessary in certain scenarios (e.g. rare disease research)[215], in many cases pseudonymised data will suffice. If a given controller cannot re-identify a specific individual based on pseudonymised data that they use in their research (e.g. genetic data with no direct identifiers, and no access to the key code for de-pseudonymisation), Article 11(1) GDPR will relieve the researcher from having to obtain additional information (such as contact information) on the data subjects solely for complying with the GDPR.[216] This argument stands even in the case of genetic data, which due to its inherently identifying nature could still potentially enable identification in a different or future context (though obtained for research purposes without direct identifiers).

Although the WP29 have referred to Article 11(1) GDPR in their guidelines regarding transparency under the GDPR, they have done so whilst addressing the 'disproportionate effort' exception without further explanation and by simply hinting at its possible relevancy.[217] They have also emphasized that "Article 11 of the GDPR should be interpreted as a way of enforcing genuine data minimisation without hindering the exercise of data subject rights".[218] In the opinion of the author there is nothing disingenuous about researchers not obtaining or maintaining contact information of individuals where research purposes can be attained without such information. Hence, Article 11(1) GDPR

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[215] M.G. Hansson et al. The risk of re-identification versus the need to identify individuals in rare disease research. *European Journal of Human Genetics* 24 (2016), pp 1553–1558.

[216] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, p 31, para 64.

[217] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, p 31, para 64.

[218] Ibid., p 34, para 68.

is likely to be of relevance whenever pseudonymised data is used in research (presuming that the key code is not accessible for purposes of re-identification).

However, in regard to genetic research specifically, it is important to recognize that if the pseudonymised data to be used in research is or includes genetic data, identification of individuals might still be possible by, e.g., using comparative data in existing databases, accumulating additional data on the same individual (e.g. facilitated via the entity holding the key code), or using future (yet unknown) technological means. Whether a given controller can identify an individual based on their genetic data without direct identifiers, effectively depends on variables such as whether that particular controller has (or will have at any point in time) access to comparative data in existing databases, or acquires (at some point in the future) additional data that can be linked to the genetic data and potentially enable identification. As put by M. Taylor (2012) in regard to anonymity of data, "Data can be identifiable in one context, anonymous in another, and it may shift between these states depending upon the availability and accessibility of relevant interpretative frameworks."[219] The same logic applies to pseudonymised data that might at one point in time be anonymous from the perspective of a particular controller who cannot re-identify the individuals concerned.

Thus, once a researcher has obtained data for research purposes without contact information – whether the data is pseudonymised or not – an argument for the impossibility of providing information to data subjects can be made and the relevant exception invoked. This means that the stream of informedness towards individuals is essentially cut off once the third party data controller obtains data for research purposes without valid contact information.

4.2.2. 'Disproportionate effort' in the context of genetic research

In regard to the 'disproportionate effort' exception, first, it is unclear whether the disproportionality of the required effort is subject to an objective assessment, or a subjective one from the perspective of the data controller.[220] According to the WP29, in order to rely on the 'disproportionate effort' exception, controllers have to "carry out a balancing exercise to assess the effort involved for the data controller to provide the information to the data subject against the impact and effects on the data subject if he or she was not provided with the information."[221] Hence it seems to be more a matter of a subjective assessment from the perspective of the controller, rather than an objective one.

Second, in determining when the provision of information could constitute a 'disproportionate effort' for the controller specifically in regard to processing

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[219] M. Taylor (2012), p 132.

[220] Paal/Pauly. Datenschutz-Grundverordnung. Bundesdatenschutzgesetz: DS-GVO BDSG. 2. Aufl. 2018, C.H.Beck. Art. 14 Rn 40a.

[221] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, p 31, para 64.

for scientific research purposes, according to Recital 62 GDPR, "the number of data subjects, the age of the data and any appropriate safeguards adopted should be taken into consideration." Putting this into the context of genetic research, as to the number of data subjects, in many cases, this criterion would speak in favour of invoking the disproportionate effort exception, as the data of large cohorts of participants may be needed in genetic research.[222] Whereas the age of the data should rather be an argument against invoking this exception since the informative potential of genetic data will increase over time (instead of declining, as is the case with many other types of personal data).[223] The third criterion laid out in Recital 62 GDPR – 'any appropriate safeguards' – is as ambiguous as a criterion can be.[224] One 'safeguard' expressly named in Article 89(1) GDPR concerning processing for research purposes is pseudonymisation. Hence, where pseudonymised data is used, this might tip the scale in favour of invoking the disproportionate effort exception. However, in the case of pseudonymised data, the impossibility exception discussed above is likely to be of primary relevance (depending on, inter alia, whether the data is pseudonymised by the primary controller before making the data available to the third party controller, or by the third party controller himself – if the data is already obtained in pseudonymised form by the third party controller, the lack of contact information would trigger the impossibility exception, as discussed above).

Both in the case of the impossibility and the disproportionate effort exceptions, it will be a matter of a case-by-case assessment of whether these exceptions can be invoked or not. Although alternative measures, like making the information publicly available, apply, these are not likely to facilitate any transparency in relation to the individual for reasons discussed below.

4.2.3. 'Appropriate measures' as an alternative to the obligation to inform

In case one of the above-discussed exceptions to the obligation to inform is invoked, Article 14(5)(b) GDPR requires 'appropriate measures' to be adopted by the controller, including making the information publicly available. The position of the WP29 is that controllers always have to make the information publicly available whenever one of the exceptions under Article 14(5)(b) GDPR is

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[222] See, e.g., C. Wijmenga and A. Zhernakova. The importance of cohort studies in the post-GWAS era. *Nature Genetics* 50 (2018), 322–328, https://doi.org/10.1038/s41588-018-0066-3.

[223] K. Pormeister. The GDPR and Big Data: Leading the Way for Big Genetic Data? Supra n 69, pp 14–15.

[224] See, e.g., D. Korff. Working Paper No 2: Data protection laws in the EU: The difficulties in meeting the challenges posed by global social and technical developments. European Commission Directorate-General Justice, Freedom and Security, Centre for Public Reform, 20 January 2010, p 73.

invoked.[225] As to other appropriate measures, these will depend on specific circumstances, but according to the WP29 they may include inter alia "undertaking a data protection impact assessment; applying pseudonymisation techniques to the data; minimising the data collected and the storage period; and implementing technical and organisational measures to ensure a high level of security."[226] In this light, the 'appropriate measures' referred to in Article 14(5)(b) GDPR seem to coincide with the 'safeguards' under Article 89(1) GDPR (i.e. adopting technical and organizational measures, minimization, pseudonymisation). Since adopting safeguards within the meaning of Article 89(1) GDPR would be required in any case in which personal data is used in research,[227] and Article 14(5)(b) GDPR furthermore specifically refers to Article 89(1) GDPR safeguards when invoking an exception to the obligation to inform, it seems that the further reference to 'appropriate measures' in the second sentence of Article 14(5)(b) GDPR adds little substance in the research context – other than the expressly mentioned measure of "making the information publicly available".

However, making information publicly available does not equal due notification.[228] Instead of direct communication to the individual, making information publicly available is done by addressing the public in general via, e.g., the controller "putting the information on its website, or by proactively advertising the information in a newspaper or on posters on its premises."[229] The obligation to make the information publicly available in the context of Article 14 GDPR contains a logical fallacy. First, there is the question of which controller needs to comply with the said obligation if one data controller has obtained the data from another. From the wording of Article 14(1) GDPR it seems this would be the third party controller – i.e. the controller that has obtained the data from another data controller – as it is the third party controller who can be in a situation where "data have not been obtained from the data subject". However, in this case, it is questionable which, if any, connections are individuals presumed to have with the third party controller in order to happen to visit the third party controller's website or premises for the publicly available information to have any practical meaning in regard to the individuals concerned. Making information publicly available would have a potential impact in scenarios falling under Article 13 GDPR where data has been obtained from data subjects directly since there would be a connection between the data subject and the controller – this is not the case when data has been obtained from other sources.

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[225] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, p 31, para 64.

[226] Ibid.

[227] See Arts. 9(2)(j) and 89(1) GDPR, supra n 1.

[228] K. Pormeister. The GDPR and Big Data: Leading the Way for Big Genetic Data? Supra n 69, p 15.

[229] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, p 31, para 64.

To exemplify the above from the perspective of the GDPR as a whole in the research context the following example can be used. Researcher A has carried out a research project and collected genetic and health data from more than 1,000 individuals based on informed consent. In the process of obtaining consent the individuals have been informed that their data will be used for scientific projects X and Y (with specific details regarding these projects) and additionally possibly for future purposes of oncological research. The information provided includes the fact that the data might be shared with other researchers in the field of oncology. Thus, as required by Article 9(2)(a) GDPR, and, arguably, allowed by Recital 33 GDPR, the individuals concerned have provided consent for the use of their data in certain specific projects and for future use in a certain scientific area. With the provision of this data, researcher A has simultaneously fulfilled his obligations under Article 13 GDPR. Researcher B, interested in using the genetic and health data collected by researcher A, requests said data from the latter. National law provides a legal basis for data to be processed without consent if it is done for research purposes. Researcher B has no need for direct identifiers, but simply pseudonymised data that enables linking the collected health and genetic data. As established in Article 11(1) GDPR, researcher B should not ask for contact information purely for purposes of fulfilling obligations under the GDPR. Since researcher B does not obtain direct identifiers or contact information of the individuals, provision of information to the data subjects is objectively not possible and the 'impossibility exception' under Article 14(5)(b) GDPR can be applied. As required, researcher B makes the fact and purposes of obtaining the data publicly available on the website of his institution. However, the data subjects have no connection to researcher B or his institution. Since the purpose and storage limitations do not apply – and national law allows for processing without consent for research purposes – once having obtained the data, researcher B is able to use the data further for purposes not communicated to data subjects by researcher A (whilst researcher B cannot inform individuals due to the lack of contact information).

Hence the connection between the individual and their personal data, and the data subject's informedness in regard to the use of their data, is essentially cut off once the data is acquired by a third party controller for research purposes.

4.2.4. Conclusive remarks on the exceptions to the obligation to inform

The WP29 have made two important conclusions in regard to the exceptions established in Article 14(5)(b) GDPR. First, controllers who do not use personal data for research or statistical purposes cannot routinely rely upon the referred exceptions.[230] From this it can be concluded that, vice versa, controllers who *do* use the data for research can routinely rely on this exception. Although the

[230] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, p 30, para 61.

WP29 have set out that measures regarding transparency (incl. providing information to data subjects) are part of the requirement of "privacy by design and by default",[231] it seems that the possibility to routinely rely on the exceptions under Article 14(5)(b) GDPR effectively counteracts this position in the research context.

Second, the WP29 note that the circumstances giving rise to invoking Article 14(5)(b) GDPR have to be related to the fact that the data was obtained from sources other than the data subject (i.e. since the exception is specifically provided only under Art. 14, but not Art. 13 GDPR).[232] However, given the above-discussed impact of the principle of data minimisation and Article 11(1) GDPR in research scenarios, the invocation of the exceptions under Article 14(5)(b) in the research context will, in the majority of cases, be related to the fact the data was not obtained directly from data subjects. The latter fact will likely either bring about a disproportionate effort for the researcher as the third party data controller in contacting individuals where the researcher has acquired the data of a larger group of individuals, or – even more likely – it will render the provision of information impossible due to the lack of contact information (as acquiring this information is generally not necessary for attaining research purposes). As argued above, whenever data is obtained from another data controller for research purposes, the third party controller receiving the data should refrain from asking any data not necessary for fulfilling the intended research purposes – i.e. the third party controller should not request contact details of data subjects or any other personal data solely for the purposes of complying with the GDPR.

To conclude, in a context in which a researcher obtains personal (incl. genetic and health) data of individuals from sources other than the data subjects themselves (e.g. from another researcher or a database), Article 14(5)(b) GDPR allows for a routine reliance on exceptions from the obligation to inform data subjects about the processing of their data. However, as argued below, even when the referred exceptions cannot or simply are not invoked, as far as the research context is concerned, the obligation to inform under the GDPR suffers design flaws that render it ineffective in facilitating transparency in relation to data subjects.

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[231] Ibid., pp 22–23, para 43.

[232] Ibid., supra n 8, p 30, para 62.

4.3. The design flaw of the obligation to inform

4.3.1. The obligation to inform and the specificity of processing purposes

In a research context – both in regard to the primary and secondary use of data, regardless of the source of the data – a significant point of contention is how broadly the purposes of processing may or have to be communicated to data subjects in order for (future) processing activities to be transparent to the individual.

In terms of the provision of information during consent procedures addressed in the previous chapter, the question of the specificity of processing purposes to be communicated to data subjects was two-folded. First, whether the principles expressed in Recital 33 GDPR in regard to the breadth and specificity of consent in research are directly applicable. Second, if answered in the affirmative, the question became one of how broadly can 'certain areas of scientific research' be communicated to the individual within the meaning of the referred recital. Whether or not it establishes a directly applicable legal rule, Recital 33 GDPR serves at least as a sort of guideline in terms of the communication of processing purposes in the research context when it comes to processing based on consent of the individual. Whereas the general obligation to inform under Articles 13 and 14 GDPR lacks any such indicators as to how specific the processing purposes communicated to the individual need to be.

One factor in regard to the specificity of processing purposes under the general obligation to inform is the requirement of 'clear and plain language'. The latter is part of the general obligation of transparency[233] and stipulated by Article 12(1) GDPR. As explained in Recital 39 GDPR in regard to this requirement, "In particular, the specific purposes for which personal data are processed should be explicit and legitimate and determined at the time of the collection of the personal data." According to the WP29, this applies to both the grammatical approach of the language used (e.g. "avoiding complex sentence and language structures") and the clarity of the information provided (i.e. concrete and definitive information with no ambivalent or abstract terms).[234] However, none of this addresses research purposes specifically or provides any indicators such as that provided by Recital 33 GDPR in terms of the specificity of consent in research – whether processing purposes must be communicated on the basis of, e.g., singular research projects, research areas, or in any other form.

In regard to the research context, as noted earlier, the WP29 have emphasized as an example concerning the requirement of clear and plain language that what is not sufficient is a communication in the following manner: "We may use

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[233] Recital 39 GDPR, supra n 1.

[234] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, p 8, para 12.

your personal data for research purposes."[235] According to the WP29, "it is unclear what kind of research this refers to".[236] Regrettably, the WP29 have not offered insight as to how research purposes *may* be communicated in order to comply with the GDPR. One option would be to apply the same logic as with the breadth of consent in research under the guidance offered in Recital 33 GDPR, i.e. by communicating the use of the data in "certain areas of research". However, as was demonstrated in the previous chapter, this would offer little help to outline any boundaries in practice. For example, if a hospital were to notify individuals that their data might be later used for research in the fields of oncology, epidemiology, genomics, epigenetics, hepatology, and haematology, would this fulfil the obligation to inform data subjects about the purposes of processing?

