Contribution to the EDPB Public Consultation 1/2026 'Guidelines 1/2026 on processing of personal data for scientific research purposes'

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1. Introduction

The EDPB's Draft Guidelines on processing for scientific research purposes form an important milestone in clarifying how the General Data Protection Regulation (GDPR) operates in a research context. We welcome the Draft Guidelines and the clarifications on many important aspects they are providing. Still, coming from the perspective of researchers actively involved in many cross-disciplinary research projects, we find that the Draft Guidelines could be more clear on some aspects, while other issues we encountered in our research are not yet addressed.

With this contribution to the public consultation, we aim to assist the EDPB in further finetuning the final version of their guidance by listing (i) issues we find in need of clarification; and (ii) open questions that could be addressed. Our comments are focused on four aspects of the Draft Guidelines: (1) aspects concerning the scope of application of the guidelines; (2) questions around the proposed conceptualisation of scientific research; (3) clarifications for the appropriate safeguards in the context of Article 89 GDPR; (4) clarifications regarding the conceptualisation of biometric data in a research context; and (5) remarks on the processing of special categories of personal data for scientific research purposes.

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2. The scope of application of the Guidelines 1/2026

2.1 Archiving in the public interest

Clarification of public interest -- In their Draft Guidelines, the EDPB emphasises the need to distinguish genuine research from pure marketing strategies. While welcoming this necessary clarification, the opportunity to clarify on the values the EU considers to be data processing in the public interest should not be missed. Once the lines along which the EU wishes to stimulate research are clear, data processing for scientific research in the public interest can be safeguarded and stimulated.

Archiving in the public interest -- Article 89 GDPR includes archiving in the public interest as a purpose with almost completely similar rules than scientific research. Moreover, researchers are one of the primary users of archives. It would therefore be opportune to clarify how the Draft Guidelines are relevant from an archival perspective, and whether specific guidelines for processing of personal data for archiving in the public interest are forthcoming.

Use of registries -- The fact that researchers use 'registries' is taken for granted in the Draft Guidelines (see for example para. 8). Therefore, the perspective of these registries, such as research data repositories or archives, should be considered by the EDPB. A strict separation between scientific and archival processing activities under the GDPR, risks to legal uncertainty due to overlap and lacunas.

Request for the EDPB: To understand which research can benefit from the research exemption it would be beneficial to add **more clarifications of what constitutes a 'public interest' for the purposes of Article 89 GDPR**. Moreover, considering the role of archives and data depositories for scientific research, we recommend more clarifications on **how the guidelines are relevant for processing of personal data for archiving in the public interest and what role registries and archives have for personal data processing for research**.

2.2 Interaction with the definition of the Digital Omnibus Proposal

Diverging definitions between the Draft Guidelines and the Digital Omnibus Proposal -- The Draft Guidelines appear to adopt a more stringent approach to the definition of scientific research than the definition proposed in Article 4(38) of the GDPR in the Digital Omnibus Proposal by the European Commission. In the Digital Omnibus Proposal the requirement that scientific research should be conducted autonomously and independently is not included, neither is the requirement that research activities should aim to produce verifiable results that are open to criticism and shared with other parties. Interestingly, the EDPB and the EDPS have called upon the inclusion of these elements in their Joint Opinion on the Digital Omnibus Proposal. Without discussing the issue in detail at this stage, it should already be noted that the inclusion of these two elements as indicators of scientific research raises certain concerns. While these elements may be characteristic of certain forms of academic research, their relevance as determinative criteria for scientific research across all disciplines is questionable. This issue will be examined in greater detail in section 3.

Clarification of applicable definition -- The stricter approach adopted in the Draft Guidelines might be the result of the more flexible application of certain GDPR provisions for processing of personal data in the context of scientific research. From this perspective, the EDPB may have considered it necessary to define scientific research more narrowly. Nevertheless, it is

questionable whether this is the most appropriate way to address such concerns. Moreover, the Digital Omnibus Proposal further seeks to simplify the requirements for scientific research, for example with regard to transparency obligations and the presumption of compatibility for further processing. It is striking that the Draft Guidelines refer to the Digital Omnibus Proposal in the context of these simplified requirements, while they do not engage with the proposed definition of scientific research in the Digital Omnibus Proposal.

