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Comments on the EDPS' Preliminary Opinion on Scientific Research

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Summary

The following is a response to the open call for comments and reactions to the EDPS Preliminary Opinion on data protection and scientific research. The following issues with the Opinion are addressed in detail:

- The exclusion of scientific **infrastructure** projects from the scope of scientific research
- The exclusion of **private research** from the scope of scientific research
- The unclear use of the concept of the **'essence'** of the right to data protection
- The lack of discussion of the issues concerning the concept of **anonymity** in research
- The need for clarification as to whether Member State derogation from the right to **data portability** is possible under Article 89(2)
- The need to highlight that the legislative history of Recital 50 supports the need for **secondary use** to be legitimated under Article 6 or 9.
- The need for clarification as to why Member State derogations under **Article 9(4)** should require a new law
- The need for clarification as to whether Member State derogations under **Article 9(4)** can include both increases and decreases from the standard outlined in the GDPR
- The lack of discussion of national conceptualisations of the impossibility to use **consent** under Article 9(2)(a) to legitimate research
- The need to clarify and justify the idea that requirements and conditions of **consent** under the GDPR should differ from those outlined in ethics or other areas of law
- The need to clarify the concept of **consent**, not as necessary for the legitimation of research, but rather as a safeguard to protect research subject rights
- The lack of recognition of the need to specify minimum standards of **technical and organisational safeguards** for specific sectors of research
- The need to address questions of scientific data sharing and **data transfer** to third states, respectively the use of non-EU scientific databases, data sharing instruments and/or infrastructure
- The lack of consideration of the many data protection issues concerned with **scientific publishing**
- The conflation of the need for oversight and the need for research as justifications for granting researchers access to **platform data**
- The limited recognition of the range of data protection issues in **genetic research**

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1. Introduction

To begin, the importance of the Opinion should be highlighted. There has long been a gap in official clarification as to how the data protection rules in the GDPR should apply to scientific research. The Opinion will help to close this gap. In turn, there are numerous aspects of the Opinion which deserve praise. These include, in particular: the position taken on Recital 50 and the recognition of the need for instances of secondary processing in scientific research to seek a legitimate ground under Articles 6 or 9; the recognition of the limitations on Articles 9(2)(g) and (j) as justifications for engaging in scientific research – not least as the required national laws are not yet all in place; the fact the Opinion addresses issues concerning scientific research and social media platforms – including the ethics of use by platforms and affiliated researchers of users' personal data and the need for access by independent researchers to users' personal data in order to research urgent matters of public interest. Despite the above, however, there remain issues with the Opinion. In the following, these issues are clustered into three groups: definitional issues; technical issues; and fundamental issues.

2. Definitional Issues

Infrastructure Projects and the Definition of Scientific Research

The Opinion refers to certain criteria for the definition of scientific research – such as the need for a hypothesis and the need to follow a discipline specific methodology (see pages 9-12). The criteria mentioned – whilst undoubtedly relevant and significant – taken alone, would exclude all scientific **infrastructure** projects from the definition of scientific research. These criteria would exclude, for example, European infrastructure projects such as the European Open Science Cloud and national infrastructure projects such as the German National Research Data Infrastructure (NFDI)[1]. It is true that such infrastructure projects are not, themselves, scientific research. It is also true, however, that scientific infrastructures – scientific databases, biobanks etc. – are essential, indeed inseparable, from much current scientific research activity. How, for example, would longitudinal genomics studies function without supporting biobanks?[2] In this regard, it seems legitimate to regard such infrastructures in terms of scientific research activity – if not necessarily scientific research. It thus seems legitimate that their activities should be covered by the exceptions and derogation possibilities in the GDPR concerning scientific research. This would mandate the activity of such infrastructures be classified as 'scientific research'. Perhaps the Opinion could address this issue?

Private Research and the Definition of Scientific Research

The Opinion also seems to adopt, at several points, a definition of the concept of 'scientific research' which would exclude **private research** (see pages 9-12). The

[1] https://www.dfg.de/en/research_funding/programmes/nfdi/index.html.
[2] See, for a discussion of the importance of biobanks, and networks of biobanks, for medical research: Martin Asslaber, Kurt Zatloukal, 'Biobanks: transnational, European and global networks' [2007] 6(3) Briefings in Functional Genomics and Proteomics 193.