This question remains pre-eminent in the discussion regarding transparency in relation to the individual independent of the exact scenario: i.e. whether data is obtained from data subjects or other sources, whether processing is based on informed consent or an alternative legal basis, whether the research use of the data is the primary or secondary purpose of processing. The specificity of the purposes to be communicated to data subjects will determine if and at what point the obligation to inform can be deemed as fulfilled.

4.3.2. The obligation to inform as a one-off communication

The above addressed question of specificity when it comes to the communication of processing purposes to individuals – particularly in the context of genetic research – leads to a fundamental problem concerning the obligation to inform as a modality of transparency in relation to the individual; namely, the nature of the obligation to inform as a 'one-off deal'. As already pointed out by M. Taylor (2012) in regard to the predecessor of the GDPR, "the responsibility to provide information to a data subject on the purposes of processing, at least as required by the Directive, is not expressly an ongoing responsibility."[237] The same critique is still relevant in terms of the GDPR.

In general, the WP29 indicate to the right to transparency as an ongoing right.[238] The nature of the obligation to inform as an ongoing right is expressed in the fact that the controller would have to notify data subjects of changes in the aspects of processing already communicated to individuals, e.g., changes in processing purposes or changes regarding the identity of the controller.[239] The controller would also have to inform data subjects about any changes regarding

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[235] Ibid., p 9, para 12.

[236] Ibid.

[237] M. Taylor (2012), p 207.

[238] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, p 10, para 15.

[239] Ibid., pp 16–17, para 29.

the recipients of the data. This is particularly emphasized in Article 14(3)(c) GDPR regarding the timing of provision of information where disclosure to another recipient is planned. In terms of research, this would mean for example that data transfers between researchers would trigger the obligation to inform if the recipients were initially defined on an individual basis. However, both Articles 13(1)(e) and 14(1)(e) allow for the recipients of the data to be listed as categories. Hence, defining possible recipients as entities engaged in (certain) research activities may suffice,[240] and data exchange in the framework of research co-operation is thus not likely to re-trigger the obligation to inform.

As to secondary processing purposes, these are not to be equated with a change in primary processing purposes. For example, the collection of health and genetic data in clinical facilities is primarily conducted for purposes of clinical care – the primary processing purpose of this data remains clinical care, whereas possible later utilization of the same data in research is a secondary purpose. The communication of secondary processing purposes, as analysed above, is addressed in Articles 13(3) and 14(4) GDPR, which oblige controllers to inform data subjects of their intentions for processing the data for a purpose other than for which the data was obtained (prior to commencing such processing).[241] The latter could theoretically create an ongoing aspect to the obligation to inform. However, in the research context this is unlikely to happen for the following reasons.

The required level of specificity of secondary processing purposes in the research context is just as unclear as in the case of primary purposes. As concluded in the previous section, it is not clear how broadly or specifically processing purposes can or have to be communicated in terms of the obligation to inform (other than excluding a general reference to 'research purposes', which has been expressly rejected by the WP29 as being not specific enough). This impacts the obligation to inform data subjects of secondary processing purposes in two ways.

First, in scenarios in which the primary purpose for processing is research, whether the obligation to communicate secondary processing purposes is triggered will depend on when secondary processing purposes can be deemed to be different from the primary purpose. Second, when secondary processing purposes have been communicated once, the specificity of the purposes will determine whether the obligation is re-triggered after the first communication. This is less relevant in terms of Article 14, as exceptions to the obligation to inform are likely to be applicable in the research context. Whereas in regard to

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[240] According to the WP29, if recipients of the data are expressed as categories rather than on an individual basis, the information "should be as specific as possible by indicating the type of recipient (i.e. by reference to the activities it carries out), the industry, sector and sub-sector and the location of the recipients." Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, Annex, p 37.

[241] The only difference between Arts. 13(3) and 14(4) is that the former uses the term 'collected' and the latter the term 'obtained'.

Article 13 it is of central importance as this article does not contain exceptions to the obligation to inform. The specificity of the processing purposes communicated to data subjects will determine in practice whether the obligation to inform is a one-time communication or whether it can be regarded as an ongoing obligation.

As a general rule, Article 13(1) GDPR requires information to be provided to data subjects at the time the data is being obtained. In the case of secondary processing purposes, however, Article 13(3) GDPR requires these to be communicated to data subjects prior to such processing – which could effectively refer to the time at which data is being collected from the individual, or any later point in time (as long as it is done prior to commencing processing for secondary purposes).[242] If secondary processing purposes are defined broadly, they can be communicated to data subjects at the time of the collection of the data with no need for further communication, thus rendering the obligation to inform a one-off communication. Referring back to the example used in the previous section on specificity of purposes, the question remains whether notifying patients that their data might be later used for research in a number of possible medical fields (e.g. oncology, epidemiology, genomics, epigenetics, hepatology, and haematology) would be specific enough. If answered in the affirmative, the obligation to inform in the context of research could effectively be limited to a one-off communication by listing all possible areas of research that the data could potentially be used in.

The problems regarding the specificity of the communication of processing purposes and the issue of the obligation to inform being a one-off communication are not novel problems in terms of genetic research, but ones that have not been effectively addressed during the data protection reform and within the framework of the GDPR (although the latter has established transparency in relation to data subjects as one of three core principles of personal data protection). Combined, the issue of the specificity of processing purposes and the obligation to inform as a one-off communication lead back to the general dilemma of prior informedness in genetic research.

4.3.3. The dilemma of prior informedness in genetic research

The above-addressed issues regarding the specificity of the processing purposes and the provision of the relevant information being limited to a one-time communication lead to a fundamental problem in genetic research in regard to transparency in relation to individuals: the general inefficacy of prior informedness and the need for ongoing informedness. Without ongoing provision of information, transparency in relation to the data subject cannot be attained in genetic research.

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[242] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, p 14, fn 30.

As was concluded in the previous sections, whether it be consent procedures during which information is provided to individuals or the general obligation to provide information, the provision of information to data subjects in a research context can be limited to a one-off communication via broadly defined research purposes; and if data has been obtained from sources other than the data subject, exceptions to the general obligation to inform may routinely be relied upon. As far as the research use of personal data is concerned, the GDPR fails to establish an ongoing obligation to provide information that would effectively facilitate transparency in relation to data subjects. Hence what remains in terms of provision of information to individuals is prior informedness – as opposed to ongoing informedness. Prior informedness, however, cannot adequately facilitate transparency in relation to individuals in an environment in which genetic data can be stored indefinitely, shared with little limits (within the EU) and used for a myriad of research purposes.

Scholars have long challenged the concept of prior informedness in genetic research. Though this has mainly been done in regard to prior informed consent, the same critiques can be applied to prior informedness in general (whether facilitated through consent procedures or the general obligation to inform). Thus the following arguments concerning prior informed consent shall mutatis mutandis be applied to prior informedness as such.

As Laurie and Postan (2013) note in terms of consent, in contrast to the general aim of informed consent in disclosing information to facilitate certain autonomous decisions, "research itself is an inherently uncertain exercise."[243] In other words, as the (future) uses of genetic data in research cannot be foreseen, consent could not be truly informed unless it were (re)obtained for future uses that were unknown at the time that consent was obtained; otherwise consent would be rendered meaningless and "paying mere lip-service to the principle of respect for autonomy" as Laurie (2002) has put it.[244] As Taylor (2012) argues, even the use of broad consent would not resolve this issue as "the chances of being able to communicate effectively all of the possibilities regarding future uses of data – and the associations that might provoke – are, in any case, extremely slight."[245] These arguments are not limited to the notion of informed consent as the core issue they address is not consent itself, but the limits of prior informedness in genetic research.

On the opposite end of the spectrum regarding views on prior informedness, some scholars have presented arguments that essentially purport that informedness is not important, as an autonomous decision can be made on the simple consideration of 'to participate in research, or not' – rather than deciding upon more or less specific research purposes. At the heart of this stance is the call for

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[243] G. Laurie and E. Postan. Rhetoric or reality: what is the legal status of the consent form in health-related research? *Medical Law Review* 21 (2013), pp 371–414, 374.

[244] G. Laurie (2002), pp 292–293.

[245] M. Taylor (2012), p 207.

a shift in the understanding of informed consent, with the underlying argument being that the notion of open consent would serve the principle of autonomy since there is no one clear answer as to *how* informed one should be prior to giving consent,[246] including views that preclusion of deception and coercion would suffice for autonomy to be respected[247].

First, this approach is at odds with the simple fact of advancements in technology. Prior informedness is limited to the current state of art of technology and science – what constitutes 'scientific research' in a given area is inevitably subject to change over time. Furthermore, unlike in the case of processing based on informed consent – which would at the very least entail a conscious 'opt in' choice to have ones data used for research purposes – as demonstrated in the previous chapter, informed consent is not the only alternative as a legal basis for using personal (incl. genetic) data in research. In cases in which personal data use in research is based on legal grounds other than informed consent there is no 'opt in'. An 'opt out', however, would presume at least informedness regarding the fact of processing. Of course, in cases in which none of the exceptions to the obligation to inform can be invoked, one could still argue that information regarding the basic fact of processing for 'research purposes' as such would suffice (i.e. a one-off communication providing the individual with the knowledge that their data will be used for 'research purposes'). However, this type of all or nothing choice would not serve the interests of any stakeholders, as individuals who might be interested in contributing to only certain research (or on certain conditions), might wish to opt out of participation entirely. Given the myriad of possibilities for using genetic data in research, this kind of singular option does not serve the interests of the scientific community since apprehension towards specific areas of research might keep individuals from wanting to contribute to research altogether.[248]

Regarding the problems associated with prior informed consent, the notion of 'dynamic consent' has been advocated by, e.g., Kaye et al. (2015)[249] who have proposed "an interactive personalised interface that allows participants to

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[246] A. Nõmper (2005), p 120.

[247] O. O'neill (2002), p 97.

[248] For example, people might be apprehensive in having their genetic data used in research aiming to establish associations between genes and violent or criminal behaviour, because of the possible future association of the findings with the individuals whose data was used. See, e.g., S. Sohrabi. The criminal gene: the link between MAOA and aggression (REVIEW). *BMC Proceedings* 9(Suppl. 1) (2015), A49.

On a different note, one might not want their genetic data to be used in research trying to identify the 'gay gene', not because of individual association, but rather due to the possible future (ab)use of the general knowledge. See, e.g., K. O'Riordan. The life of the gay gene: from hypothetical genetic marker to social reality. *The Journal of Sex Research* 49(4) (2012), pp 362–368.

[249] J. Kaye et al. Dynamic consent: a patient interface for twenty-first century research networks. *European Journal of Human Genetics* 23 (2015), pp 141–146.

engage as much or as little as they choose and to alter their consent choices in real time." This interface would allow individuals to exercise their individual consent preference, e.g. whether they would prefer to give broad consent, or be approached on a case by case basis to give specific consent for certain projects, etc. Kaye et al. suggest that, "The options offered to participants can be set by the biobank or researcher according to their requirements." However, Steinsbekk et al.[250] argue that dynamic consent would essentially give primacy to private interests over public interests, rendering the approach "overly individualistic and by implication un-solidaristic"[251]. Furthermore, in a context where each researcher gets to decide whether broad or specific consent is appropriate, transparency would still require ongoing informedness (both in terms of broad consent; and in regard to specific consent if secondary processing without consent would still be possible under national law).

In regard to the peculiarities of genetic data specifically, a further challenge attached to prior informedness is the fact that genetic data is more frequently obtained for prenatal diagnostics, and routine prenatal whole genome sequencing might become a reality in the near future.[252] Information provided to parents prior to giving consent could not provide for informedness on part of the individual whose genetic data is concerned (i.e. the individual to be born). As genetic data remains constant throughout an individual's life and post mortem, there cannot be transparency without ongoing informedness. As Dondorp and de Wert (2013) point out, prenatal whole genome testing will reveal more information about a child "than is considered justifiable for neonatal screening", meaning that already before birth knowledge about, e.g., the individual's susceptibility for severe late on-set disease like hereditary breast cancer or Huntington's disease, will be available.[253] Dondorp and de Wert also point out that one of the underlying arguments for expanding prenatal whole genome testing is the need to obtain a research population as large as possible, thereby blurring the lines between care and research.[254] In order to facilitate transparency in relation to the individual whose data was included into research prior

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[250] K.S. Steinsbekk et al. Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem? *European Journal of Human Genetics* 21(9) (2013), pp 897–902.

[251] B. Schmietov. Ethical dimensions of dynamic consent in data-intense biomedical research: paradigm shift, or red herring? In D. Strech and Marcel Mertz (Eds.) "Ethics and Governance of Biomedical Research: Theory and Practice". Springer (2016), pp 197–209, 203.

[252] See, e.g., S.C. Chen and D.T. Wasserman. A Framework for Unrestricted Prenatal Whole-Genome Sequencing: Respecting and Enhancing the Autonomy of Prospective Parents. *The American Journal for Bioethics* 17(1) (2017), pp 3–18.

[253] W.J. Dondorp and G.M.W.R. de Wert. The 'thousand-dollar genome': an ethical exploration. *European Journal of Human Genetics* 21 (2013), pp S6–S26, S18.

[254] Ibid.

to birth or during infancy or childhood, in terms of facilitating transparency there is no other alternative to ongoing informedness.[255]

Essentially, any provision of information regarding intended (future) research uses of genetic data is limited not just by the foreseeable intentions of one given researcher or group of researchers, but also by the state of knowledge and technology at the time of the formulation of the state of informedness of the individual. This means that if the provision of information is designed to be a one-off communication, the state of informedness of the data subject is temporary. In turn, if the state of informedness of the data subject is rendered temporary, there can be no claim of transparency in relation to the data subject in terms of the (future) uses of their genetic data in research.

4.4. Transparency in practice on the example of the Estonian Health Information System

Much like privacy and data protection in general, transparency is a matter of infrastructural design as part of the 'privacy by design' and 'data protection by default' requirements under the GDPR.[256] In this section, the Estonian Health Information System will be used as an example of the potential practical implementation for transparency in relation to the data subject. Currently, this system does not facilitate transparency in relation to the individual as far the secondary research use of data is concerned, however, it has untapped potential for doing so.

4.4.1. The Estonian Health Information System

In Estonia, health data of the entire population is stored in the Health Information System (HIS), which is a digital database that is part of the state information system.[257] In addition to keeping detailed medical records in institutional record systems, health care providers are obliged to submit information concerning

[255] For an in-depth discussion on the matter of personal data protection in regard to prenatally obtained genetic data, See K. Pormeister, L. Drozdzowski. Protecting the genetic data of unborn children under the GDPR – a critical analysis. *European Data Protection Law Review* 4(1) (2018), 53–64.

[256] Recital 78 GDPR, supra n 1. See also Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, pp 22–23, para 43.