Request for the EDPB: Even if the factors for scientific research in the Draft Guidelines are merely indicative, **greater consistency between the Draft Guidelines and the Digital Omnibus Proposal is necessary**. This might require waiting for the final result of the Digital Omnibus legislative process. At present, the relationship between the two instruments remains unclear and creates legal uncertainty. In particular, it is unclear whether the stricter criteria developed in the Draft Guidelines will continue to play a decisive role if the definition of scientific research, as proposed by the European Commission, is adopted.

2.3 Interplay with other acts of the EU's digital rulebook

Interplay with AI and AI Act -- The Draft Guidelines mention 'artificial intelligence' two times throughout the document (once in the executive summary, and once in a minor footnote i.e. fn. 11). Despite such mentions, the guidance does not provide extensive remarks on the relevance of AI is use research, how data protection obligations apply when AI systems process personal data within scientific research contexts, and the interplay between the GDPR and the AI Act in this context. First, adding remarks about the growing use of AI could be helpful, given its increasing integration with other technologies in research. Second, the guidance could benefit from adding possible data protection obligations applicable to AI used in scientific research – e.g. it could be useful to address the case when AI is used for the *further* processing of personal data for scientific research, vis-à-vis the functioning of the principles of data processing as well as the possible chain of actors when AI is used in research. Third, regarding the interplay with the AI Act, it might be relevant to acknowledge that the AI Act also refers to the concept of 'scientific research' and to clarify the extent to which the concept of research within the AI Act differs from the GDPR's concept, from a data protection point of view.

I**nterplay with the European Health Data Space (EHDS) Regulation --** The Draft Guidelines refer to the EHDS Regulation in footnote 111, paragraph 75 and paragraph 112. These references could be expanded, and there could be more elaboration on the interplay between the GDPR and the concept of scientific research of the EHDS Regulation. First, paragraph 75, especially, which clarifies the relevance of EHDS Regulation's Article 53(1)e within Article 9(2) GDPR (derogations laid down in Union or Member States law), could be further expanded with a practical example – as healthcare stakeholders will highly use this reference in the future. Furthermore, in continuity with the previous point raised on AI, it could be relevant considering an example that is AI-relevant (given that Article 53(1)e EHDS Regulation refers to 'training, testing and evaluation of algorithms, including in medical devices, in vitro diagnostic medical devices, AI systems and digital health applications'). Second, about the interplay with the EHDS Regulation, it might be relevant to acknowledge – similarly to the above point on the AI Act – that the EHDS Regulation also refers to the concept of 'scientific research' and to express to what extent such concept differs from the GDPR's one, from a data protection point of view.

Request for the EDPB: To clarify the interplay with the EU's digital rulebook, we recommend, first, to consider **emphasizing the role of AI in scientific research** and its impact on data protection requirements relevant to scientific research (e.g. further processing vis-à-vis principles of data processing and chains of actors within AI;. Moreover, we would find it helpful if the EDPB could **clarify the interplay with the AI Act and the EHDS Regulation** further, for example by adding disambiguation remarks about the concept of scientific research. Finally, we suggest to add **practical examples** on the application of Article 9(2) GDPR for Article 53(1)(e) EHDS Regulation, including (but not limited to) healthcare AI in section 4.4.3 on 'Derogations laid down in Union or MS law'.

3. The definition of scientific research

3.1 Scope of the definition

Narrow understanding of scientific research -- Overall, the Draft Guidelines appear to be narrowly focused on a particular model of research, namely traditional academic research. This is primarily due to the emphasis placed on criteria such as verifiability, publication and independence. With regard to independence, the Draft Guidelines indicate that researchers processing personal data should possess academic qualifications (e.g. a PhD) or scientific qualifications (e.g. proven experience or recognition) in the relevant field of research. With regard to verifiability and publication, the Draft Guidelines emphasize that research should be open to criticism, normally following peer review, and that research results should be shared with other parties. That said the Draft Guidelines acknowledge that access to results may be restricted in order to protect intellectual property rights or trade secrets.

Non-traditional research -- This raises questions as to whether the Draft Guidelines adequately accommodate other forms of research. For example, it is not evident how research conducted by NGOs would satisfy these criteria. A strict interpretation could suggest that NGOs would need to collaborate with universities or similarly recognised research institutions in order to benefit from the scientific research framework, even where they possess the expertise and capacity to conduct research separately.

