National Research Ethics Committees

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The European Data Protection Board (EDPB)

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Response to EDPB Guidelines 1/2026 on Processing of Personal Data for Scientific Research Purposes

The National Research Ethics Committees (NREC) in Norway is a public body assisting researchers and research institutions in their work with research ethics by developing guidelines, handling cases, making statements, and organising public meetings to promote research ethics in the research system. The committees were founded by the Parliament in 1990, and FEK has been a separate government agency under the Ministry of Education and Research since 2013.

This response is submitted on behalf of the following independent committees:

- The National Committee for Medical and Health Research Ethics (NEM)
- The National Committee for Research Ethics in Science and Technology (NENT)
- The National Committee for Research Ethics in Social Sciences and Humanities (NESH)

In general, NREC supports the initiative from The European Data Protection Board (EDPB) formulating guidelines on the processing of personal data for scientific research purposes. The guidelines clarify many difficult questions related to the interpretation of the General Data Protection Regulation (GDPR) from 2018, and with respect to the broader provisions in the Omnibus simplification package from 2025, it provides a more ethically responsible framework for the processing of personal data for scientific research purposes, restricted to activities that are genuinely scientific.

1. General comments

The EDPB's work provides important clarifications on the processing of personal data for scientific research purposes, including the concept of scientific research, further processing, legal bases for processing, and the rights of data subjects.

The Guidelines represent an important contribution to clarifying how the GDPR should be interpreted in a research context and provide useful guidance on key topics such as broad consent, further processing and long-term storage.

At the same time, the Guidelines appear relatively high-level in certain areas, and further clarification is needed to ensure practical applicability, particularly in complex research settings, including register-based research and the processing of sensitive data.

NREC consider that certain parts of the draft should be further specified to ensure that the regulatory framework both supports research of significant societal importance and safeguards data protection.

Given the scope and complexity of the Guidelines, they are unlikely to be applied directly by researchers. There is therefore a need for their content to be further operationalised and translated into practical guidance at institutional or national level.

Several of the issues highlighted below may have a common underlying cause, namely that the Guidelines primarily provide principled clarifications, but to a lesser extent explain how these should be applied in practice across different research contexts. This highlights the need for more structured and operational guidance.

It should also be mentioned explicitly that legal regulation alone is not sufficient to protect human dignity, personal integrity and respect for privacy. Scientific research presupposes that both researchers and research institutions also take responsibility for safeguarding research ethics and integrity, cf. ERA Action 18 is a European Research Area and ALLEA's European Code of Conduct for Research Integrity.

2. The definition of "scientific research" (Section 2)

The six criteria set out in the Guidelines for determining whether an activity qualifies as "scientific research" are useful, as several GDPR provisions applicable to research depend on such classification. It is appropriate to distinguish scientific research from other forms of analytical, developmental and innovation activities.

At the same time, there is a need to clarify how the proposed criteria relate to established national definitions and assessments of research. In Norway, the Research Ethics Act builds on the OECD definition of research as systematic work aimed at generating new knowledge. The criteria set out in the Guidelines largely align with this understanding, for example by emphasising systematic methodology, knowledge production, transparency and research ethics standards. This is positive and contributes to highlighting the link between data protection, research integrity and research ethics.

However, the criteria appear relatively broad and partially overlapping, and it is unclear how they are to be applied collectively. It is not evident whether all criteria must be fulfilled or how they should be weighted in practice. This makes them difficult to apply, particularly in grey areas where activities combine multiple purposes, such as research, quality assurance and healthcare.

The requirement of "new knowledge" or "original research" may also be difficult to interpret in practice, particularly in fields where research largely builds on, validates or further develops existing knowledge, such as register-based research, method development and applied research. The lack of clarity regarding how such activities should be assessed may lead to divergent practices and legal uncertainty.

It is therefore desirable to clarify that the criteria should function as indicative assessment factors rather than a rigid or exhaustive checklist. It would also be useful to clarify how the criteria should be applied in combination in hybrid research settings.