[257] § 1(1) *Vabariigi Valitsuse 01.12.2016 nr 138 "Tervise infosüsteemi põhimäärus",* RT I, 12.03.2019, 35.

health services provided to patients to the HIS.[258] The records stored in the HIS are often referred to as e-Health Records.[259]

Patients have access to their own records via the Patient Portal, in which they can submit further health and lifestyle information that the health care provider might need for purposes of clinical care, referred to as the 'declaration of health'.[260] Submitting the health declaration is mandatory if the patient wants to receive a health certificate[261] in order to, e.g., apply for a driver's licence.[262] The declaration of health is valid for 30 days for purposes of applying for a health certificate, which means that all the submitted data needs to be updated at some point in the future (for, e.g., receiving a new health certificate in order to re-new the driver's licence).[263]

Since health care providers have a legal obligation to submit data on the patient's care to the HIS, health care providers can refuse to enter into a contract with an individual (i.e. refuse to provide health care services, except for emergency situations) if the individual demands the health care provider not to submit data to the HIS.[264] This means that storage of health data in the HIS is not a matter of choice for the patient.

Part of the strategical vision of the e-Health system in Estonia for the next decade is to include genetic data into the HIS, and additionally to create a database to accumulate pseudonymised health and genetic data that could be used for both scientific research and also to further business developments.[265] Professionals in the health care system would submit the genetic data (and other

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[258] § 59^2(1)(3) of the Estonian Health Services Organisation Act. RT I 2001, 50, 284. Available in English at https://www.riigiteataja.ee/en/eli/508012018001/consolide [Accessed 7 July 2019].

[259] See, e.g., official website of the e-Estonia Briefing Centre at https://e-estonia.com/solutions/healthcare/e-health-record/ [Accessed 7 July 2019].

[260] § $59^2(1^2)$ of the Estonian Health Services Organisation Act, supra n 258.

In the declaration of health, the patient submits data on their lifestyle, working conditions, allergies, mental health, nervous system, eyes and eyesight, ears, nose, throat, respiratory system, metabolic disorders, cardiovascular conditions, bones, joints and muscles, infectious diseases, other chronic diseases, conditions or symptoms, previous treatments, traumas, pregnancy, skin, digestive organs, urogenital system, blood problems, medical devices they use, and sleep. Appendix 34, *Sotsiaalministri 18.09.2008 määrus nr 56 "Tervishoiuteenuse osutamise dokumenteerimise tingimused ja kord",* RT I, 03.05.2019, 3.

[261] § 106^{13} of *Sotsiaalministri 18.09.2008 määrus nr 56 "Tervishoiuteenuse osutamise dokumenteerimise tingimused ja kord",* ibid.

[262] § 101(1) of the Estonian Traffic Act, RT I 2010, 44, 261. Available in English at https://www.riigiteataja.ee/en/eli/525032019002/consolide [Accessed 7 July 2019].

[263] Appendix 34 of *Sotsiaalministri 18.09.2008 määrus nr 56 "Tervishoiuteenuse osutamise dokumenteerimise tingimused ja kord"*, supra n 260.

[264] P. Varul et al. (2009), § 760.

[265] E-Health vision 2025. E-Health strategic development plan 2020. (*E-tervise visioon 2025. E-tervise strateegiline arengukava 2020*). Estonian Health Strategy 2020. Government Office, supra n 73, pp 29–31.

health data) to the HIS. For example, if a patient has been referred to a clinical geneticist and the latter has prescribed a genetic test for diagnostic purposes (e.g. whole exome sequencing is a routine part of clinical genetics in Estonia),[266] the sequencing data would then be submitted to the HIS as well. This means that eventually the HIS would contain data on an individual's medical conditions and care, lifestyle information referred to above (incl., e.g., working and sleeping conditions etc.), and genetic data. This will provide a rich source of data for genetic research.

4.4.2. Access to HIS data for research purposes

Two of the primary purposes of the HIS are ensuring the quality of health services and protecting the rights of patients.[267] As such, health care providers all across Estonia can access the HIS for purposes of clinical care of the patient (as opposed to being limited to institutional records or patients having to provide medical records themselves). At the same time, patients can keep track of their own medical data via accessing the HIS through the Patient Portal. Other than access for the clinical care of patients and access by patients themselves, access of other persons to the data in the HIS is subject to a respective right established by law.[268] In addition, HIS data may be accessed based on consent of the patient, or without the patient's consent for purposes of scientific or historical research and national statistics or for establishing the truth in offence or judicial proceedings.[269]

As laid out in the previous chapter of this analytical compendium (Section 3.4.3.), the Estonian Data Protection Act (DP Act) provides for a legal basis for personal data (incl. genetic and health data) to be used in research without the consent of an individual. As made clear in the explanatory note to the DP Act, if the legal requirements established in the DP Act are met, the researcher must be provided with the requested data.[270] In case special categories of data are to be used in research, an ethics review is mandatory to determine compliance with the conditions set by the DP Act.[271]

The ethics review requirement under the DP Act is duplicated by a respective clause in the Health Services Organisation Act (HSOA) according to which

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[266] Whole exome sequencing and interpretation is listed for 1671,67 EUR in the list of health care services adopted annually by the government, based on which the national Health Insurance Fund covers medical costs of insured persons. *Vabariigi Valitsuse 20.06.2019 määrus nr 54 "Eesti Haigekassa tervishoiuteenuste loetelu"*, RT I, 28.06.2019, 11.

[267] § 59^1(1) of the Estonian Health Services Organisation Act, supra n 258.

[268] § 59^3 (6) of the Estonian Health Services Organisation Act, ibid.

[269] § 59^3 (7) of the Estonian Health Services Organisation Act, ibid.

[270] *Seletuskiri isikuandmete kaitse seaduse eelnõu juurde* (Explanatory note to the DP Act), supra n 203.

[271] § 6(4) of the Estonian Personal Data Protection Act, supra n 65.

access to the data in the HIS for research purposes is subject to an ethical review by a research ethics committee.[272] In addition to reviewing compliance with the DP Act, the committee has to evaluate "the extent of ethical risks and the background of the person conducting the research, by finding a balance between the protection of fundamental rights and the purposefulness of the research."[273]

However, none of the conditions set by the DP Act (discussed in Section 3.4.3.), or the ethics review required under the HSOA, facilitate transparency in relation to the data subject. Although the ethics review can be seen as a 'safeguard' within the meaning of Article 89(1), in terms of transparency in relation to the data subject the question is not one of applicable safeguards, but one of whether and to what extent patients are informed of the fact of the processing of their data in the HIS for research purposes.

4.4.3. Transparency in relation to patients within the HIS

As noted, patients can access their health records stored in the HIS by logging into the Patient Portal.[274] In addition to providing access for patients to their health records, the Patient Portal contains a Logbook, which is meant to provide an overview of inquiries made into patients' data, access thereto and modifications thereof (i.e. submission, modification, and deletion of data).

The Logbook contains the following information about actions taken in regard to HIS data: date (of submission of, access to, or changes made to data, or the adding or deleting of data); data (i.e. type of data concerned); person's name (taking the action); organisation/registry code; justification (for the action taken). However, the Logbook contains only information regarding inquiries made via the X-tee system[275]. This means that the Logbook reflects actions taken in regard to HIS data via other information systems connected to the X-tee system (i.e. by health care providers, or other databases). As to access to and submission of HIS data for research purposes, this is of a different technical nature,[276] as the submission of HIS data requires the permission of the Ministry of Social

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[272] § 59[4] of the Estonian Health Services Organisation Act, supra n 258.

[273] Ibid.

[274] See the Patient Portal at https://www.digilugu.ee/login [Accessed 12 July 2019].

[275] The Information System Authority has described the X-tee system in the following manner, "X-tee, the data exchange layer for information systems, is a technological and organizational environment enabling a secure Internet-based data exchange between information systems." See official website of the Information System Authority at https://www.ria.ee/en/state-information-system/x-tee.html [Accessed 18 July 2019].

[276] Regrettably, there are no official publicly available sources that can be cited. This explanation was provided to the author by the Information System Authority on 18 July 2019 via e-mail as a reply to the author's inquiry, and confirmed by a representative of the Health and Welfare Information Systems Centre via e-mail on 29 August 2019. The relevant e-mail exchange is in Estonian and can be provided by the author.

Affairs,[277] which is granted on a case-by-case basis. This means that the Patient Portal Logbook does not contain information on the research use of the HIS data – information on HIS data utilization in research is kept in internal logs, which are not public or accessible to patients. Patients can submit a request for information in order to receive confirmation whether or not their HIS data has been accessed for research purposes or not (i.e. patients can exercise their right of access under Art. 15 GDPR).[278]

In the Patient Portal[279], patients do have the option of controlling access to their health data. However, this does not concern the research use of the data. The means of control provided to patients are largely divided into three. First, under a rather misleading general label of "Managing accesses to health data", patients have the specific option to disable access rights of the medical committees of the Estonian Ministry of Defence.[280] Second, patients can disable access to single case summaries.[281] However, disabling access to case summaries means that the patient's own doctor will no longer have access to the data. Thus, disabling access to case summaries can negatively affect the medical care of the patient as health care professionals will no longer have access to the patient's medical history that might be relevant for the patient's clinical care. In fact, when clicking on the option to disable access to a case summary, a warning appears, including the remark that, "By locking the data, you assume responsibility for the possible deterioration of the treatment quality."

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[277] The Ministry of Social Affairs is the data controller in regard to HIS data within the meaning of the GDPR. § 5, *Vabariigi Valitsuse 01.12.2016 määrus nr 138 "Tervise infosüsteemi põhimäärus",* RT I, 12.03.2019, 35.

[278] These conclusions cannot be made based on legal acts or publicly available information. The Ministry of Social Affairs is the data controller in regard to the HIS, but the management of the system is part of the tasks of the Health and Welfare Information Systems Centre as a data processor. The documentation concerning the internal logs regarding HIS data use is not public. The conclusions are based on relevant explanations and confirmation provided to the author by an official of the Ministry of Social Affairs via e-mail on 29 July 2019. A representative of the Health and Welfare Information Systems Centre confirmed these conclusions via e-mail on 29 August 2019. The relevant e-mail exchange is in Estonian and can be provided by the author.

[279] The Patient Portal was accessed with the mobile-ID of the author on 13 July 2019 on the English version of the website.

[280] According to § 14 of the Militarty Service Act, healthcare providers on the medical committees of the Ministry of Defence can access HIS data subject to consent of the individual, however, in the Patient Portal their access rights are subject to an 'opt-out' approach with the individual having the possibility to disable such access.

For more details on the access rights of the Ministry of Defence to HIS data, See § 14 of the Estonian Military Service Act, RT I, 10.07.2012, 1. Available in English at https://www.riigiteataja.ee/en/eli/511042019005/consolide [Accessed 13 July 2019].

[281] By clicking on "Case summaries" listed under the heading "Health data" in the Patient Portal.

Third, patients have the option to disable access to all of their health data in the HIS.[282] This includes case summaries, examination results, dental care documents, immunizations, prescriptions, notifications, health certificates and declarations, ambulance charts, referrals, time critical data and working ability assessments. However, again, disabling access to the referred data will include access by health care professionals who might need the data for the clinical care of the patient. The same warning regarding the quality of future medical care appears as described above concerning disabling access to single case summaries.

This approach of managing access rights to health data is questionable, as it remains dubious why patients' options should be limited to an 'all or nothing' approach where disabling access to data is likely to negatively affect future medical care of the patient. An alternative would be to provide patients with the option to disable access of third parties not related to the patient's care, i.e. to disable the use of personal data stored in the HIS for any purpose other than the clinical care of the patient. Considering that storage of health data in the HIS is not subject to a patient's will as it is an obligatory system enforced by the state, access by third parties for purposes other than the individual's medical care should be the primary concern in regard to transparency in relation to patients and the exercise of their rights.

Although by exercising their right of access, patients can obtain information on the research use of their HIS data via submitting a request for information, within the current system it is not made transparent to patients that such use of their HIS data even exists. The Logbook contains no indication to the fact that HIS data might be accessed for purposes and made available to parties other than those visible in the Logbook. Furthermore, although patients have a basic option of disabling access to their HIS data (thereby risking the quality of future medical care), there is no reference to the fact that HIS data is still accessible for purposes other than clinical care (e.g. for research purposes by parties not involved in the patient's clinical care).

Regardless of its current shortcomings, the HIS system along with the Patient Portal contain the basic infrastructure to provide for ongoing informedness of individuals in regard to the secondary use of their health data in research. By accumulating data from different health care providers across the country the HIS system serves both patients' interests, and at the same time serves research interests by providing a valuable source for research data. However, considering the principle of transparency under the GDPR, the secondary research use of HIS data should be made transparent to patients. The existing Logbook feature of the Patient Portal could serve as an effective means of facilitating transparency in relation to data subjects in the research context if it were to contain information regarding every single access to a patient's data with a transparent description of information regarding the processing (i.e. the identity of the researcher or research entity, the type of data made available for research, and the research purposes).

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[282] By clicking on the general heading "Health data" in the Patient Portal.

V. CONCLUSIONS AND NORMATIVE PROPOSITIONS

In the transition from human subject research to human data research, the protection of the rights and interests of the individual is no longer primarily a matter of research or general human rights regulations, but instead depends largely on the personal data protection legal framework. In the EU, the latter is established under the GDPR.

One of the main principles under the GDPR is transparency of data processing in relation to the data subject, i.e. on the most basic level the notion that it should be transparent to individuals if, by whom and for what purposes their data is processed. However, the GDPR is not specifically designed to govern research, although it both directly and indirectly does so in many regards. On the one hand, the GDPR leaves the research use of special categories of personal data (incl. genetic data) to be regulated by Member State or other EU law, whilst also setting certain limits, such as the breadth of consent in research, as referred to in Recital 33 GDPR. On the other hand, the GDPR creates a number of exceptions from general data protection rules when it comes to research, like setting the research use of personal data free from the purpose limitation. As shown on the Estonian example, if national law provides legal bases for data processing in research without consent, this might lead to an outcome where consent given for (more or less) specific research purposes does not actually limit the further use of the data to the previously determined purposes. In this context, ironically, allowing for a broader determination of processing purposes within consent procedures would be likely to create more transparency in relation to data subjects, as opposed to more narrowly defined processing purposes, which do not actually limit the further use of the data in research without renewed consent. Although in such scenarios the general obligation to inform under the GDPR should still facilitate transparency in relation to data subjects, it was argued in this dissertation that the obligation to inform might not be efficient in this regard for two reasons. First, exceptions to the obligation to inform are likely to apply in the research context, particularly if data has been obtained from sources other than the data subject. Even where data has been obtained from data subjects directly, adhering to the principle of data minimisation and the principle expressed in Article 11(1) GDPR might result in the provision of information regarding secondary processing being rendered de facto impossible. Second, even if no exceptions apply and the provision of information to data subjects is possible, it is unclear how specific the processing purposes to be communicated need to be in a research context. Broadly defined purposes, however, render the obligation to inform a one-off communication, which will not suffice in making (future) research purposes for processing transparent to data subjects. As a result, the GDPR fails to deliver on the basic transparency promise when it comes to the research context.