Commercial research -- Similar concerns arise for commercial companies and start-ups engaged in research and development in fields such as life sciences, artificial intelligence, and other technology sectors. Although the Draft Guidelines expressly acknowledge that also research activities carried out by commercial companies can fall under the definition of scientific research, it is unclear how such actors would satisfy requirements relating to independence, verifiability and publication in practice. A strict interpretation of the Guidelines could therefore create the impression that collaboration with universities or similarly recognised research institutions is necessary in order to qualify as scientific research.

Research outside of the 'hard' sciences -- Furthermore, the Draft Guidelines appear to be focused predominantly on a specific sector, namely the medical and health research sector. There are 25 examples currently provided in the draft guidelines, 10 of which are aimed at clinical trials or otherwise health-related research (namely, examples 1, 7-9, 11, 15, 18, 22, 23, 25). While this is undoubtedly an important topic, it is at the same time heavily regulated (especially as related to clinical trials), and its compliance usually contains less ambiguity than other types of scientific research. Providing as diverse examples of scientific research as possible is of crucial importance for the Draft Guidelines to reach the target audience and make a tangible impact. Reading the whole text of the Draft Guidelines the overall impression is that they were drafted with having medical research in mind; however, in reality, medical research is only a part of the total research performed which constitutes a wide range of topics and actors involved. Therefore, it is very important to provide guidelines which address the needs of a representative variety of researchers.

Request for the EDPB: The Draft Guidelines should provide further **clarification on the application of the concept of scientific research beyond the traditional academic context**. In particular, clarification is recommended regarding the position of NGOs, commercial companies, public-private partnerships, and R&D-driven start-ups. For example, it is currently unclear whether collaboration with universities or similarly recognised research institutions would be

required in order to meet the criteria set out in the Draft Guidelines. Such an interpretation would appear rather restrictive and difficult to reconcile with the recognition that scientific research may also be conducted in other non-academic settings. The Draft Guidelines should also be reviewed and updated where necessary to show that not only is medical research is important but that other types of research can rely on the same rules that the EDPB aims to address with the Draft Guidelines provided.

3.2. Meaning of the individual key indicators

3.2.1 Transparency and verifiability

Publication of research -- The Draft Guidelines specify that research results should be shared with other parties, for example by publication, or that they will be shared in the future, with due regard to legitimate limitations to access such as the protection of intellectual property rights and trade secrets. While we have previously pointed out that the Draft Guidelines appear to be primarily informed by a traditional academic research context, questions arise even within academia as to how this requirement should be applied in practice.

Confidential research outcomes -- Concretely, many research projects funded under programmes such as Horizon Europe include deliverables that are classified as confidential or sensitive and are therefore not fully publicly disseminated (they often can be shared upon request depending on the requesting party). In this regard, it remains unclear what is meant by the requirement that research results should be 'shared with other parties'. It is uncertain whether it is sufficient that results are shared within the consortium or with project partners and fellow researchers, or whether a broader form of external or public accessibility is required. The Draft Guidelines do not provide a clear answer to this question, thereby leaving considerable uncertainty as to the scope of this criterion.

Transparency of research results -- Moreover, it is questionable whether compliance with such broad and general publication criteria would adequately satisfy the requirement of verifiability and transparency. The pertinent question is the extent to which a given publication actually informs the public of a project's wider scope and findings. In EU-funded research, for instance, the publications associated with a project may be numerous yet collectively disclose only a fraction of the research undertaken. Dissemination obligations do not, as a rule, require the communication of a representative cross-section of findings spanning the project's full subject matter. Key Performance Indicators (KPIs) for dissemination are typically defined by the number of publications rather than their scope or content. In practice, a research consortium may produce a substantial volume of publications confined to narrow findings on highly specific aspects of the research. The mere fact that publications have been produced may therefore be insufficient to guarantee the transparency of the research as a whole.

Verifiability of research -- As for verifiability, this factor is framed in exclusively propositional terms: research is verifiable insofar as 'the hypotheses, methods, data and conclusions' are 'open to criticism, normally following peer review', with results shared 'by publication'. This clashes with the GDPR's own recognition, reflected in Recital 159, that scientific research includes 'technological development and demonstration' and applied research, much of which produces not a publishable proposition but tools, software, and other deployable artefacts at high technology readiness levels (TRL). It is unclear how other researchers would replicate the results of a project whose output is a functioning system, particularly in the law-enforcement and

security domains, where intellectual-property, trade-secret, or operational-security constraints frequently limit publication and independent replication.