rationale for this exclusion is, to a degree, understandable – to restrict the possibility for an overly-broad concept of 'scientific research' to be applied to ostensibly non-research activities to avoid relevant safeguards. Yet, this approach raises several issues. Three are particularly significant. First, the definition appears difficult to square with the text of the GDPR itself, which, in Recital 79, recognises the concept of scientific research to encompass private research. Second, the definition is at direct odds with several national constitutional traditions – for example the German – which recognise private research as constituting scientific research and focus more on the methodological aspect of scientific research.[3] Third, the definition is difficult to square with private activities which most people would intuitively recognise as scientific research – pharmaceutical research, industry funded technology research etc., for example. Perhaps the Opinion could focus on definitions of research based around process and outcome, as opposed to sector and funding? Indeed, taking this point and the previous point together, perhaps the Opinion would do well to approach the issue from another perspective and also consider the question: what does not constitute research?

The Concept of the 'Essence' of the Right to Data Protection

The Opinion suggests the concept of the **'essence'** of the right to data protection refers to a range of different aspects of the right to data protection: 'data subject rights, appropriate organisational and technical measures against accidental or unlawful destruction, loss or alteration, and the supervision of an independent authority' (see page 18). Yet it is not clear from where the Opinion draws this understanding. The Opinion's use of the concept does not seem to fit any of the CJEU's uses of the concept of 'essence' in relation to the right to data protection.[4] Nor does the Opinion's use of the term seem to fit any of the academic conceptualisations of the concept – many of which indeed highlight the difficulty in identifying the specifics of the concept.[5] It would be useful – both for clarity in the Opinion itself as well as generally – if the Opinion would provide a more detailed explanation of its understanding and use of the concept of 'essence'.

3. Technical Issues

Anonymity and Scientific Research

The Opinion scarcely touches on the significant debates going on around the concept of **anonymity** in research (see the limited references on pp. 14 and 24). The precise legal situation concerning when personal data is anonymous in research is not currently clear. Given the ever-increasing need for large data-sets in research – for example in AI research – this is already one of the most significant discussions in the interaction of research and data protection. For example, there is a case-specific difference between

[3] German Basic Law, Article 5(3) 1949 (updated 2019). See also: Jochen Taupitz, Jukka Weigel, 'The Necessity of Broad Consent and Complementary Regulations for the Protection of Personal Data in Biobanks: What Can We Learn from the German Case' [2012] 15 Public Health Genomics 263, 265.
[4] Case C-362/14 *Maximillian Schrems v Data Protection Commissioner* [2014] ECLI:EU:C:2015:650, para 94.
[5] See for example: Maja Brkan, 'The Essence of the Fundamental Rights to Privacy and Data Protection: Finding the Way Through the Maze of the CJEU's Constitutional Reasoning' [2019] 20(6) German Law Journal 864.

anonymised and anonymous personal data. On the one hand, previous opinions by the Article 29 Working Party suggested the concept related to *de facto* anonymity and suggested a very high standard needed to be reached – i.e. it needs to be almost impossible to re-identify the data subject.[6] On the other hand, however, the CJEU *Breyer* judgment recently suggested that *de jure* obstacles to re-identification could also serve to render personal data anonymous – i.e. data may qualify as anonymous if the user is legally prohibited from accessing supplemental data necessary for reidentification.[7] It remains unclear from the case, however: i) if the principle of *de jure* obstacles should apply in all contexts; and ii) which *de jure* obstacles should serve as capable of rendering personal data anonymous – should contract terms, for example, be included? In light of this uncertainty, a number of different interpretations have emerged as to when personal data can be anonymous in the research context. Certain interpretations stay close to the Article 29 Working Party position. Other interpretations take more relaxed positions. The position of the RatSWD, for example, suggests that personal data might be regarded as anonymous if, after a general evaluation of technical circumstances, re-identification is merely unlikely.[8] The Opinion would be a useful forum to provide clarity to this discussion.

Article 89(2) and Derogations from the Right to Data Portability

The Opinion discusses the possibility, under Article 89(2), for Member States to derogate from certain generally applicable provisions in national legislation relating to scientific research (see pages 21-22). Recital 156, which ostensibly concerns national derogations for scientific research, however, includes a reference to the possibility for Member States to derogate from other provisions, not mentioned in Article 89(2). In particular the Recital includes a reference to the possibility for Member States to derogate from 'information requirements…[and the right to] **data portability'**. Should the rights referred to in Recital 159, but not in Article 89(2), be considered as derogable under the same conditions as the rights explicitly listed in Article 89(2)? If not, should these rights still be considered as derogable under another set of conditions? If not, should these rights not be considered derogable at all and the Recital be ignored? The Opinion would provide a good forum for a clarification of these uncertainties.