Due to a number of factors, the problem of transparency in relation to the data subject becomes amplified when it comes to research involving genetic (i.e. DNA sequencing) data. First, one important aspect setting genetic research

apart from other human data research is the nature of genetic data, which provides for essentially limitless potential in research. Second, although identification of individuals based on any data is relative to context, it is notably so in the case of genetic data, which is inherently identifying by its nature, regardless of additional information or identifiers present or available. Third, as the informative potential of genetic data is relative to technological advancements over time, it is not possible to determine its possible (future) uses at a certain point in time. Fourth, whilst the research value of genetic data will increase in time subject to technological advancements, privacy interests related to it will not simultaneously decrease as genetic data remains constant from prior to birth to beyond the lifetime of an individual – to the contrary, as the informative potential of genetic data increases, so do privacy interests and risks associated with it.

Furthermore, as the GDPR does not limit the definition of scientific research on an institutional basis, the circle of possible data controllers processing personal data for research purposes within the meaning of the GDPR is essentially unlimited (as long as their use of personal data can be regarded as scientific research as defined by the WP29). For example, private testing companies are increasingly accumulating genetic data, and using it and distributing it for research purposes.[283] Thus, given that the potential uses and the potential users of genetic data for research purposes cannot be determined beforehand, in order to facilitate transparency in relation to data subjects in genetic research ongoing informedness is necessary.

It is the opinion of the author that transparency in relation to data subjects regarding the use of their genetic data in research should be recognised as essential not just for the protection of individual rights and interests, or the sake of adhering to the principle of transparency as required by the GDPR, but because transparency enables self-correction within any ecosystem of data governance and is a cornerstone of public trust. Instead of providing exceptions from the obligation to inform where the performance of this obligation might be practically challenging or burdensome, the design of the obligation to inform in the context of genetic research should be reconceptualised and the development of necessary IT infrastructures should be required to enable the provision of information. The provision of information to data subjects should not be left to be a matter of possibility or effort – which is subjective depending on the given data controller engaged in research – instead, it should be an objective part of infrastructure design requirements whenever genetic data is accumulated.

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[283] See, e.g., K.V. Brown. 23andMe Is Selling Your Data, But Not How You Think. *Gizmondo* 14.04.2017. Available at https://gizmodo.com/23andme-is-selling-your-data-but-not-how-you-think-1794340474 [Accessed 22 March 2018]; A. Lardieri. 23andMe is Using Your DNA for Genetics Research: The personal genome company is using DNA collected from consumers for more than just ancestry information. *U.S. News* 13.09.2017. Available at https://www.usnews.com/news/health-care-news/articles/2017-09-13/23andme-is-using-your-dna-for-genetics-research [Accessed 22 March 2018].

Because the contexts in which genetic data might be accumulated, and (further) used for research purposes, are not limited to specific fields like health-care or clinical research – the data might be readily available in a myriad of entities, from, e.g., direct-to-consumer genetic testing companies to various research entities – the obligation to provide information should not be subject to specific regulations in specialised areas, but is to be best addressed within the data protection framework. As the only over-arching legal instrument in the European legal sphere concerning the processing of personal data, that is both directly applicable and a general instrument by nature, it is the GDPR that has the most potential to effectively address concerns regarding transparency in the context of genetic research. Though individual Member States might regulate and address issues specific to genetic research in more detail and perhaps more strictly in their national laws, this will not suffice in the light of the fact that the EU is increasingly becoming an interconnected research area. Considering that the matter of applicable law under the GDPR – specifically in the research context – remains an unsolved and ambiguous matter,[284] a fragmented approach under national laws cannot effectively safeguard the interests of data subjects, or those of researchers and the public in general. Moreover, as the GDPR applies to processing in both the public and private sectors, is not limited to data processing in certain fields or areas, and encompasses a broad approach to the concept of 'research', it thereby has the potential to influence any and all scenarios of utilising genetic data in research (be it in the context of health-related research, clinical trials, or product development qualifying as research, etc.).

In order to facilitate transparency in relation to data subjects in genetic research, the following normative changes within the GDPR are proposed:

1. Redefining the concept of 'genetic data' and re-examining the approach to identifiability in regard to genetic data under the GDPR. The current definition under Article 4(13) GDPR qualifies DNA sequencing data as 'genetic data' if it is 'personal' data within the meaning of the GDPR, i.e. if it directly or indirectly enables identification of the individual. Based on current available technology, DNA sequencing data alone with no comparative or additional data would not enable identification of an individual. However, DNA is constant whereas technology and its availability are subject to change over time. As long as DNA sequencing data as such is not expressly recognized as 'personal' data, and thus 'genetic data' within the meaning of the GDPR, the latter will not apply to the processing of DNA sequencing data without additional information or identifiers. This, in turn, renders the existing safeguards and the following normative propositions ineffective, as although DNA sequencing data without further information or identifiers might be de jure anonymous within the meaning of the GDPR, it cannot be de facto de-identified, and the possibility to

[284] K. Pormeister. Genetic research and applicable law: the intra-EU conflict of laws as a regulatory challenge to cross-border genetic research. Supra n 115.

identify a data subject based on DNA sequencing data will always remain relative to context.

Furthermore, recognizing DNA sequencing data as 'personal data' regardless of additional identifiers or information would bridge the gap between regulations concerning data and those concerning biosamples from which the data is derived. Although biosamples as data carriers are not per se covered by data protection rules[285], once a biosample is used to sequence DNA, this would fall under the concept of personal data processing if human DNA sequencing data as such would be recognized as personal and thus genetic data within the meaning of the GDPR.

2. Establishing the breadth of consent and further rules regarding consent for the processing of genetic data for research purposes within the GDPR. The matter of the breadth of consent for the use of special categories of personal data (incl. genetic data) for research purposes is currently ambiguous. The author has argued that under the current framework, this matter is subject to national (or other EU) law. From the opinion of the WP29 it appears that Recital 33 GDPR is to be applied directly. In either case, there is no practical guidance for compliance on this matter (other than the WP29 excluding 'research purposes' as such as not clear enough). Adding to this the unresolved issue of intra-EU applicable law in the research context, [286] the author suggests addressing this matter within the GDPR (i.e. in the legally binding clauses, and not in the recitals). Although unsuccessful efforts in this regard were made during the drafting process of the GDPR, the outcome in the form of Recital 33 GDPR is a compromise between the stricter proposals made during the drafting process and the possibility of not regulating the matter in the GDPR at all. However, the principle expressed in Recital 33 GDPR should be part of the legally binding clauses of the GDPR if the aim of the drafters was to create a directly applicable exception to general consent rules (as suggested by the WP29). Whether part of the recitals or legally binding clauses of the GDPR, practical guidance from the European Data Protection Board on the practical meaning of 'certain areas of research' in regard to genetic research is necessary. Broadly defined research areas (such as 'genetic research' as an area of research) or the listing of various research areas in the consent as processing purposes might nullify the aim of Recital 33 GDPR in setting boundaries to the breadth of consent in regard to personal data processing for research purposes.

In addition to the breadth of consent, further conditions should be set in regard to the information to be provided to data subjects when obtaining consent for data processing. Most importantly, when giving consent, data subjects must

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[285] Opinion 4/2007 on the concept of personal data. Article 29 Data Protection Working Party, 01248/07/EN WP 136. Available at https://www.clinicalstudydatarequest.com/Documents/Privacy-European-guidance.pdf [Accessed 22 March 2018].

[286] K. Pormeister. Genetic research and applicable law: the intra-EU conflict of laws as a regulatory challenge to cross-border genetic research. Supra n 115.

be notified of the fact that regardless of the processing purposes listed in the consent, the same data might later be used for (different) research purposes without renewed consent. Data subjects must be informed that by giving consent for their data to be processed for whatever purpose, the said data will potentially be indefinitely available for any kind of research.

3. Redesigning the obligation to inform under the GDPR in regard to genetic research and creating a centralised approach to the research use of genetic data to effectively facilitate transparency in relation to data subjects. The matter of the specificity of the information to be communicated to data subjects in regard to the research use of their genetic data needs to be clear under the GDPR, as the determination of this question will decide whether the obligation to inform is an ongoing one or not, and thus whether it can effectively facilitate transparency in relation to data subjects. Where genetic data has been obtained from sources other than the data subject, instead of establishing exceptions to the obligation to inform based on arguments of impossibility or disproportionate efforts, the GDPR should adopt a transparency by design and by default approach that would uphold the obligation to inform in the context of genetic research. In this light, concerning the use of genetic data in research, the following propositions are made in regard to the obligation to inform under the GDPR.

1) Processing purposes to be communicated to data subjects should be defined per research project. In its current form under the GDPR, the obligation to inform has two major design flaws as far as transparency in relation to data subjects in the context of genetic research is concerned. First, the provision of information prior to processing encounters the same fundamental dilemma as the provision of information prior to obtaining consent. Namely, the question of how broadly research purposes may be communicated to data subjects. As noted above, it is clear that the WP29 have ruled out "for research purposes" as being sufficient,[287] however the level of required precision remains unclear. Considering that genetic data is constant, but the possibilities for its utilisation in research are evolving over time, for the processing of genetic data to be transparent to data subjects the communication of processing purposes should be project-specific. For a project-specific ongoing provision of information to be practicable, an exclusively centralised system for genetic data use and sharing in research is suggested.
2) An exclusively centralised approach to genetic data use and sharing in research should be adopted to effectively facilitate transparency in relation to data subjects via the ongoing provision of information. For a project-specific ongoing provision of information to data subjects to be practicable, the use and sharing of genetic data in research should be exclusively centralised. In this centralised system, the controller obtaining the genetic data from the

[287] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, p 9, para 12.

data subject (i.e. the primary controller) should be obliged to provide information to the data subjects with no exceptions to this obligation – unlike the current approach, this provision of information should as well include information on processing conducted by third party controllers with whom the primary controller has shared the data.

Research exchange of genetic data should be limited so that third party controllers who obtain the genetic data from sources other than the data subject are not allowed to further share this data. All research purposes for which third party controllers process the genetic data must be communicated to the primary controller for the latter to communicate this information to data subjects.

However, the above should not rule out approaches where the centralisation takes a different form, as is the case with, e.g., the Estonian HIS. As laid out in the analytical compendium, in this system providers of healthcare services are primary controllers as they obtain medical data from data subjects. Healthcare providers are obligated by law to submit medical data of patients to the HIS. From the HIS, in turn, the data may be shared for research purposes. In this kind of context, in which healthcare providers as primary controllers are obligated by law to share personal data with a third party controller (i.e. the Ministry of Social Affairs as the data controller in regard to the HIS), it would not be reasonable for primary controllers to be put in a position to be responsible to provide information to data subjects on processing activities carried out by or going beyond the third party controller.

3) No exceptions should apply to the obligation to inform regarding the research use of genetic data. Instead of providing for exceptions from the obligation to inform where data has been obtained from sources other than the data subject, in the above-proposed centralised system third party controllers should provide the necessary information regarding the use of genetic data in research to the controller who obtained the data from the data subjects, who then would communicate the information to the data subjects. Thus, as a general rule, the third party controller can still adhere to the principle of data minimisation and should not acquire any more data (e.g. contact information) than is strictly necessary for the sought research purposes. However, in this centralised system the primary controller should not be able to refer to the principle of data minimisation and Article 11(1) GDPR in regard to secondary processing of genetic data, as the technical contact means and the necessary data to provide information to data subjects on an ongoing basis should be part of IT infrastructure designs (e.g. as is the case with the Estonian HIS and patient access thereto). The processing of genetic data (for research purposes) should be conditional upon the possibility of providing information to data subjects regarding the fact and purposes of processing, and the identity of the data controller.

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SUMMARY IN ESTONIAN

Geeniuuringute läbipaistvus andmesubjekti suhtes – Eesti näitel põhinev analüüs

25.05.2018 kohaldunud Euroopa Liidu isikuandmete kaitse üldmääruse [288] (üldmäärus) eesmärk on isikuandmete kaitse taseme üleeuroopaline ühtlustamine. Sellest hoolimata on üldmäärus jätnud mitmed olulised andmekaitseaspektid liikmesriikide reguleerida. Üheks valdkonnaks, mida üldmäärus ainult osaliselt reguleerib ning mis on ülejäänud osas jäetud liikmesriikide pädevusse, on isikuandmete töötlemine teadusuuringute eesmärgil. [289] Samas tulenevad üldmäärusest mitmed olulised põhimõtted, mis ka teadusvaldkonda mõjutavad. Üheks neist on andmetöötluse läbipaistvuse nõue.

Isikuandmete töötlemise läbipaistvuse nõue on üldmääruse järgi üks kolmest andmetöötluse põhiprintsiibist. [290] Läbipaistvuse põhimõte on ka osa teaduseetikast, kuid teaduseetikas on läbipaistvusega seotud nõuded olemuselt üldmääruses sätestatust erinevad. Teaduseetikas on läbipaistvus pigem suunatud kas sissepoole – väljendudes näiteks nõudes toimida teadustöö tulemuste avaldamisel ja tõlgendamisel läbipaistvalt või läbipaistvuse nõudes kolleegide teadustöö retsenseerimisel ja hindamisel – või üldsusele.[291] Isikuandmete kaitse eesmärgil kehtestatud läbipaistvuse nõue isikuandmete töötlemisel on suunatud konkreetsele isikule, kelle andmeid töödeldakse, ehk andmesubjektile.[292] Kuivõrd üldmäärus ja sellest tulenevad isikuandmete kaitse reeglid kehtivad ka isikuandmete töötlemisel teadusuuringute eesmärgil,[293] tuleb autori hinnangul läbipaistvuse printsiipi teaduskontekstis käsitleda kahetasandilisena. Esimese tasandina võib eristada läbipaistvuse printsiipi, mis väljendub teaduseetilistes normides ja mis on suunatud teadustöö läbipaistvusele teadusmaailma siseselt ning suhtlusele avalikkusega. Teise tasandina võib eristada läbipaistvuse printsiipi, mis tuleneb isikuandmete kaitse üldmäärusest. Teise tasandi puhul on tegemist printsiibiga, mis on suunatud kindlale subjektile, kelle andmeid teadusuuringute eesmärgil kasutatakse. Andmekaitseõiguses eeldab läbipaistvuse nõue eelkõige seda, et andmesubjektile oleks teada, et tema andmeid töödeldakse, milline on isikuandmete töötlemise eesmärk ning vastutava töötleja isik.[294]

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[288] Supra n 1.