It is positive that research ethics standards are identified as a key characteristic of scientific research. In Norway, research must be conducted in accordance with recognised ethical standards under the Research Ethics Act, and these are reflected, inter alia, in guidelines developed by the National Research Ethics Committees.

This underlines the importance of research ethics, research integrity and independent ethical review. It should be clarified how national systems for ethical review and research integrity can be taken into account when assessing whether an activity constitutes scientific research.

This is particularly relevant for medical and health research. In Norway, such research is regulated under the Health Research Act and reviewed by the Regional Committees for Medical and Health Research

Ethics (REK). It should therefore be clarified how the proposed criteria interact with established national systems for ethical review and sector-specific legislation, to avoid parallel or conflicting assessments of what constitutes research.

The definition of "scientific research" based on the framework of the World Medical Association (WMA) Declaration of Helsinki has a bias towards biomedicine. While most of these fundamental principles are also relevant for research in other areas, the practical implications might vary, for instance when it comes to the concept of consent, which is *not* necessarily commonplace in all other fields of research, cf. 2.1, point 11, ii.

The reference in note 15 to the document provided by the European Commission, Ethics in Social Science and Humanities (5.7.2021) is also outdated, as this document is currently under revision, cf. the input to this process from the ENRIOs Working Group on Ethics in Social Sciences and Humanities (31.03.2025) which provides more updated perspectives.

In general, since different definitions of "scientific research" has different epistemic and normative implications, it should be explicitly stated that the proposed definition is only relevant within the framework of the GDPR and should not be used uncritically in other contexts.

3. Further processing (Section 3.1.1)

It is positive that further processing for research purposes is, as a general rule, considered compatible with the original purpose, thereby facilitating efficient use of existing data.

At the same time, the Guidelines indicate that the legal basis may not always be relied upon in further processing, particularly where it is based on consent or legal obligation, without clearly explaining how this should be addressed in practice.

This creates challenges, particularly in cases involving consent, where it must be assessed whether further use falls within the scope of the original consent or requires a new legal basis. In practice, consent is often used as an ethical basis, while the GDPR legal basis is often public interest and research purposes. This distinction may create uncertainty for both researchers and participants, particularly with regard to transparency and participants' reasonable expectations concerning further use of their data.

There is therefore a need for clearer assessment criteria for handling legal bases in further processing, including the relationship between the original consent, alternative legal bases and the need to ensure predictability and control for data subjects.

4. Storage beyond the original purpose (Section 3.2)

The Guidelines provide an important clarification by allowing personal data to be stored beyond the duration of the original research project where further research is expected. This is a necessary condition for efficient use of existing data and crucial for scientific quality.

In medical and health research, long-term storage is often essential, for example for studies of long-term effects of treatment and environmental exposure. Research infrastructures such as biobanks, registries and cohort studies are established specifically to enable future research over time and are typically not limited to a single defined project.

At the same time, it remains unclear how concrete and likely future use must be to justify continued storage. In practice, storage is often justified by a broad and forward-looking research potential rather than clearly defined purposes, making the necessity assessment challenging.

There is also a need for clearer guidance on how the necessity requirement should be assessed over time. In practice, the need for storage may change, and it can be difficult to determine when continued storage is no longer necessary. This illustrates a fundamental tension between the need for flexibility in research contexts and the requirements of storage limitation and necessity under the GDPR.

We support the establishment of routines for regular assessment of the need for continued storage and that data should be deleted or anonymised when no longer necessary. However, this requires clearer guidance on how such assessments should be carried out and documented in practice.

There is also a need for clearer guidance on how necessity assessments should be balanced against participants' reasonable expectations, particularly where data are stored for long periods for future and partly unspecified use.

5. Pseudonymisation and research on health data (Section 8.3)

We support the recommendation to use anonymisation or, where this is not possible, pseudonymisation as measures to protect personal data in research projects. At the same time, the Guidelines should more clearly acknowledge that full anonymisation is often not compatible with the purposes of many health research projects.