Secondary Use and Legitimation under Article 6 or 9

The Opinion discusses the concept of **secondary use** and whether, in relation to scientific research, such a secondary use requires a legal ground under Article 6 or 9, or, as outlined by Recital 50, whether such a secondary use requires no supplemental legal ground (see pages 22-23). The Opinion takes the position that a legal ground under Article 6 or 9 is necessary. The position is logical and welcome – it would make little doctrinal sense for all secondary uses which fulfil the criteria laid out in Article 6(4) to be permissible without also requiring a legal ground under Article 6 or 9. The Opinion,

[6] Article 29 Working Party, *Opinion 05/2014 on Anonymisation Techniques* (Policy, 0829/14/EN WP 216, 2014) 8.
[7] Case C-582/14 *Patrick Breyer v Bundesrepublik Deutschland* [2014] ECLI:EU:C:2016:779, paras 46-47.
[8] Thomas Runge, 'Digitalisierung, Datenschutz, Impact: RatSWD debattiert aktuelle EU-Wissenschaftspolitik' (*Informationsdienst Wissenschaft*, 16 July 2018) <https://idw-online.de/de/news699425> accessed 7 February 2020.

however, could go further in justifying its position. Further support for the position is to be found in an analysis of the legislative history concerning the development of the relationship between the legal grounds in Articles 6 and 9 and the concept of secondary use. The Opinion could strengthen its position by considering academic work dealing with this legislative history and highlighting Recital 50 as less definitive and significant than it initially appears.[9]

Article 9(4) and the Need for Specific EU or Member State Law

The Opinion discusses the possibility, outlined by **Article 9(4)**, for Member States to derogate from the provisions of the Regulation in relation to the processing of certain types of sensitive data (see page 17). The Opinion, however, suggests: 'Member States are also able under the GDPR to enact 'further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health' (Article 9(4)). This is therefore a new area and requires adoption of EU or Member State law before the use of special categories of data for research purposes can become fully operational.' Yet, the full text of Article 9(4) begins prior to the section cited in the Opinion and states: 'Member States *may maintain* or introduce further conditions' (emphasis added). This part of the text suggests no new law, as implied by the Opinion, need be adopted in order for Member States or the EU to make use of Article 9(4). It would be useful if the Opinion would address this apparent contradiction.

Article 9(4) and the Scope of Possible Derogations

Continuing with **Article 9(4)**, the Opinion makes no comment as to the scope and range of derogations which may happen under Article 9(4) (see page 17). Article 9(4) states Member States may 'introduce further conditions, *including limitations* (emphasis added)'. The concept of 'limitations' may, however, be understood in different ways. The concept may be understood to refer only to the possibility for Member States to enact supplemental limitations applicable to the processing of the categories of personal data referred to in 9(4). Under this interpretation, the concept implies derogations may only serve to increase protection already available under the GDPR. The concept of 'limitations' may alternatively be understood to refer to further limitations to the provisions laid out in the GDPR. Under this interpretation, Article 9(4) would justify all types of derogation – both increasing and removing protection granted by the GDPR. Given Article 9(4) includes no limitation to the range of GDPR provisions to which it applies, this latter interpretation would cast Article 9(4) as an enormous opening clause indeed. The Opinion would be an ideal forum to offer authoritative guidance as to the correct interpretation.

Member State Exclusion of Consent as a Legitimation in Relation to Public Research

The Opinion, in its section on **consent**, does not discuss the national interpretations of the utility of consent under Article 9(2)(a) which suggest that the Article cannot be used

[9] See, for an extensive discussion of Recital 50: Tobias Herbst, 'Art. 5 Grundsätze für die Verarbeitung personenbezogener Daten' in Jürgen Kühling and Benedikt Buchner (eds.), DatenschutzGrundverordnung/ BDSG (Beck 2018) 228.

to legitimate state supported scientific research – see, for example, the approach adopted by the UK (see pages 18-21).[10] The justification for this approach seems to find its basis in Recital 43 of the GDPR and its reference to the illegitimacy of consent in situations of power imbalance. Recital 43, however clarifies that any consideration of power imbalance and dependence must be taken in relation to 'a specific case'. The Recital thus does not outline a general prohibition on the use of consent under the GDPR by public bodies, or publicly supported entities – or indeed any specific type of entity.[11] That this is the case, and that consent may be relied on by public authorities has support in Article 29 Working Party Guidance on the GDPR.[12] The Opinion would be an ideal place to clarify the inaccuracy of this interpretation of the scope of Article 9(2)(a) and Recital 43.