[289] Vt üldmäärus, art. 9(2)(j) ja (4), supra n 1.

[290] Üldmäärus, Art. 5(1)(a), ibid.

[291] Vt nt The European Code of Conduct for Research Integrity (Revised edition). ALLEA – All European Academies 2017, supra n 90.

[292] Üldmääruse art. 5(1)(a) järgi peab isikuandmete töötlemine olema andmesubjektile läbipaistev, supra n 1.

[293] Üldmäärus, põhjenduspunkt 159, ibid.

[294] Üldmäärus, põhjenduspunktid 39 ja 60, ibid.

Inimuuringutes, kus toimub füüsiline või psühholoogiline sekkumine inimesel, toimub uuringus osalejale teabe tagamine tavapäraselt informeeritud nõusoleku võtmise käigus, st nõusoleku küsimisele eelnevalt edastatava teabe näol. Inimuuringus osalemiseks võetava informeeritud nõusoleku fookuses on eelkõige uuringu raames toimuv füüsiline või psühholoogiline sekkumine ning sellega kaasnevad võimalikud riskid ja mõju uuritavale.[295] Geeniuuringute puhul võib selliseks sekkumiseks olla koeproovi (nt vere- või süljeproovi) võtmine. Nõusoleku võtmise eelselt tuleb planeeritava sekkumise osas isikut teavitada näiteks muu hulgas sellest, millal ja kuidas ning kes verd võtab, kui palju verd võetakse, millised on vere võtmisega seotud riskid. Viidatud nõusolekut inimuuringus osalemiseks tuleb eristada üldmäärusest tulenevast informeeritud nõusolekust isikuandmete töötlemiseks.[296] Viimane puudutab isiku nõusolekut tema andmete kasutamiseks. Geeniuuringute puhul tähendaks see isiku nõustumist tema geeniandmete kasutamiseks (teatud) teaduslikel eesmärkidel. Viidatud kahe nõusoleku võtmine toimub paralleelselt ning need võivad olla dokumenteeritud ühes nõusoleku vormis.[297] Nõusolek, mis antakse isikuandmete töötlemiseks teadusuuringute eesmärgil, peaks tagama andmete töötlemise läbipaistvuse andmesubjekti suhtes, kuid nõusoleku võtmise eelse teavitamisega tekib geeniuuringutes läbipaistvuse printsiibi tagamisel eelkõige kaks probleemi.

Esimene neist probleemidest puudutab küsimust sellest, kui kitsalt või laialt tuleb geeniuuringute puhul määratleda nõusolekus andmete kasutamise eesmärgid. Geeniandmete võimalik teaduslik otstarve korrelatsioonide otsimisel geenide ja välismaailma vahel on praktiliselt piiritu,[298] mistõttu tuleks teaduse edendamise kaalutlustel pooldada laiema eesmärgimääratluse lubamist nõusolekus, et kogutud andmeid saaks teaduses võimalikult laiaulatuslikult kasutada. Eesmärkide lai määratlus aga ei pruugi tagada andmetöötluse läbipaistvust andmesubjekti suhtes. Andmesubjekti perspektiivist on geeniandmete kui eriliselt tundliku andmekategooria[299] puhul töötlemise läbipaistvus oluline, kuivõrd geeniandmed on muuhulgas unikaalsed ehk olemuslikult isiku tuvastamist võimaldavad andmed. Lisaks on geeniandmed konstantsed ehk muutumatud, samas kui nende informatiivne potentsiaal on ajas kasvav, sõltudes tehnoloogia arengust ja kättesaadavusest, mistõttu on nende võimalik (teaduslik) otstarve

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[295] Vt nt Oviedo konventsioon, artiklid 16(v) ja 5, supra n 9.

[296] Üldmäärus, art. 4(11), art. 7 ja art. 9(2)(a), supra n 1.

[297] Üldmääruse järgi peaks isikuandmete töötlemiseks antav nõusolek olema selgelt eristatav muudest samas dokumendis käsitletud küsimustest. Üldmäärus, art. 7(2), supra n 1.

[298] Vt nt E. Vayena and A. Blassime. Health Research with Big Data: Time for Systemic Oversight, lk 121, supra n 53.

[299] Geeniandmed kuuluvad üldmääruse järgi eriliiki andmekategooriate hulka (üldmäärus, art. 9(1)). Lisaks on üldmääruses tunnustatud tervise-, geeni- ja biomeetrilisi andmeid kui kõrgendatud kaitset vajavaid andmekategooriaid, kuivõrd art. 9(4) järgi on liikmesriikidele jäetud õigus viidatud andmekategooriate puhul säilitada või sätestada täiendavaid tingimusi, sh piiranguid viidatud andmete töötlemisel. Üldmäärus, supra n 1.

ajas muutuv. Pidades silmas, kui laiahaardeline on geeniandmete võimalik (tulevane) otstarve teaduses ning kaaludes seejuures geeniandmetega seotud andmesubjekti huve, tekibki teadusuuringute eesmärgil toimuva geeniandmete töötlemise puhul eesmärgimääratluse dilemma. Näiteks on küsitav see, kas geeniandmete töötlemise teadusliku eesmärgi määratlusena võib nõusolekus märkida "geeniuuringud" üldiselt, nagu seda on Eestis tehtud inimgeeniuuringute seaduses[300] Geenivaramu puhul.

Enne üldmäärust kehtinud isikuandmete kaitse direktiiv 95/46/EÜ[301] teadusuuringute eesmärgil andmete töötlemiseks võetava nõusoleku küsimust ei reguleerinud. Üldmäärus käsitleb nõusolekut andmetöötluseks teadusuuringute eesmärgil põhjenduspunktis 33, milles tunnustatakse vajadust lubada teadusuuringute eesmärgil andmetöötluseks antava nõusoleku puhul määratleda töötlemise eesmärke laiemalt ehk teadusuuringuvaldkondade põhiselt. Autor analüüsib teadusuuringu eesmärkidel toimuvaks andmetöötluseks antava nõusoleku küsimust üldmääruse raames ning andmekaitse direktiivi 95/46/EÜ artikli 29 alusel loodud andmekaitse töörühma (andmekaitse töörühm) arvamuste põhjal ning vastandub oma järeldustes töörühma seisukohtadele. Andmekaitse töörühma hinnangul tuleks teadusuuringute eesmärgil toimuva andmetöötluse korral eesmärkide määratlemise osas lähtuda üldmääruse põhjenduspunktis 33 väljendatud põhimõttest. Autori hinnangul on töörühma seisukohad vastuolus kohtupraktikaga ning sisuliselt vasturäägivad. Autor jõuab järeldusele, et kirjeldatud küsimus tuleb kehtiva õiguse kohaselt lahendada riigisiseses või EL õiguses, lähtudes põhjenduspunktis 33 väljendatust kui diskretsioonipiiridest.

Teine probleem, mis tekib läbipaistvuse tagamisel geeniuuringutes nõusoleku võtmise eelse teavitamisega, on seotud asjaoluga, et geeniandmete kasutamine teadusuuringute eesmärgil on võimalik ka ilma isiku nõusolekuta. Kuivõrd geeniuuringud on muutunud tavapäraseks osaks kliinilisest meditsiinist,[302] võivad isiku koeproov ja geeniandmed olla talletatud kliinilise ravi käigus. Samuti võivad koeproovid ja geeniandmed kättesaadavad olla ettevõtetele, kes osutavad tarbijatele geenitesti teenust. Eeltoodud näidete puhul, kus isiku geeniandmed on juba eelnevalt talletatud, puudub andmete kasutamiseks teadusuuringute eesmärgil vajadus isiku suhtes ühtegi sekkumist läbi viia (nt vere- või süljeproovi võtmise näol). Kui teadusuuringuks vajalikud andmed on juba talletatud, on nende kasutamine teadusuuringute eesmärgil võimalik ka ilma andmesubjekti nõusolekuta.[303] Seda sõltumata sellest, kas andmed koguti nõusoleku

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[300] Inimgeeniuuringute seadus, § 12 lg 1, supra n 193.

[301] Supra n 38.

[302] Näiteks eksoomi sekveneerimine on osa Haigekassa poolt rahastatavatest tervishoiuteenustest. Vt Vabariigi Valitsuse 20.06.2019 määrus nr 54 "Eesti Haigekassa tervishoiuteenuste loetelu", supra n 266.

[303] Koeproovide kasutamisel kehtib Oviedo konventsiooni artiklist 22 tulenev eelneva teavitamise nõue, kui riigisisene õigus ei näe ette rangemaid nõudeid. Oviedo konventsioon, supra n 9; *Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Con-*

põhjal või muudel õiguslikel alustel. Näiteks juhul, kui isik on andnud nõusoleku oma andmete kasutamiseks teatud teadusuuringutes, on viidatud andmeid võimalik ilma nõusolekuta kasutada ka muudes teadusuuringutes, millest isikut nõusoleku võtmise eelselt ei teavitatud. Samuti on andmeid võimalik kasutada teadusuuringute eesmärgil ilma isiku nõusolekuta juhul, kui need on kogutud seaduse alusel näiteks isiku ravi eesmärkidel.[304] Autor analüüsib üldmääruse ja Eesti isikuandmete kaitse seaduse[305] pinnalt teadusuuringute eesmärgil toimuva isikuandmete töötlemise puhul seda, kuidas mõjutab ilma nõusolekuta töötlemise võimalus töötlemise läbipaistvust andmesubjekti suhtes. Autor jõuab järeldusele, et ülalkäsitletud eesmärgimääratluse puhul nõusolekus võib tekkida olukord, kus täpsem ja konkreetsem (teadusliku) eesmärgi määratlus andmesubjekti poolt antavas nõusolekus võib tegelikult mõjuda töötlemise läbipaistvusele pärssivalt, kuivõrd andmesubjektil võib tekkida õigustatud ootus, et tema andmeid töödeldakse vaid neil eesmärkidel, millest teda nõusoleku võtmise eelselt teavitati.

Sõltumata sellest, millisel õiguslikul alusel toimub isikuandmete töötlemine teadusuuringute eesmärgil, peaks reeglina kohalduma üldmäärusest tulenev üldine teavitamiskohustus.[306] Üldise teavitamiskohustuse järgi peab vastutav töötleja andmesubjekti tema andmete töötlemisest teavitama. Autor analüüsib üldise teavitamiskohustuse rakendumist teadusuuringute eesmärgil toimuva andmetöötluse puhul ning jõuab järeldusele, et geeniuuringute puhul ei pruugi üldine teavitamiskohustus tagada andmetöötluse läbipaistvust andmesubjekti suhtes eelkõige kahel põhjusel. Esiteks on tõenäoline, et olukorras, kus andmed on saadud mujalt kui andmesubjekti enda käest (nt andmebaasist), rakenduvad erandid teavitamiskohustusest. Ka olukorras, kus andmed on saadud andmesubjekti käest, võivad üldmäärusest tulenev võimalikult väheste andmete töötlemise printsiip ja artiklist 11(1) tulenev põhimõte päädida sellega, vastutaval töötlejal ei ole võimalik andmesubjekte nende andmete teisesest töötlemisest teavitada, kuivõrd selleks vajalikke kontaktandmeid ei ole kogutud või need on hävitatud. Teiseks, juhul kui ükski erand ei rakendu ning teavitamiskohustuse täitmine on võimalik, tekib teavitamiskohustuse puhul sama dilemma nagu nõusoleku võtmise eelse teavitamise puhul. Nimelt on ebaselge, kui täpselt tuleb määratleda teadusuuringute eesmärke andmesubjekti teavitamisel. Lai eesmärgimääratlus muudaks teavitamise ühekordseks üldiseks kommunikat-

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vention on Human Rights and Biomedicine, lk 21, para 137, supra n 11.
Eesti õiguse järgi võib patsiendi ja veredoonori verd teadustöös kasutada patsiendi või doonori kirjaliku nõusoleku alusel, kuid see nõusolek ei pea vereseaduse § 10 järgi olema informeeritud. Supra n 196.

[304] Näiteks Eestis on üheks seaduses sätestatud õiguslikuks aluseks isikuandmete töötlemiseks tervisehoiuteenuste korraldamise seaduse § 4^1 lg 1, mille alusel töötlevad tervishoiuteenuse osutajad tervishoiuteenuse osutamiseks vajalikke isikuandmeid ilma isiku nõusolekuta. Supra n 258.

[305] Supra n 65.

[306] Üldmäärus, art. 12–14, supra n 1.

siooniks, mis ei suudaks geeniandmete puhul tagada (tulevikus toimuva) andmetöötluse läbipaistvust andmesubjekti suhtes. Kitsam eesmärgimääratlus (nt teadusprojektipõhine teavitamine) võib aga praktikas olla keeruline või võimatu, kui selleks puudub vajalik infotehnoloogiline infrastruktuur.

Eelneva põhjal on doktoritöö eesmärk uurida, kas ja kuidas on tagatud geeniandmete töötlemise läbipaistvus andmesubjekti suhtes teadusuuringute eesmärgil toimuva andmetöötluse korral. Selleks analüüsib autor üldmäärusest tulenevaid õiguslikke meetmeid läbipaistvuse tagamiseks ning nende tõhusust andmesubjekti suhtes läbipaistvuse tagamisel geeniuuringutes. Kuivõrd teadusuuringute eesmärgil toimuv geeniandmete töötlemine on ositi jäetud liikmesriikide reguleerida, kasutatakse riigisisese õiguse näitena Eesti õigust, et tagada analüüsi terviklikkus.

Varasemalt avaldatud artiklites on autor uurinud teadusuuringute eesmärgil toimuva andmetöötluse reegleid üldmääruse raames, selgitamaks kohalduvaid nõusolekureegleid ning alternatiivseid õiguslikke aluseid andmetöötluseks teadusuuringute eesmärgil. Lisaks on varasemates artiklites uuritud erandeid üldisest teavitamiskohustusest, mis võivad rakenduda teadusuuringute eesmärgil toimuva andmetöötluse ning eriti geeniuuringute puhul. Artiklites läbiviidud analüüsi tulemuste põhjal on kokkuvõtvas ülevaateartiklis konspektiivselt käsitletud geeniandmete töötlemise läbipaistvust andmesubjekti suhtes teadusuuringute eesmärgil toimuva andmetöötluse puhul.