Transparency as a research accountability tool -- As acknowledged by the EDPS in its Preliminary Opinion cited by the EDPB in fn. 17, transparency is partly a democratic accountability mechanism. The research should 'hold powerful players to account' and the 'data protection obligations should not be misappropriated as a means for powerful players to escape transparency and accountability' (p. 2). For high-TRL security and law-enforcement tools, the trade-secrecy and operational-confidentiality pressures that obstruct replication are precisely the conditions where transparency matters most for accountability. The EDPB Guidelines fail to acknowledge this context, and by admitting exceptions for 'protection of intellectual property and trade secrets', they seem to endorse non-disclosure, without addressing how transparency and verifiability should operate where research produces tools and other non-replicable artefacts rather than knowledge alone.

Request for the EDPB: In this respect, please further **clarify the meaning of 'sharing research results with other parties'**. In doing so, account should be taken of the fact that even in publicly funded research, not all results can be made publicly available. Moreover, we suggest to clarify how verifiability and transparency would apply where the output is a tool rather than a publishable finding, and how to identify the safeguards (independent technical audit, methodological documentation, reproducible evaluation protocols, or oversight by competent bodies) that can satisfy this factor where publication and third-party replication are not feasible. Last but not least, we recommend that due consideration should be given to research conducted by NGOs and commercial companies, as previously highlighted.

3.2.2. Autonomy and independence

Assessing independence and autonomy -- The Draft Guidelines specify that research activities should be conducted autonomously and independently in relation to the prejudices of the scientific community and other external parties, as well as the researchers' own prejudices, in an environment free from undue pressures. In order to achieve this, the Draft Guidelines further specify the profile of researchers by linking independence to the possession of academic qualifications (e.g. a PhD) or scientific qualifications (e.g. proven experience or recognised expertise) in the relevant field of research. In this regard, it remains unclear how these requirements should be interpreted in practice. It is, for example, uncertain whether a PhD should be regarded as a necessary condition, or how concepts such as 'proven experience' or 'recognised expertise' are to be assessed and operationalised. Moreover, it is unclear how researchers with more than one position, e.g. working at a university and a company, should demonstrate their autonomy and independence.

Request for the EDPB: We recommend that the EDPB further **clarifies the meaning of 'academic and scientific qualifications'.** In doing so, due consideration should also be given to research conducted by NGOs and commercial companies, as previously highlighted. Moreover, more **examples of researchers with non-academic affiliations** demonstrating their autonomy and independence would be useful.

3.2.3 Objectives of the research

Clarifying societal interests -- The Draft Guidelines indicate on page 10, that 'research activities are carried out with the aim of contributing to the growth of society's general knowledge and wellbeing'. Given the current state of global affairs, marked by numerous ongoing conflicts and rising military and defence research budgets, the term 'society's general knowledge and wellbeing' cannot be assumed to carry a self-evident meaning. Which society is being referred to: European society, or humanity as a whole? Depending on how this question is answered, certain military or defence projects may fall outside the scope of scientific research. This is not inherently problematic, but it underscores the need to clarify what is meant by 'society's general well-being and knowledge'.

Request for the EDPB: Further **specification of the terms 'society' and 'general knowledge and well-being' is required**. This would be beneficial for several areas of research, not least to clarify potential ambiguities concerning military and defence projects.

3.3 Accountability for the key indicators

Functionality of the key indicators -- Paragraph 11 of the Draft Guidelines ends with the suggestion that if all the listed factors are met, the assessed research activities can be presumed to constitute scientific research. At the same time, the same paragraph suggests that even if not all factors are met, the data controller needs to justify and be able to demonstrate why the activities constitute scientific research and the more factors listed in paragraph 11 are met, the 'more likely' is that activities constitute scientific research. In other words, the EDPB provides a list of key-indicative factors but their importance for the overall scientific research definition is arbitrary. The last paragraph essentially undermines the overall idea of having key-indicators and introduces further ambiguity into the process of determining which activities constitute scientific research. The provided key-indicators now raise the question of – 'why these and not the others' if in any case the controller can be able to justify the existence of research activities. Additionally, there are no clarifications provided on how these other justifications by the data controller could look like or what is the overall importance of the justification – for example, does it have to be formally internally documented before processing data or is it significant only upon the request by the supervisory authority?