In practice, research activities such as record linkage, longitudinal follow-up and validation of research results often require that data can be linked to the same individual. This means that pseudonymised solutions are in many cases necessary to carry out research in a scientifically sound manner.

It may also be difficult to determine whether data are truly anonymised in cases involving biological data and complex datasets, such as health data. Such data may contain information that enables re-identification, thereby limiting the possibility of achieving genuine anonymisation.

This also means that assessing whether data are in fact anonymised can be challenging. Where there is a risk of re-identification, the data should still be considered personal data, with the associated rights and obligations, including requirements relating to transparency.

We therefore recommend that the Guidelines more clearly highlight pseudonymisation as a central and, in many cases, necessary safeguard in medical and health research, and clarify how such measures may form part of the "appropriate safeguards" required under the GDPR.

6. Broad and dynamic consent (Section 4.1.2)

The Guidelines' interpretation of freely given and informed consent in a research context is consistent with established requirements, and it is positive that they address key issues relating to the specificity requirement, dynamic consent and the use of broad consent where research purposes are not fully known at the time of data collection.

This is particularly relevant for medical and health research, where biobanks, cohort studies and longitudinal research projects are often established to facilitate future research over time. In such contexts, broad consent may be linked to a defined area of research, such as cancer research, without specifying individual projects in advance.

At the same time, it remains unclear how the requirement to define a "research area" should be interpreted in practice, and where the threshold lies for sufficient specificity. This creates challenges when assessing whether subsequent uses fall within the scope of the original consent and may lead to inconsistent practices.

Dynamic consent is presented as a potential solution to enhance flexibility and participant control, but there is limited guidance on the conditions necessary for such approaches to function in practice.

The Guidelines could therefore more clearly set out relevant assessment criteria relating to the use of broad and dynamic consent, including how research areas should be defined, how further use should be assessed, and how participants' expectations can be safeguarded over time.

We also recommend clarifying that broad consent, combined with ethical approval, ongoing information to participants and appropriate organisational measures, may constitute a solution consistent with Recital 33 of the GDPR.

7. The distinction between consent as a legal basis and consent to participate in research (Section 4.1.3)

The Guidelines clarify an important distinction between consent as a legal basis under the GDPR and consent to participate in research under ethical and national frameworks. This is a useful clarification, as these forms of consent are often conflated in practice.

However, the Guidelines provide limited support on how this distinction should be understood and addressed in practice. While the distinction is legally clear, research participants are likely to perceive consent as a single decision to participate, without distinguishing between its different functions.

This may lead to uncertainty regarding participants' rights and expectations, particularly in relation to further use of data and the level of control retained by individuals.

The Guidelines could therefore more clearly address how information about consent can be presented in a way that supports genuine understanding, without obscuring the distinction between its legal and ethical roles.

Such clarification would contribute to greater transparency, better alignment with participants' expectations and increased trust in research.

8. Use of personal data from social media (Section 4.4.2)

The Guidelines allow the use of data that are "manifestly made public", which is a necessary adaptation to digital data sources.

However, it remains unclear how this criterion should be applied in practice. On social media, technical accessibility does not necessarily correspond to what users can reasonably expect regarding further use in a research context.

There is therefore a need for clearer assessment criteria, including factors such as context, privacy settings, the nature of the data and user expectations.

Given the high threshold for relying on this exemption, scientific research on social media could rather be based on the exemption for "scientific research" in GDPR Article 9(2)(j), which also has references to necessary safeguards according to GDPR Article 89(1) and other fundamental freedoms and rights.

9. Legitimate interest (Section 4.3)

The guidelines suggest that "legitimate interest" could be used as a legal basis for scientific research, cf. GDPR Article 6(1)(f), provided that a balancing test is applied in relation to the data subjects' interests or fundamental rights or freedoms. This qualitative assessment of the reasonable expectations of the data subjects might not provide sufficient protection according to recognised principles of ethical and

responsible research. Thus, the controller should consider using either “consent” or “public interest” as a legal basis, cf. GDPR Article 6(1)(a or e), to foster trust in scientific research in general.