Doktoritöö põhineb autori poolt neljal varem avaldatud ja ühel avaldamisele kuuluval õigusteaduslikul artiklil:

1. Pormeister, Kärt (2017). Informed consent to sensitive personal data processing for the performance of digital consumer contracts on the example of "23andMe". Journal of European Consumer and Market Law, 6 (1), 17–23. Artikkel analüüsib geeniandmete töötlemist lepingulistes suhetes tarbijale suunatud geenitesti teenuse osutamise raames. Analüüsist tuleneb muu hulgas, et ärilistel eesmärkidel informeeritud nõusoleku põhjal teenuse osutamiseks kogutud geeniandmeid on kommertsteenuseid pakkuval ettevõttel hiljem võimalik kasutada teadusuuringute eesmärgil ilma selleks eraldi nõusolekut küsimata.
2. Pormeister, Kärt (2017). The GDPR and Big Data: Leading the Way for Big Genetic Data? In: Schweighofer, E. et al. (Eds.). Privacy Technologies and Policy (3–18). Springer. (Lecture Notes in Computer Science). Artiklis analüüsitakse, kuidas mõjutab üldmäärusest tulenevaid andmesubjektide õigusi ja vastutavate andmetöötlejate kohustusi asjaolu, et geeniuuringute raames on sageli tarvis töödelda suure arvu isikute geeni- ja muid isikuandmeid. Selgub, et puudutatud andmesubjektide suur arv võib vabastada andmetöötleja mõningatest kohustustest nagu teavitamiskohustus. Artiklist koorub välja järeldus, et üldmääruse artiklite 14(5)(b) ja 11(1) koostoimel võib olla negatiivne mõju andmetöötluse läbipaistvusele andmesubjekti suhtes, kuivõrd andmetöötleja võib vabaneda kohustusest teavitada andmesubjekte nende andmete töötlemisest.

3. Pormeister, Kärt (2017). Genetic data and the research exemption: is the GDPR going too far? International Data Privacy Law, 7 (2), 137–146, https://doi.org/10.1093/idpl/ipx006. Artiklis analüüsitakse, kas ja kuidas on teadusuuringute eesmärkidel toimuv andmetöötlus üldmääruses reguleeritud. Üldmääruse teadustööd puudutavaid sätteid võrreldakse varasemalt kehtinud direktiiviga Eesti riigisisese õiguse näitel. Võrdluse tulemusel hinnatakse, milline on üldmääruse eeldatav mõju teaduseesmärkidel toimuvale isikuandmete töötlemisele ning mis ulatuses on vastav küsimus jäetud liikmesriikide reguleerida.
4. Pormeister, Kärt (2018). Genetic research and consent: on the crossroads of human and data research. Bioethics, 33(3), 347–356, https://doi.org/10.1111/bioe.12475. Artiklis käsitletakse geeniuuringutes rakenduvaid nõusolekureegleid, pidades silmas, et geeniuuringute puhul võib, aga ei pruugi, toimuda koeproovide kogumine – st geeniuuringutega võib kaasneda füüsiline sekkumine inimesel, kuid uuringud võivad tugineda ka olemasolevate koeproovide või geeniandmete teisesele kasutusele. Analüüsi tulemusel selgub, et koeproovide kasutamisele teadusuuringute eesmärgil kohalduvad erinevad nõusolekureeglid sõltuvalt sellest, millises kontekstis koeproovid on kogutud (st kas teadusuuringute või muudel, eelkõige raviga seotud eesmärkidel). Seejuures rakenduvad koeproovidele ja neist tuletatud geeniandmetele erinevad reeglid nende kasutamiseks teadusuuringute eesmärgil, kuigi koeproovide kasutamise eesmärk on neist andmete tuletamine.
5. Pormeister, Kärt. Regulatory environment for biobanking in Estonia. In: Slokenberga, S. et al. (Eds.). Individual rights, public interest and biobank research. Article 89 GDPR and European legal responses. Springer 2020 (to be published). Artiklis uuritakse biopankadele kohalduvat õiguslikku reeglistikku Eestis. Seejuures analüüsitakse Eesti Geenivaramu suhtes kehtestatud erireegleid ning ka üldisi reegleid, mis tulenevad eelkõige andmekaitseõigusest. Muu hulgas kaardistatakse ja analüüsitakse kriitiliselt 2019.a jõustunud Eesti isikuandmete kaitse seaduse reegleid andmekasutuseks teadusuuringute eesmärgil ilma isiku nõusolekuta.

Doktoritöö eesmärkide täitmiseks on autor püstitanud viis uurimisküsimust. Järgnevalt esitatakse väitekirjas püstitatud uurimisküsimused koos analüüsi tulemusel selgunud vastustega.

1. Millised on üldmääruses andmesubjekti suhtes läbipaistvuse tagamiseks kehtestatud õiguslikud meetmed, mis kohalduvad geeniuuringutes?

Autor uurib üldmäärusest tuleneva läbipaistvuse printsiibi ja nõuete olemust ning üldmäärusest tulenevaid õiguslikke meetmeid läbipaistvuse tagamiseks. Kuivõrd andmetöötluse läbipaistvuse printsiip ei olnud varasemalt kehtinud

andmekaitse direktiivi 95/46/EÜ[307] järgi üks andmetöötluse põhiprintsiipidest ning tegemist on üldmääruse raames uue kohustusega,[308] ei ole viidatud küsimust varasemalt käsitletud.

Andmekaitse töörühma käsitluse järgi on läbipaistvuse printsiip üldmääruses üldine kohustus, mis hõlmab kolme põhilist valdkonda: andmesubjektile vajaliku teabe tagamine; vastutavate töötlejate poolt andmesubjektide individuaalsete õigustega seotud teabe edastamine; vastutavate töötlejate poolt andmesubjektide õiguste maksmapaneku võimaldamine.[309] Üldmääruse põhjenduspunktide järgi eeldab läbipaistvuse põhimõte eelkõige andmesubjekti teavitamist vähemalt asjaolust, et tema andmeid töödeldakse, töötlemise eesmärgist ning vastutava töötleja isikust.[310]

Autor eristab üldmäärusest tuleneva läbipaistvuse printsiibi puhul erinevaid tasandeid. Autori käsitluse järgi tuleb esmasel tasandil mõista läbipaistvust üldmääruse raames kui andmesubjekti teavitamist vähemalt andmetöötluse faktist, eesmärgist ning vastutava töötleja isikust. See on eelduseks täiendavatele kohustustele seoses läbipaistvuse nõudega (nt art. 12 tulenevad nõuded seoses keelekasutusega teavitamisel või andmekaitse töörühma poolt viidatud individuaalsete õiguste maksmapaneku võimaldamine). Täiendavaid läbipaistvuse printsiibist tulenevaid kohustusi saab autori hinnangul pidada läbipaistvuse printsiibi täiendavateks tasanditeks. Seega on autori käsitluses andmesubjekti teavitamine läbipaistvuse printsiibi esmane ja peamine tasand, millele saavad lisanduda täiendavad tasandid vaid eeldusel, et andmesubjekt on üldse teadlik tema andmete töötlemise faktist ja eesmärgist ning vastutava töötleja isikust.

Seetõttu käsitleb autor primaarse meetmena läbipaistvuse tagamisel üldmääruse raames artiklites 13 ja 14 sätestatud üldist teavitamiskohustust.[311] Üldise teavitamiskohustuse rakendumine ei sõltu sellest, millisel õiguslikul alusel andmeid töödeldakse. Kuivõrd teadusuuringute eesmärgil võib toimuda andmete töötlemine ka informeeritud nõusoleku alusel ning nõusoleku võtmine juba eeldab andmesubjekti teavitamist vähemalt vastutava töötleja isikust ja töötlemise eesmärkidest,[312] võib teavitamine toimuda nõusoleku võtmise käigus. Seega tuleb ka nõusoleku võtmise eelset teavitamist lugeda läbipaistvuse tagamise primaarseks meetmeks.

Üldmääruses võib isikuandmete töötlemise läbipaistvuse tagamise meetmena käsitelda ka üldmääruse artiklis 5(1)(b) kehtestatud eesmärgi piirangut. Artiklis 5(1)(b) kehtestatud eesmärgi piirangu kohaselt võib üldreeglina isikuandmeid

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307 Supra n 38.

308 Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, lk 4, para 1.

309 Ibid.

310 Üldmäärus, põhjenduspunktid 39 ja 60, supra n 1.

311 Sekundaarseteks meetmeteks tuleb autori hinnangul pidada meetmeid, mis rakenduvad autori poolt eristatud läbipaistvuse täiendavate tasandite puhul (nt selge keelekasutusega seotud nõuded).

312 Üldmäärus, art. 4(11) ja põhjenduspunkt 42, supra n 1.

töödelda vaid neil eesmärkidel, millisel neid koguti. Isikuandmete piiratud töötlemisõigus ehk õigus töödelda isikuandmeid vaid eesmärkidel, millisel neid koguti, tagab andmete töötlemise eesmärkide läbipaistvuse. Samas kehtestab viidatud säte erandi eesmärgi piirangust muu hulgas juhul, kui töötlemine toimub teadusuuringute eesmärgil. See tähendab, et eesmärgi piirang kui läbipaistvuse tagamise meede ei rakendu, kui isikuandmete töötlemine toimub teadusuuringute eesmärgil.

Kokkuvõttes jõuab autor järeldusele, et geeniuuringutes andmesubjekti suhtes läbipaistvuse tagamise meetmetena üldmääruses saab käsitelda eelkõige andmesubjekti teavitamist andmetöötluse faktist, eesmärkidest ja vastutava töötleja isikust. Andmesubjekti teavitamine võib toimuda osana informeeritud nõusoleku võtmise protsessist, kui andmetöötluse õiguslikuks aluseks on nõusolek, või üldise teavitamiskohustuse raames, sõltumata andmetöötluse õiguslikust alusest.

2. Kas ja kuidas tagab informeeritud nõusolek läbipaistvuse põhimõtte järgimise andmesubjekti suhtes geeniuuringutes ning mis on informeeritud nõusoleku piirid läbipaistvuse tagamise meetmena?

Autori analüüs geeniuuringutes rakenduvate nõusolekureeglite ja ilma nõusolekuta töötlemise võimalustest teadusuuringute eesmärgil toimuva andmetöötluse puhul kujutab endast esmakordset sellelaadset terviklikku käsitlust üldmääruse raames ja ühe liikmesriigi riigisisese õiguse näitel, hõlmates seejuures ka koeproovidele kohalduvat õiguslikku režiimi ning ravimite kliiniliste uuringute erijuhtumit.

Doktoritöös defineeritakse geeniuuringud kui uuringud, mille raames töödeldakse geeniandmeid. Geeniandmete mõistet käsitletakse seejuures kitsamalt, kui üldmääruses. Kui üldmääruse järgi võib geeniandmeteks lugeda ka üksikuid fakte, mis avaldavad teavet isiku geneetiliste omaduste kohta,[313] siis käesoleva väitekirja mõttes tähendavad geeniandmed inimese DNA sekveneerimise andmeid. Seeläbi loetakse geeniuuringuteks uuringud, milles analüüsitakse muu hulgas inimese DNA sekveneerimise andmeid. Autor eristab doktoritöös eritüüpi geeniuuringuid nõusoleku nõude perspektiivist: (1) uuringud, mille raames toimub füüsiline sekkumine isikult koeproovi saamiseks ja sellest geeniandmete tuletamiseks; (2) uuringud, mis põhinevad koeproovide ja/või geeniandmete teisesel kasutamisel. Omaette kategooriana eristatakse väitekirjas veel ravimi kliinilise uuringu raames toimuvaid geeniuuringuid, kuivõrd sellisel juhul kohaldub andmetöötluse reeglite osas lisaks üldmäärusele ka ravimi kliiniliste uuringute määrus[314] (määrus 536/2014).[315]

Uuringud, milles toimub füüsiline sekkumine koeproovi võtmiseks, on inimuuringud Oviedo konventsiooni mõttes ning eeldavad uuritava informeeritud

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313 Üldmäärus, art. 4(13), ibid.

314 Supra n 56.

315 Üldmäärus, põhjenduspunkt 161, supra n 1.

nõusolekut.[316] Selle nõusoleku eesmärk on eelkõige teavitada uuritavat uuringuga kaasnevatest sekkumistest ning riskidest (nt geeniuuringute puhul vere- või süljeproovi võtmine). Kui koeproov võetakse muul kui teadusuuringute eesmärgil (nt ravi käigus), kuid seda soovitakse hiljem teadusuuringute eesmärgil kasutada, ei ole enam tegemist inimuuringuga Oviedo konventsiooni mõttes ning viidatud konventsioonist tulenev nõusoleku nõue ei rakendu,[317] kuigi nõusolek võib siiski olla nõutav riigisisese õiguse kohaselt.[318]

Nõusolekut inimuuringus osalemiseks tuleb eristada infomeeritud nõusolekust üldmääruse mõttes. Viimase informatiivne sisu puudutab isikuandmete töötlemisega seotud küsimusi (sh töötleja(te) isik(ud), töötlemise eesmärk, andmete säilitamise viis ja aeg jne). Inimuuringu puhul rakenduvad kaks viidatud nõusolekut paralleelselt.[319]

Nõusoleku puhul geeniandmete töötlemiseks teadusuuringute eesmärgil on praktikas oluline küsimus sellest, kui laialt võib nõusolekus töötlemise eesmärke määratleda. See, kuidas geeniandmete töötlemise eesmärgid nõusolekus määratletakse, määrab töötlemise läbipaistvuse andmesubjekti suhtes (st kas nõusoleku andmisel saadud informatsiooni põhjal on isikul võimalik ette näha ja olla teadlik sellest, mis eesmärkidel tema geeniandmeid võidakse (tulevikus) töödelda). Üldmääruse artiklist 9(2)(a) tulenevad üldreeglid eeldavad nõusolekus konkreetsete eesmärkide määratlemist, mis teadusuuringute eesmärgil toimuva töötlemise puhul tähendaks kindlate teadusprojektide nimetamist nõusolekus. Samas viidatakse üldmääruse põhjenduspunktis 33 vajadusele võimaldada teaduses laiemat nõusolekut, määratledes töötlemise eesmärgid uuringuvaldkondade kaupa. Andmekaitse töörühm on erinevalt Euroopa Liidu Kohtu praktikast Euroopa Liidu õigusaktide põhjenduspunktide kohta[320] käsitlenud üldmääruse põhjenduspunktis 33 väljendatud põhimõtteid justkui otsekohalduvat erandit.[321] Töörühma seisukohad põhjenduspunkti 33 praktilise tähenduse osas on mõneti vastuolulised, kuivõrd töörühma sõnul võib teadusuuringute eesmärgil andmeid töödeldes töötlemise eesmärke nõusolekus väljendada üldsõnalisemalt kui tavapäraselt nõutud, kuid eriliiki andmete (sh geeniandmete) puhul

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316 Vt Oviedo konventsioon, artiklid 16(v) ja 5, supra n 9.

317 See järeldub Oviedo konventsiooni artiklite 5 ja 16 kommentaaridest. *Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*. Supra n 11.

318 Näiteks Eestis eeldab vereseaduse § 10 patsiendi ja veredoonori kirjalikku nõusolekut, et vastavalt ravi eesmärgil võetud või annetatud verd hiljem teaduslikel (patsiendi puhul ka kaubanduslikel) eesmärkidel kasutada. Supra n 196 ja 303.

