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Response to the public consultation on Guidelines 1/2026 on processing of personal data for scientific research purposes

Introduction

The Norwegian Institute of Public Health (NIPH) welcomes the opportunity to provide comments on the Guidelines 1/2026 on the Processing of Personal Data for Scientific Research Purposes. We strongly support the EDPB's efforts to enhance legal certainty and to provide practical guidance in the area of scientific research.

The comments below focus on a number of provisions of the Guidelines where additional clarifications or further guidance would be beneficial. We would like to express our appreciation for the extensive and important work undertaken by the EDPB on these Guidelines and look forward to the publication of the final version. As a research institution, the NIPH would be pleased to provide further examples or additional input should the EDPB consider this useful.

The term «scientific research»

«Scientific research» should be considered an autonomous term to be understood uniformly across all EU legislation. The EDPB Guidelines provide a list of key-indicative factors for determining whether processing of personal data is motivated by scientific research purposes. These key-indicative factors do not fully align with criteria used by the Court of Justice of the European Union or the European Court of Human Rights. Hence, the NIPH respectfully suggests aligning the key-indicative factors with relevant jurisprudence, which will also bring it in line with the United Nations Special Rapporteur on the Right to Privacy Recommendation on the protection and use of health-related data (05.12.2019) which is referred to in the EDPB Guidelines in footnotes 11 and 12.

The assessment criteria that can be deduced from jurisprudence for considering whether an activity constitutes scientific research can be grouped into three main categories: (1) the role of the legal entity; (2) the role of those carrying out the activity; and (3) quality standards including scientific methodology and scientific publication.[1]

Regarding the first criterion, the legal entity within which the activity takes place may be relevant, although scientific research is not limited to traditional research institutions. Research may also be conducted by committees and other public or private organisations, and both publicly and privately funded research may fall

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within the concept. As regards the second criterion, not all activities carried out within universities and other research-performing organisations necessarily constitute scientific research, and the distinction between scientific research and other purposes may in some cases be difficult to draw. The third criterion concerns adherence to quality standards, including scientific methodology. Relevant case law indicates that scientific research is generally expected to be sound, serious and independent, while publication in scientific forums may also be a relevant consideration.

It has also been suggested in the legal literature that adherence to research ethical norms may constitute a fourth criterion.[1] The United Nations Special Rapporteur on the Right to Privacy incorporated this advice in the Recommendation on the protection and use of health-related data, where the four assessment criteria mentioned above, alongside the main criteria of the OECD's Frascati Manual, form the definition of 'scientific research'.

Pseudonymisation and anonymisation

The EDPB, in its recent guidance on pseudonymisation, provided a more elaborate definition of pseudonymisation. It could be useful to reflect and recall this definition in the present Guidelines as well, particularly in light of the interpretative uncertainties that have arisen following the SRB judgment.

The term «aggregated» is used three times in the Guidelines, and it appears to be used as a synonym to «anonymous». Aggregation does not necessarily result in anonymous, particularly in datasets with a small number of data subjects, as often the case in rare disease research. Further clarification on this distinction could therefore be beneficial.

More generally, the Guidelines could usefully place greater emphasis on the risk of reidentification of research participants based on the research data itself. As highlighted in the literature[2], modern scientific datasets often contain a large number of variables, which may enable reidentification through linkage with publicly available datasets or through the presence of uniquely identifiable characteristics. Recent research also demonstrates how artificial intelligence can further facilitate such reidentification.

Other appropriate safegards under Article 89

The NIPH would respectfully suggest drawing a clearer distinction between 1) informed consent to research participation and 2) a lawful basis for personal data processing, which can but does not need to be consent. Even where these are combined in one document, they may be understood as separate instruments with separate historical backgrounds and legal bases. The current wording in the EDPB Guidelines on p. 66 relating to consent could give rise to some uncertainty, as could also be the case for the accompanying text in footnote 248. A suitable sentence for the EDPB Guidelines could read "Informed consent to research participation is a research ethics instrument. It is not an instrument for data protection compliance but an additional safeguard where personal data are processed for scientific research purposes"[3]. One may also want to elaborate that informed consent to research participation is core to human dignity and the right to the integrity of the person as enshrined in the Charter of Fundamental Rights of the European Union.

Attribution of responsibility (controller and processor)

[1]Bentzen HB, «In the Name of Scientific Advancement: How to Assess What Constitutes 'Scientific Research' in the GDPR to Protect Data Subjects and Democracy», pp. 341-366

[2]Bentzen in Kloza D et al. «If it ain't broke, don't fix it? Ten improvements for the upcoming tenth anniversary of the General Data Protection Regulation», Computer Law & Security Review 2026, https://doi.org/10.1016/j.clsr.2025.106251

[3] This suggested wording is from Bentzen HB in «If it ain't broke, don't fix it? Ten improvements for the upcoming tenth anniversary of the General Data Protection Regulation» pp. 29.

Section 7 in the Guidelines provides useful guidance for distinguishing between controllers, joint controllers and processors in the context of scientific research involving the processing of personal data.

While roles and responsibilities should in principle be determined prior to the start of processing, this may be less straightforward in long-term research projects that evolve over time. Where new research questions, datasets or participating organisations are introduced under an existing research protocol, the practical distribution of influence and responsibility may shift, making it more difficult to determine whether the new research organization acts as a controller, joint controller or data processor.

While paragraph 142 usefully addresses situations where a new organisation agrees to adhere to an already established research protocol, further clarification regarding the assessment of the role of newly participating organisations in research projects could be of considerable practical value. In particular, the EDPB may wish to further elaborate on the application of Articles 4(7), 26 and 28 GDPR in such scenarios, including, where relevant, the interaction with the provisions on further processing under Article 6(4) GDPR considering the original research ethics approval. An illustrative example from the field of medical and health research could be helpful in this regard.

Newly participating research organisations may, within the scope of an already approved research protocol and agreed data access arrangements with the project owning party, pursue their own research questions insofar as these fall within, or overlap with, the approved protocol framework. These may be based on a sub-project protocol developed solely by the new participant alone or in cooperation with the original project owner. These organisations may also receive independent research funding and exercise independent scientific judgement in relation to their contributions.

In such cases, the processing may be understood differently from the perspective of the participating organisations. Although the newly participating research organisation operates within clear conditions with respect to the processing of personal data, it may also be understood as not processing personal data on behalf of the project-owning organisation.

The interplay between scientific research and use of new technology

The development and use of decision-support tools, such as artificial intelligence, may be of considerable importance for research, by identifying new correlations between, for example, lifestyle and health. This will often require access to all existing data. Such disclosures may challenge the GDPR's data minimisation requirement. Furthermore, the disclosure of extensive datasets may entail a higher risk that data subjects can be re-identified, including using artificial intelligence. The EDPB may wish to consider providing further guidance on these issues, as this would be of significant practical value to users of the Guidelines. Given the increasing use of artificial intelligence and other advanced analytical tools in scientific research, questions relating to data minimisation and re-identification risk are likely to become increasingly relevant in the years ahead.

Yours sincerely,

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