Request for the EDPB: We suggest to (1) provide **clear guidance on how controllers should in practice evaluate that they have assessed the performed activity being scientific research** (e.g., can it be an exercise similar to determining the applicable legal basis, does it have to be included in records of processing activities, etc.) in relation to paragraph 11 of the Draft Guidelines, and (2) to **explain in detail on what is the importance of key-indicative factors**, including but not limited to reconsidering – is there a need to have all of the key-indicative factors checked for an activity to constitute scientific research, if not, is there one, two, three, etc. factors that are irreplaceable and must be applied in all cases? Such additional guidance would help controllers to better understand how they should navigate the current checklist provided by the EDPB.

4. Appropriate safeguards for scientific research

Need for clarity for the suggested safeguards -- Paragraph 170 of the Draft Guidelines claims 'that it may be necessary to adopt other types of safeguards beyond anonymisation or pseudonymisation'. The EDPB, therefore, provides a list of additional appropriate safeguards; however, they are vague and without sufficient clarity on how they could improve the protection of the rights of data subjects and (or) how they should be used in practice by data controllers. For example, it is unclear in which cases which specific safeguard could be used – i.e., which specific protection aspect in relation of scientific research related data processing it helps to enhance. Additionally, the used wording of the safeguards is rather repeating the GDPR requirements which in either way apply to controllers (e.g., strict-purpose limitation) or are unclear in the used context and selected wording (for example, enhanced transparency or unconditional right to object). Without sufficiently clear guidance on appropriate safeguards, it is impossible for controllers to apply the unified practice in ensuring the protection of data subject rights in the context of scientific research.

Request for the EDPB: We recommend the EDPB to provide a **list of appropriate safeguards** that would be (1) **grouped according to specific obligations** applicable to data controllers in the context of the GDPR and scientific research (e.g., legal basis, transparency, security of data and others), (2) **provided without ambiguous wording** that would cause additional confusion to the data controllers, and (3) **sufficiently clear on how the adoption of such measures would help to enhance the protection of data subjects** in the context of scientific research.

5. Biometric data research

Consider the specific research risks of biometric data -- Subsection 8.4 of the Draft Guidelines subsumes biometric data within a predominantly genetic data framing. Paragraph 166 disposes of biometric data in a single sentence, and paragraph 167 reasons almost entirely from genetic characteristics (heritability, consanguineal kinship, permanence). The sole CJEU anchor, *Schwarz v Stadt Bochum* (C-291/12, footnote 245), concerns fingerprints in passports, that is, verification in its narrowest sense. The result is that biometric data is addressed mainly to the extent that it resembles genetic data, while the features and exploitations distinctive to biometric processing are left unexamined. These include its function as an instrument of surveillance and tracking; its discriminatory potential, given documented disparities in accuracy across demographic groups; its use to manipulate or to infer affective and other special-category data (e.g., health data, ethnic origin etc. such as via emotion recognition); and the provenance of establishing the public and or private research datasets on which research increasingly relies, including datasets scraped or assembled unlawfully and supplied by private businesses, whose tainted origin the genetic frame does not contemplate.

Request to the EDPB: The EDPB is invited to provide **a dedicated treatment of biometric data in section 8.4**, rather than addressing it by analogy to genetic data. The discussion should capture the features and technologies specific to biometric processing, as set out in the points above, including the surveillance, discrimination, and manipulation risks, and the lawfulness of dataset provenance when biometric training data is sourced from third parties.

6. Special categories of data

Expectations of the data subject in a research context with sensitive data -- The exemption in GDPR's Article 9(2)(e) concerning processing of special categories of data made manifestly public by the data subject includes a hidden assumption: that data subjects who make special categories of data manifestly public should have done so based on a realistic understanding of how their data could be processed once made public. Such an assumption may be accurate for various contexts outside of scientific research, however, scientific research should be understood and interpreted differently. By its nature, scientific research includes novelty. Various activities undertaken in the context scientific research may not be easily imaginable by ordinary citizens. For instance, public personalities speaking about their political opinions or sexual orientation five to ten years ago would not have imagined their sensitive personal data to be scraped to train AI tools, even for scientific research.

Request for the EDPB: The guidelines should be further specified and ideally adopt a **stricter approach for processing special categories of data for scientific research purposes based on the exemption of data being made manifestly public by the data subject**. People who made their sensitive data manifestly public may not be able to easily foresee their data to be processed in the context of novel scientific research activities, as opposed to more regular processing activities.