319 See ei tähenda ilmtingimata kahte eraldi nõusoleku vormi, vaid nõusoleku vastavust mõlemast õigusvaldkonnast tulenevatele nõuetele nii vormi kui sisu poolest. Vt supra n 149 ja 297.

320 *Nilsson and Others*, supra n 136.

321 Article 29 Working Party Guidelines on Consent under Regulation 2016/679, supra n 80, lk 27–29.

tuleks töörühma arvates viidatud erandit siiski rangemalt sisustada.[322] Autor ei nõustu andmekaitse töörühma seisukohaga justkui kohalduksid üldmääruse põhjenduspunkti 33 printsiibid vahetult ilma, et need oleksid kehtestatud liikmesriigi riigisiseses või mujal EL õiguses. Autori hinnangul tuleb üldmääruse põhjenduspunktis 33 väljendatut käsitelda kui piire, mis on seatud üldmääruse artiklis 9(2)(j) liikmesriikidele ja EL seadusandjatele antud diskretsioonile eriliiki andmete teadusuuringute eesmärgil kasutamise reguleerimiseks.

Andmekaitse töörühm on ainsa praktilise näitena välistanud töötlemise eesmärgi määratlemise üldsõnaliselt kui töötlemise "teadusuuringute eesmärgil", kuivõrd see ei väljenda töörühma hinnangul piisavalt täpselt töötlemise eesmärke.[323] Vaieldavaks jääb, kas geeniuuringud liigituks iseenesest eraldiseisvaks uuringuvaldkonnaks (st kas üldmäärusega oleks kooskõlas sedastada andmesubjektile andmetöötluse eesmärgina "geeniuuringud" ilma täpsustuseta, nii nagu seda on tehtud Geenivaramu puhul inimgeeniuuringute seaduse[324] § 12 lg 1 alusel).

Samas ei ole nõusolek ainus õiguslik alus geeniandmete töötlemiseks teadusuuringute eesmärgil. Sõltumata sellest, millisel alusel geeniandmeid koguti ja talletati, võib neid sõltuvalt liikmesriigi õigusest olla hiljem võimalik teadusuuringute eesmärgil kasutada ka ilma isiku nõusolekuta. Eestis loob selleks õigusliku aluse isikuandmete kaitse seaduse[325] § 6.

Autor jõuab järeldusele, et informeeritud nõusoleku tõhusus läbipaistvuse tagamisel andmesubjekti suhtes geeniuuringutes on piiratud eelkõige kahel põhjusel. Esiteks on ebaselge, kui täpselt peavad nõusolekus olema määratletud töötlemise eesmärgid, kui geeniandmete töötlemine toimub teadusuuringute eesmärgil. Teiseks, sõltumata nõusolekus määratletud töötlemiseesmärkide täpsusest on andmeid võimalik kasutada ka (muude) teadusuuringute eesmärkidel.

3. Kuidas mõjutab informeeritud nõusoleku ja geeniandmete teaduses kasutamiseks alternatiivsete õiguslike aluste suhe geeniuuringute läbipaistvust andmesubjekti suhtes?

Autor analüüsib Eesti õiguse näitel informeeritud nõusoleku ja alternatiivsete õiguslike aluste vahelise suhte mõju isikuandmete töötlemise läbipaistvusele andmesubjekti suhtes. Eesti riigisisese õiguse näitel jõuab autor järeldusele, et Eesti kontekstis ei oma eesmärkide määratluse täpsus informeeritud nõusolekus praktilist tähendust. Sõltumata sellest, milline on informeeritud nõusolekus määratletud töötlemise eesmärk, on andmeid võimalik kasutada (muude) teadusuuringute eesmärgil. Reeglina kehtib üldmääruse järgi isikuandmete töötlemisel eesmärgi piirang, mille järgi võib andmeid töödelda vaid neil eesmärkidel,

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[322] Ibid.

[323] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, lk 9.

[324] Supra n 193.

[325] Supra n 65.

millistel need koguti. Samas teeb üldmäärus erandi eesmärgi piirangust muu hulgas olukorras, kus andmeid soovitakse kasutada teadusuuringute eesmärgil.[326] Edasine töötlemine eeldab siiski õiguslikku alust töötlemiseks. Eesti isikuandmete kaitse seadus loob aluse isikuandmete töötlemiseks teadusuuringute eesmärgil ilma isiku nõusolekuta. See tähendab, et näiteks kui andmed on kogutud nõusoleku alusel konkreetse teadusprojekti tarbeks, saab neid hiljem kasutada teistsuguste teadusuuringute eesmärgil ilma isiku nõusolekuta.

Eeltoodu põhjal järeldab autor Eesti näitel, et kontekstis, milles on võimalik andmete hilisem kasutamine ilma isiku nõusolekuta muudel kui nõusolekus määratletud eesmärkidel, mõjub nõusoleku võtmise eelselt antud teave töötlemise eesmärkide kohta eksitavalt ja töötlemise läbipaistvust pärssivalt. Seejuures tagaks laiem eesmärkide määratlus nõusolekus läbipaistvust andmesubjekti suhtes suuremal määral kui kitsas eesmärgimääratlus, kui viimane ei piira andmete töötlemist (muude) teadusuuringute eesmärkidel.

4. Millisel määral kohaldub isikuandmete töötlemisel teadusuuringute eesmärgil üldine teavitamiskohustus ning kuidas see mõjutab geeniuuringute läbipaistvust andmesubjekti suhtes?

Autor analüüsib üldmäärusest tulenevat üldist teavitamiskohustust eesmärgiga uurida selle rakendumist geeniandmete töötlemisel teadusuuringute eesmärgil ning selle mõju läbipaistvuse tagamisele andmesubjekti suhtes. Varasemalt pole viidatud kohustust üldmääruse raames ning teadusuuringute eesmärgil toimuva andmetöötluse osas süvitsi analüüsitud.

Üldmäärus kehtestab artiklites 13 ja 14 vastutavale töötlejale üldise teavitamiskohustuse, mis ei sõltu sellest, millisel õiguslikul alusel andmeid töödeldakse. Artikkel 13 reguleerib olukordi, kus andmed saadakse otse andmesubjektilt, ning artikkel 14 stsenaariumeid, milles andmed saadakse mujalt allikast (nt teise vastutava töötleja või teise andmesubjekti käest). Viidatud sätted on valdavas osas analoogsed, kuid erinevalt artiklist 13 kehtestab artikkel 14 rea erandeid, mil teavitamiskohustus ei kohaldu.

Olukorras, kus vastutav töötleja on saanud andmed otse andmesubjektilt, on ainus erand teavitamiskohustusele sätestatud artiklis 13(4), mille järgi ei kohaldu viidatud kohustus juhul ja sel määral, mil andmesubjektil on teave juba olemas. Sama põhimõtte kehtestab artikkel 14. Samas tuleb ka artikli 13 puhul silmas pidada üldmääruse artiklist 5(1)(c) tulenevalt võimalikult väheste andmete töötlemise printsiipi ja artiklis 11(1) kehtestatud põhimõtet, mille kohaselt ei ole vastutav töötleja kohustatud säilitama, koguma ega töötlema lisateavet üldmäärusest tulenevate kohustuste täitmiseks olukorras, kus vastutaval töötlejal pole (enam) tarvis andmesubjekti tuvastada. Ehk kui vastutaval töölejal ei ole (enam) teadusuuringu eesmärkide täitmiseks vaja andmesubjekte tuvastada, ei ole vastutaval töötlejal kohustust koguda ega säilitada andmeid, mis võimaldaksid andmesubjektidega kontakteeruda, kui selliste andmete kogumise või

[326] Üldmäärus, art. 5(1)(b), supra n 1.

säilitamise ainus eesmärk oleks üldmäärusest tuleneva teavitamiskohustuse täitmine. Sel juhul ei ole vastutaval töötlejal võimalik teavitamiskohustust täita, sõltumata vastava erandi puudumisest üldmääruse artiklis 13. Kuigi andmete saamisel andmesubjektilt on vastutaval töötlejal kohustus ja võimalus teavitada andmesubjekti töötlemise eesmärkidest, ei pruugi kontaktandmete puudumise tõttu olla võimalik hilisem teavitamine andmete teisesest töötlemisest ja selle eesmärkidest artikli 13(3) mõttes.

Üldmääruse artiklis 14 kehtestatud nimekiri eranditest, mil teavitamiskohustus ei kohaldu, hõlmab kahte erandit, mis on mõeldud muu hulgas teadusuuringute eesmärgil toimuva andmetöötluse jaoks. Nimelt ei kohaldu teavitamiskohustus, kui andmeid töödeldakse teadusuuringute eesmärgil ning teavitamine on võimatu või eeldaks ebaproportsionaalseid jõupingutusi. Arvestades, et andmekaitses kehtib võimalikult väheste andmete töötlemise põhimõte[327] ning tuginedes üldmääruse artiklis 11(1) sedastatule, järeldab autor, et geeniuuringute puhul on tõenäoline, et üks kahest erandist teavitamiskohustusele rakendub. Olukorras, kus teadusuuringu läbiviimiseks ei ole vaja andmesubjektide kontaktandmeid,[328] ei tohiks vastavalt võimalikult väheste andmete töötlemise põhimõttele selliseid andmeid koguda ega säilitada. Nagu ülal selgitatud, tuleneb üldmääruse artiklist 11(1) lisaks, et kui vastutav töötleja ei saa andmesubjekti (enam) tuvastada (nt kodeeritud andmete kasutamisel, kui koodivõti pole nimetatud vastutava töötleja valduses), ei pea vastutav töötleja täiendavaid andmeid koguma või säilitama vaid selleks, et üldmäärusest tulenevaid kohustusi täita. See tähendab, et uuritavate kontaktandmeid ei tuleks koguda ega säilitada vaid selleks, et täita teavitamiskohustust. Ilma kontaktandmeteta pole teavitamiskohustuse täitmine võimalik. Eeltoodust järeldab autor, et juhul, kui teadusuuringute eesmärgi täitmiseks pole andmesubjekti kontaktandmeid (enam) vaja, ei tohiks selliseid andmeid koguda ega säilitada, mistõttu peaks kirjeldatud olukorras rakenduma artiklis 14(5)(b) kehtestatud erand teavitamiskohustele teavitamise võimatuse tõttu.

Olukorras, kus uurijal on uuritavate kontaktandmed olemas, võib siiski rakenduda ebaproportsionaalse jõupingutuse erand. Viimase rakendamisel tuleb muu hulgas võtta arvesse andmesubjektide arvu, andmete vanust ja asjakohaseid kaitsemeetmeid. Andmesubjektide arv võib geeniuuringutes olla üsna suur,[329] kuna korraga võidakse analüüsida kümnete või isegi sadade tuhandete andmesubjektide geeniandmeid, mistõttu võib individuaalne teavitamine eeldada jõupingutusi, mida võib pidada ebaproportsionaalseks. Samas andmete vanus geeniandmete puhul erandi rakendamist põhjendada ei tohiks, kuivõrd geeniandmed

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[327] Üldmäärus, art. 5(1)(c), supra n 1.

[328] See võib olla vajalik teatud olukordades, mille raames soovitakse uuritavatega ühenduses püsida või uuesti kontakti saada andmestiku täiendamiseks või uuendamiseks, näiteks haruldasi haigusi puudutavate uuringute puhul. Vt nt M.G. Hansson et al. The risk of re-identification versus the need to identify individuals in rare disease research, supra n 215.

[329] Vt nt C. Wijmenga and A. Zhernakova. The importance of cohort studies in the post-GWAS era, supra n 222.

on konstantsed ning nende informatiivne väärtus on sõltuv tehnoloogia arengust ning seega ajas kasvav. Kolmas kriteerium (asjakohased kaitsemeetmed) on umbmäärane ning selle põhjal pole võimalik anda hinnangut ilma konkreetseid asjaolusid kaalumata.

Andmekaitse töörühm on selgitanud, et üldmääruse artiklis 14(5)(b) toodud eranditele ei saa rutiinselt tugineda vastutavad töötlejad, kes ei kasuta andmeid teaduslikel või statistilistel eesmärkidel.[330] Sellest teeb autor ümberpööratult järelduse, et vastutavad töötlejad, kes kasutavad isikuandmeid teadusuuringute eesmärgil, saavad viidatud erandeid rutiinselt rakendada.

Eeltoodu pinnalt hindab autor tõenäoliseks, et geeniuuringute puhul on võimalik teavitamiskohustusest vabaneda üldmääruse artiklis 14(5)(b) kehtestatud erandite alusel. See tähendab, et kui andmed saadakse mujalt kui andmesubjektilt endal (st eelkõige teise vastutava töötleja käest, nt andmebaasist), on andmed saanud kolmandast isikust vastutaval töötlejal võimalik rakendada erandit teavitamiskohustusest ning andmesubjekte ei pea teavitama nende andmete töötlemisest. Juhul, kui andmed on saadud andmesubjektilt, võivad võimalikult väheste andmete töötlemise põhimõte ja üldmääruse artikli 11(1) rakendumine päädida sellega, et vastutaval töötlejal ei ole võimalik andmesubjekte teavitada teisesest töötlemisest, kuna ta pole teavitamiseks vajalikke kontaktandmeid kogunud või säilitanud.

Isegi juhul, kui teavitamiskohustus rakendub, ei taga see geeniuuringute läbipaistvust andmesubjekti suhtes. Autori hinnangul esinevad üldmäärusest tuleneva teavitamiskohustuse ülesehituses disainivead, mis piiravad selle tõhusust läbipaistvuse tagamisel teadusuuringute eesmärgil toimuva andmetöötluse puhul. Esimene probleem on analoogne informeeritud nõusoleku puhul käsitletuga. Töötlemise eesmärkidest teavitamisel on teadusuuringute eesmärgil toimuva andmetöötluse puhul määravaks küsimus, kui täpselt tuleb eesmärgid määratleda. Erinevalt nõusolekust ja üldmääruse põhjenduspunktis 33 sedastatust ei ole üldise teavitamiskohustuse puhul üldmääruses selle küsimuse kohta ühtegi juhist ega indikaatorit (st puudub vastus küsimusele, kas teavitama peaks andmesubjektile tema andmete kasutamist näiteks teadusprojektipõhiselt või uuringuvaldkondade kaupa). Sellest, kui täpselt tuleb andmesubjektile sedastatavaid töötlemise eesmärke määratleda, sõltub hinnang sellele, millal võib teavitamiskohustuse täidetuks lugeda. Iseenesest kohustavad nii üldmääruse artikkel 13(3) kui 14(4) vastutavat töötlejat teavitama andmesubjekti ka kavatsetava teisese töötlemise eesmärkidest – st kui andmeid soovitakse kasutada muul eesmärgil kui neid koguti, tuleb andmesubjekti sellisest töötlemisest teavitada. Eesmärkide määratluse täpsus või konkreetsus on aga praktikas määravaks küsimuseks nii esmase kui teisese töötlemise puhul. Näiteks kui töötlemise eesmärke võib määratleda uuringuvaldkondade kaupa, siis võiks haigla, kes töötleb patsientide andmeid raviteenuse osutamise eesmärgil, täita teavitamiskohustuse raviandmete hilisemaks kasutamiseks teadusuuringute

[330] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, lk 30.

eesmärgil seeläbi, et loetleb andmesubjektile teisese töötlemise kohta teavet andes kõikvõimalikud meditsiinieriala uuringuvaldkonnad. Geeniuuringute puhul tõusetub jällegi küsimus, kas üldmäärusega oleks kooskõlas määratleda töötlemise eesmärgiks üldsõnaliselt "geeniuuringud" (nii nagu seda on näiteks Eestis tehtud inimgeeniuuringute seaduse[331] § 12 alusel Geenivaramu puhul).