4. Fundamental Issues

Divergence of Equivalent Principles in the GDPR, in Ethics and in Other Areas of Law

The Opinion refers to the possibility for the requirements of data protection law to diverge from those of generally accepted ethical or legal principles in relation to the same underlying concepts (see page 18). For example, the Opinion suggests that whilst **consent** may be regarded as 'freely given' in relation to a clinical trial according to accepted ethical norms and according to EU Clinical Trials law, this consent would not be regarded as freely given according to data protection law. This raises two clear issues. First, conceptually, would it not make more sense that: concepts in EU data protection law – being omnibus legislation – are, wherever possible, adapted to the elaboration of the same concepts in sector specific ethics or legal instruments?[13] In the case of freely given consent in a clinical trial for example, there seems no reason the concept of consent in data protection law could not be interpreted in line with the ethics and law of clinical trials. Second, practically, how can such dichotomies be adequately explained to research subjects? How can the following clearly be communicated to research subjects: you are in the position to freely decide to enter a clinical trial and risk physical injury even death, you are not, however, in the position to freely decide whether your personal data should be processed?

Consent as a 'Safeguard' Rather than a Legitimation

The Opinion refers to the idea that **consent** may not be required under the GDPR to legitimate processing in scientific research, but may nevertheless be employed as a

[10] NHS Health Research Authority, 'Consent in Research' (*NHS Health Research Authority*, 2017) <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-law-says/consent-research/> accessed 7 February 2020.
[11] See also: Dara Hallinan, 'Broad consent under the GDPR: an optimistic perspective on a bright future' [2020] 16(1) Life Sciences, Society and Policy 1, 5 <https://link.springer.com/article/10.1186/s40504-019-0096-3> accessed 7 February 2020.
[12] Article 29 Working Party, *Guidelines on consent under Regulation 2016/679* (Policy, 17/EN WP259 rev.01, 2017) 6-7.
[13] See, for example, the discussion of the need, in the biobanking context, to adapt the choice of legal ground under the GDPR with existing norms of consent in genomic research: Dara 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?* (VUB Doctoral Thesis, 2018) 386.

safeguard for research subject rights: 'There may be circumstances in which consent is not the most suitable legal basis for data processing, and other lawful grounds under both Articles 6 and 9 GDPR should be considered. However, even where consent is not appropriate as a legal basis under GDPR, informed consent as a human research participant could still serve as an 'appropriate safeguard' of the rights of the data subject' (see page 20). This is a difficult position to understand and requires more elaboration to be justified. Two issues, in particular, require further clarification. First, conceptualising consent as a safeguard of data subject rights seems problematic. Consent is the mechanism giving voice to the underlying right of the individual to informational self-determination.[14] How does giving consent serve as a safeguard in relation to the protection of other rights? Second, if consent is relevant at all, then presumably this is an indication that an individual has the right to informational self-determination. In this case, surely consent should also be chosen as the relevant legitimation under Article 6 or 9 of the GDPR – all other legitimations essentially reflecting the underlying assertion that other interests override the research subject's right to informational self-determination?

Specific Technical and Organisational Safeguards

The Opinion recognises that if Member States derogate from the generally applicable principles of the GDPR based on **technical and organisational safeguards** under Article 89(2) GDPR, then: '[t]he scope of the derogations to the rights to restriction and objection in the field of scientific research should […] remain limited to cases where the integrity of research would be compromised by the exercise of data subject's rights' (see page 21). This argument is welcome. The argument is logically founded on the core goal of the GDPR – the protection of rights and freedoms as outlined in Article 1(2) – in light of Article 8(2) CFEU. However, whilst recognising that selection of technical and organisational measures based on available human and financial resources is not a justification for weakening the protection of rights, the Opinion fails to clarify outline the necessity for sector specific minimum standards. Surely it would be better to recommend the adoption of minimum required standards, for specific fields of research, on top of which case-specific choices could be made? This would reflect the principle of integrity and confidentiality in Article 5(1)(f) GDPR in relation to scientific research, the technical basis of Article 8(2) CFEU and resolve uncertainties regarding when technical standards of data protection have been met.