10. Exemptions from the obligation to provide information (Section 5.4.2)

The Guidelines allow for exemptions from the obligation to provide information in research contexts, for example where informing data subjects would involve disproportionate effort or would seriously impair research objectives. This is a necessary adaptation for large-scale research and secondary data use.

At the same time, the guidance is relatively high-level and provides limited support for how such assessments should be carried out in practice. This is particularly the case for the concept of “disproportionate effort” and the factors that should be taken into account.

This lack of clarity may lead to divergent practices and makes it difficult to ensure consistent and accountable decision-making.

It is also important to highlight the tension between the legal possibility to rely on such exemptions and ethical principles of transparency and respect for participants. Even where exemptions are legally justified, they may affect participants’ understanding, trust and sense of control.

There is therefore a need for clearer guidance on relevant assessment criteria and on how transparency can be safeguarded where direct information is not provided.

11. Risk assessment and DPIA (Section 8.2)

The Guidelines clarify that risk assessments in research contexts should include broader impacts, including effects on third parties such as family members. This provides a more holistic understanding of potential consequences and is particularly relevant where data may have implications beyond the individual participant.

At the same time, it remains unclear how the requirement for a DPIA should be assessed in practice in research settings. In many cases, risks are more closely related to the nature, scope, duration and purpose of the data rather than the technical systems used.

This makes it difficult to apply existing thresholds for “high risk” and may result in inconsistent practices across institutions.

There is therefore a need for clearer guidance on how research-specific risk factors should be assessed, including factors such as data volume, sensitivity, long-term storage and the breadth of research purposes.

It would also be useful to clarify how impacts on third parties and broader societal consequences should be assessed and managed in a structured and accountable manner.

12. The role of research ethics and national regulatory frameworks (Section 8.5)

The Guidelines emphasise research ethics as an important indicator that an activity qualifies as scientific research. This is especially relevant for medical and health research, which operates within a comprehensive regulatory framework extending beyond the GDPR. In Norway, such research is governed by international ethical principles such as the Declaration of Helsinki, along with national legislation including the Research Ethics Act, the Health Research Act, the Biobank Act and the Health Register Act. These frameworks require assessments of scientific quality, societal benefit, necessity, proportionality and ethical acceptability before personal data may be processed. For Norwegian institutions, approval by ethics committees, regulation of health registries and governance of

biobanks constitute key mechanisms for safeguarding participants' rights and interests. We therefore recommend that the EDPB more clearly recognise *national* ethical approval systems as examples of "appropriate safeguards" under Article 89(1) GDPR.

More generally, given that researchers must comply with both the GDPR and sector-specific regulations, clearer references to how *national* frameworks may serve as safeguards would be beneficial. In Norway, research ethics in non-medical research is fostered through adherence to ethical guidelines provided by the national committees. The responsibility, however, is delegated to the researchers and the research institutions in accordance with the general framework of the Research Ethics Act. Consequently, the fact that adherence to ethical rules, including approval, assessment or advice provided by ethical committees or boards, varies across different fields of science and between countries should be more pronounced and systematically reflected in the guidelines.

It should also be clarified how ethical and data protection assessments relate to each other in practice and how they collectively contribute to the required safeguards.

13. Artificial intelligence and data-driven health research

The Guidelines refer to new technologies and artificial intelligence but provide limited practical guidance on the use of personal data in AI-based research.

We recommend that the final version include more concrete examples and clarifications relating to the use of personal data in data-driven research methods, including machine learning on health data and the development of clinical decision-support systems.

14. Conclusion

The Guidelines represent an important contribution to clarifying the application of the GDPR in a research context. At the same time, there is a need for further clarification of several key assessments.

To ensure more consistent and predictable practices, we recommend that the Guidelines more clearly specify relevant assessment criteria and how these should be applied in practice.

Yours sincerely

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