Eeltooduga vahetult seotud teine probleem teavitamiskohustuse puhul on teavitamise ühekordne olemus. Juhul, kui teavitamisel võib töötlemise eesmärke määratleda laialt nagu eeltoodud haigla näite puhul, siis piirdub teavitamine ühekordse suhtlusega vastutava töötleja ja andmesubjekti vahel. Ühekordse kommunikatsiooni vahendusel laialt määratletud töötlemiseesmärkide sedastamine ei saa tagada töötlemise läbipaistvust andmesubjekti suhtes. Pidades silmas, et andmekaitse töörühm ei ole pidanud üldmäärusega kooskõlas olevaks töötlemise eesmärgi määratlemist kui andmete kasutamist "teadusuuringute eesmärgil"[332], kuna see ei väljenda piisavalt selgelt, millise teadustööga on tegemist, siis ei tohiks pädeda ka ülaltoodud haigla näites kirjeldatud toimimisviis.

Kokkuvõtvalt järeldab autor, et geeniuuringute puhul on tõenäoline, et on võimalik rakendada erandit, mis vabastaks vastutava töötleja teavitamiskohustusest juhul, kui geeniandmed on saadud mujalt allikast kui andmesubjektilt endalt. Olukorras, kus andmed on saadud andmesubjektilt, võivad võimalikult väheste andmete töötlemise põhimõtte ja artikli 11(1) rakendumine päädida sellega, et andmesubjekti pole hiljem võimalik teavitada teisesest töötlemisest ja selle eesmärkidest. Juhul, kui teavitamiskohustus rakendub ja seda on võimalik täita, on teavitamise puhul keskseks küsimuseks, kui laialt võib või kui kitsalt tuleb määratleda teadusuuringute eesmärke. Laiem eesmärgimääratlus muudab teavitamiskohustuse ühekordseks formaalsuseks, mis väljendub vaid eelnevas teavitamises (nagu nõusoleku võtmisele eelneva teavitamise puhul). Eelnev teavitamine seevastu ei saa tagada andmetöötluse läbipaistvust andmesubjekti suhtes geeniuuringutes, kuivõrd geeniandmete võimalikku (tulevast) otstarvet (teaduses) ei ole võimalik kindlal ajahetkel üheselt määratleda. Seetõttu on ainus viis andmetöötluse läbipaistvuse tagamiseks andmesubjekti suhtes geeniuuringutes andmesubjekti jooksev teavitamine.

5. Kas ja milliseid normatiivseid muudatusi on vaja kehtestada, et tagada geeniuuringute läbipaistvus andmesubjekti suhtes?

Doktoritöös analüüsitud ja tuvastatud probleemistiku lahendamiseks teeb autor kolm normatiivset ettepanekut. Autori hinnangul tuleks muudatusettepanekud kehtestada üldmääruses. Üldmääruses ei ole isikuandmete kasutust teadusuuringute eesmärgil eraldi reguleeritud, kuigi seda püüti määruse loomisel teha. Samas tulenevad üldmäärusest mitmed põhimõtted, mis isikuandmete töötlemist teadusuuringute eesmärgil oluliselt mõjutavad. Üldmääruses on

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[331] Supra, n 193.

[332] Article 29 Working Party Guidelines on Transparency under Regulation 2016/679, supra n 8, lk 9.

püütud piirata teadusuuringute eesmärgil toimuva andmetöötluse puhul kasutatava nõusoleku ulatust (st põhjenduspunktis 33 sedastatud piiride näol). Samaaegselt on kindlal eesmärgil antud nõusoleku alusel saadud andmeid hiljem võimalik (muude) teadusuuringute eesmärgil kasutada – eeldusel, et selleks esineb õiguslik alus nagu Eesti riigisisese õiguse puhul isikuandmete kaitse seaduse § 6. Asjaolud, et teadusuuringute eesmärgil andmete töötlemisel ei kehti eesmärgi piirang ning andmeid on võimalik töödelda ilma isiku nõusolekuta, muudab andmetöötluse andmesubjekti jaoks läbipaistmatuks. Seda enam, et teadusuuringute eesmärgil andmeid töödelda võivate isikute ring pole piiratud, vaid määravaks on, et tegemist oleks valdkonnale vastavale metoodikale ja eetilistele standarditele vastava teadusprojektiga.[333]

Kuigi üldmääruse raames peaks sõltumata andmetöötluse õiguslikust alusest kohalduma üldine teavitamiskohustus, selgus väitekirjas esitatud analüüsi tulemusel, et teadusuuringute eesmärgil isikuandmete töötlemisel ei pruugi teavitamiskohustus praktikas tagada andmetöötluse läbipaistvust kahel põhjusel. Esiteks on tõenäoline, et juhul, kui andmed on saadud mujalt allikast kui andmesubjektilt, on võimalik rakendada erandeid teavitamiskohustusest. Ka olukorras, kus andmed on saadud andmesubjektilt, võib osutuda võimatuks andmesubjekti hilisem teavitamine teisesest töötlemisest. Teiseks, isegi juhul, kui erandeid pole võimalik rakendada ning teavitamiskohustust on võimalik täita, ei eelda teavitamiskohustuse täitmine praegusel kujul jooksvat teavitamist, vaid võib piirduda ühekordse üldise teavitusega.

Tagamaks isikuandmete töötlemise läbipaistvuse andmesubjekti suhtes geeniuuringutes, tehakse doktoritöös kolm normatiivset ettepanekut:

1) Geeniandmete mõiste ümber mõtestamine üldmääruses. Üldmääruse järgi käsitletakse DNA sekveneerimisandmeid ‘geeniandmetena’ eeldusel, et tegemist on isikuandmetega. See tähendab, et üldmäärus kohaldub DNA sekveneerimisandmetele vaid juhul, kui need võimaldavad otseselt või kaudselt isikut tuvastamist. Kuivõrd praeguse tehnoloogia taseme juures ei ole ainuüksi DNA sekveneerimisandmete põhjal isiku tuvastamine ilma täiendava informatsioonita (nt võrdlus- või lisaandmed) võimalik, ei pruugi üldmäärus viidatud andmetele kohalduda olukorras, kus neid töödeldakse ilma täiendavate andmeteta. DNA sekvneerimisandmete potentsiaal isiku tuvastamiseks sõltub lisaks täiendavatele andmetele ka tehnoloogilistest võimalustest. Nii täiendavate andmete kui uute tehnoloogiliste võimaluste kättesaadavus sõltub kontekstist ja on ajas muutuv, samas kui inimese DNA on konstantne. Seetõttu ei ole võimalik tagada andmetöötluse läbipaistvust andmesubjekti suhtes geeniuuringutes ilma, et läbipaistvuse meetmed rakenduks ka olukorras, kus töödeldakse DNA sekveneerimisandmeid ilma täiendavate andmeteta või identifikaatoriteta.

   Lisaks aitab geeniandmete mõiste ülaltoodud viisil ümbermõtestamine ühtlustada geeniandmetele ja koeproovidele kohalduvat õiguslikku režiimi.

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[333] Article 29 Working Party Guidelines on Consent under Regulation 2016/679, supra n 80, lk 27–28.

Kui DNA sekveneerimisandmed loetaks geeniandmeteks üldmääruse mõttes sõltumata täiendavatest andmetest, kohalduks andmekaitseõigus alates hetkest, mil koeproovidest DNA andmeid sekvneeritakse (st isegi kui tegemist on nö anonüümse koeprooviga).

2) Teadusuuringute eesmärgil kasutatava andmetöötluse informeeritud nõusoleku ulatuse reguleerimine üldmääruses. Autor on väitekirjas jõudnud seisukohale, et kehtivas õiguses on informeeritud nõusoleku lubatud ulatus teaduses liikmesriikide (või muu EL) õiguse reguleerida. Andmekaitse töörühma seisukohtade järgi kehtestaks üldmääruse põhjenduspunkt 33 justkui otsekohalduva erandi üldistest nõusoleku reeglitest. Sõltumata eeltoodud vaidlusküsimusest jääb selgutsetuks, kui täpselt peavad teadusuuringute eesmärgil toimuva isikuandmete töötlemise puhul olema töötlemise eesmärgid nõusolekus määratletud. Andmekaitse töörühm on välistanud "teadusuuringute eesmärgi" kui üldsõnalise määratluse, kuid pole seejuures selgitanud, kui lai määratlus oleks aktsepteeritav ja kooskõlas üldmäärusega.

   Pidades silmas teadusuuringute eesmärgil isikuandmete töötlemisel EL-sisest kohalduva õiguse dilemmat[334] ning samas suunda ühtse teadusruumi poole, on autor seisukohal, et informeeritud nõusoleku ulatuse küsimus teadusuuringute eesmärgil toimuva andmetöötluse puhul tuleks lahendada üldmääruses. Kuigi üldmääruse vastuvõtmise käigus tehtud ettepanekud meditsiiniuuringute reguleerimiseks nurjusid, on põhjenduspunktis 33 esitatu kompromiss luhtunud ettepanekute ja küsimuse reguleerimata jätmise vahel. Küll peaks põhjenduspunkti 33 sisu olema osa üldmääruse õiguslikult siduvatest sätetest mitte põhjenduspunktidest. Igal juhul on vaja Euroopa Andmekaitsenõukogu juhiseid selle kohta, kuidas praktikas sisustada põhjenduspunktis 33 määratletud teaduses kasutatava nõusoleku ulatust ning seda eriti geeniuuringute puhul.

   Lisaks nõusoleku ulatuse reguleerimisele tuleks selge kohustusena sätestada andmesubjekti teavitamine asjaolust, et nõusoleku andmine andmete töötlemiseks kindlal (teaduslikul) eesmärgil ei välista hiljem samade andmete kasutamist (muude) teadusuuringute eesmärgil. Andmesubjektile peab olema selge, et kui ta annab nõusoleku oma andmete töötlemiseks ükskõik millisel eesmärgil, võib neid andmeid olla võimalik määramata aja jooksul kasutada piiramata hulgal teaduslikel eesmärkidel.

3) Üldmääruses teavitamiskohustuse ümberkujundamine geeniuuringute osas ja andmete jagamisel tsentraalse lähenemisega andmetöötluse läbipaistvuse tagamine andmesubjekti suhtes. Teavitamiskohustuse kui läbipaistvuse tagamise meetme tõhusus sõltub olulisel määral sellest, kui täpselt tuleb teadusuuringute eesmärgil toimuva isikuandmete töötlemise puhul määratleda töötlemiseesmärke. Mida laiemalt on eesmärgid määratletud, seda tõenäolisemalt piirdub teavitamiskohustuse täitmine ühekordse kommunikatsiooniga. Küsimus töötlemiseesmärkide määratlemise ulatusest teavitamiskohustuse

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[334] K. Pormeister. Genetic research and applicable law: the intra-EU conflict of laws as a regulatory challenge to cross-border genetic research. Supra n 115.

täitmisel teadusuuringute eesmärgil toimuva andmetöötluse puhul tuleb üldmääruses lahendada. Autori hinnangul tuleks geeniuuringute korral töötlemiseesmärkidest teavitada projektipõhiselt, kuivõrd laiem määratlus muudab (tulevase) andmetöötluse andmesubjekti suhtes läbipaistmatuks.

Selleks, et andmesubjektide projektipõhine teavitamine oleks praktikas võimalik, tuleb andmete jagamisel ja teavitamisel luua tsentraalne süsteem. See tähendab, et andmesubjektilt andmeid kogunud vastutav töötleja (st esmane vastutav töötleja) oleks kohustatud teavitama andmesubjekte nende andmete töötlemisest ka ulatuses, mis puudutab teadusuuringute eesmärgil töötlemist kolmandast isikust vastutava töötleja poolt, kes on andmed saanud esmaselt vastutavalt töötlejalt. Kolmandast isikust vastutava töötleja õigused geeniandmete edasiseks jagamiseks teaduskoostöö eesmärkidel peaksid olema piiratud. Kolmandast isikust vastutav töötleja peaks esmast töötlejat teavitama kõigist töötlemiseesmärkidest.

Samas ei tohiks kirjeldatud ettepanek välistada alternatiivseid lähenemisi tsentraalsele andmejagamisele ja -teavitamisele. Näiteks Eesti Tervise Infosüsteemi (TIS) puhul on esmaseks töötlejaks tervishoiuteenuse osutajad, keda seadus kohustab patsientide andmeid TIS-i edastama. Samas väljastab TIS omakorda andmeid teadusuuringute eesmärgil kasutamiseks. Sellises stsenaariumis oleks ebamõistlik eeldada, et tervishoiuteenuse osutajad peaksid teavitama andmesubjekti andmetöötlusest, mis toimub pärast nende edastamist TIS-i (sh andmete edasine väljastamine TIS-st teadusuuringute eesmärgil). Sellistel juhtudel peaks teavitamiskohustus jagunema siiski selliselt, et TIS andmeväljastuste kohta teadusuuringute eesmärgil teavitab andmesubjekte TIS vastutav või volitatud töötleja.

Kirjeldatud tsentraliseeritud lähenemise puhul poleks ka põhjendatud erandite kehtestamine teavitamiskohustusest olukorras, kus andmeid teadusuuringute eesmärgil töödelda sooviv vastutav töötleja on andmed saanud mujalt kui andmesubjektilt endalt. Kui andmesubjekte pole võimalik teavitada nende geeniandmete töötlemisest (teadusuuringute eesmärgil), peaks töötlemine olema välistatud.

PUBLICATIONS

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2013–2014	Lawyer/Attorney, Law Firm VARUL
2012–2013	Research and Editorial Assistant to Professor William B. Simons, General Editor of *Review of Central and East European Law* and the monograph series *Law in Eastern Europe*

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2011–2013	Master of Arts in Law, University of Tartu (*summa cum laude*)
2012	The Hague Academy of International Law Summer School on Public International Law; directed studies; The Hague, The Netherlands
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