Transfer of Data to Third States

The Opinion does not touch upon the crucial topic of **scientific data transfer to third states**. Researchers and research institutions are often involved in multi-national research projects requiring the use of non-EU partner databases, data sharing instruments and/or infrastructure. While part of the data sharing problem might be better addressed in future by programmes such as the European Open Science Cloud, researches are currently still confronted with varied research management policies,

[14] The conditions of consent might be regarded as safeguards in relation to this right, but not the right to consent itself – which is the embodiment of the right.

subject-specific sharing solutions and missing information on GDPR compliant sharing opportunities. The Opinion would be a great forum to clarify how multi-national research consortia should best address questions of international scientific data sharing and which legal, technical and practical solutions are most suitable for use in this context.

Scientific Publishing and Data Protection

The Opinion deals only briefly with **scientific publishing** (see page 19). Yet, there are several important issues which remain unconsidered. Two are particularly noteworthy. First, how should the publication of research datasets including personally identifiable information be legitimated: to what degree is consent adequate and under which conditions, and if consent cannot be obtained, what other legal ground may be relevant, and under which conditions? Second, should the publication of research datasets in online repositories be regarded as constituting an international transfer – especially given that, in many cases, international transfers might be clearly foreseen in advance of publication? In this regard, it is noteworthy that previous EDPS Opinions have considered transfers from internationally accessible online databases as international transfers under data protection law.[15] If such publications should be considered as international transfers, which justification under the GDPR might be used to legitimate such transfers? Adequacy cannot be assumed, derogations based on specific safeguards or BCRs are not relevant, consent cannot apply given the specifics of transfers in question are not known in advance. Article 49(1)(d) seems a possibility but to use this Article in this regard would have implications for the general concept of an 'important' public interest elsewhere in the Regulation. The Opinion would be a good forum to offer some clarity in relation to these questions.

Conflation of Research and Oversight in Relation to Platform Data

Later in the Opinion, the issue of researcher access to **platform data** is addressed. The Opinion is to be applauded in its discussion of the problem of platforms restricting access to researchers in relation to important matters of public interest – for example the spread of disinformation (see page 26). However, the Opinion seems to further suggest that research may act as a form of oversight in relation to the legitimacy of the behaviour of platforms. The Opinion further seems to suggest that such research-oversight function might be considered a justification for researchers to be given more extensive access to platform data. It is certainly possible that research into platforms may highlight issues with the – ethical or legal – legitimacy of platform behaviour, or as to other aspects of platforms' role in the causation of social problems. It is, however, problematic to conflate the function of scientific research with that of oversight. The function of scientific research is to expand the boundaries of human knowledge and possibilities. If the goal is to open-up platforms' data to scientific research, then the argument should be made that scientists need access to this data, for scientific purposes under conditions relevant for scientific research. The function of oversight is

[15] European Data Protection Supervisor, *The transfer of personal data to third countries and international organisations by EU institutions and bodies* (Position Paper, 2014)) 6-7.

to check for compliance with accepted legal or ethical norms. If the goal is rather to secure better oversight of platforms, scientific research need not enter the discussion at all.

The Specifics of Genetic Research

The Opinion touches on the specifics of **genetic research** – in particular regarding the fact that information about relatives may also be revealed from a research subject's genome (see page 25). The Opinion, however, could go further and highlight a number of other data protection issues associated with the use of the human genome in research. Three, in particular, come to mind. First, the Opinion could address the fact that information about genetic groups might be extracted from a research subject's genome and that these groups may also claim to have rights in relation to this data.[16] Second, information may be extracted from the research subject's genome the content of which the research subject may not already be aware. This raises issues as to whether the research subject has the right to know or not know and, in some cases whether the researchers may have an obligation not to inform.[17] Third, the Opinion could address the issue of whether the biological sample should be considered as personal data – as suggested by the ECtHR and certain national laws.[18]

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[16] See, for an overview of the discussion around genetic groups: Dara Hallinan and Paul De Hert, 'Genetic Classes and Genetic Categories: Protecting Genetic Groups Through Data Protection Law' in Linnet Taylor, Luciano Floridi and Bart van der Sloot (eds.), *Group Privacy* (Springer 2017) 175.
[17] See, for example, the discussion in: Ruth Chadwick, Mairi Levitt and Darren Shickle (eds.), *The Right to Know and the Right Not to Know: Genetic Privacy and Responsibility* (Cambridge University Press 2014).
[18] See, for an overview of the discussion and for an argument supporting the inclusion of samples as personal data: Dara Hallinan and Paul 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 Brent Mittelstadt and Luciano Floridi (eds.) *The Ethics of Biomedical Big Data* (Springer 2016) 119.