EDPB Guidelines 1/2026 on the processing of personal data for scientific research purposes

The European Data Protection Board's (EDPB) guidelines on the processing of personal data in scientific research provide an important and timely clarification of the application of the GDPR in research activities. The objective is to clarify how personal data may be used in scientific research while ensuring that the rights of data subjects remain protected. Overall, the guidelines appear supportive of research. They recognize scientific research as a key objective of the European Union and acknowledge the important role of personal data, particularly in medical research, the development of new technologies, register-based research, and large-scale research infrastructures. At the same time, the guidelines recognize that technological development also increases risks to privacy and the protection of personal data. However, the guidelines would benefit from greater clarity regarding the extent to which licensing authorities and data holders are expected to assess the scientific nature of research projects. Such assessments should focus on whether research is conducted in an appropriately organized and ethical manner rather than on evaluating its scientific novelty or societal significance.

Requested revisions to the Guidelines

We respectfully suggest that the EDPB revise the Guidelines in the following ways:

- **Clarify that data protection authorities, data holders and licensing bodies should not conduct a substantive scientific peer review of research projects.** Their assessment should focus on whether the research is appropriately organised, documented, ethically conducted and subject to suitable safeguards, rather than on the scientific novelty or societal value of the project.
- **Provide clearer criteria for identifying scientific research by considering established research institutions, recognised academic qualifications and existing governance structures.** Research conducted by qualified researchers within legally recognised universities, public research institutes or comparable non-commercial research organisations should normally be presumed to fall within the scope of scientific research, provided that appropriate ethical and data protection safeguards are in place.
- **Clarify how criteria 5 and 6 should be applied in practice.** The assessment of whether research advances societal knowledge or generates new scientific knowledge should primarily remain with the research community, ethics committees, funders and peer-review processes, not with data access authorities or data holders.
- **Provide concrete examples of acceptable broad consent in longitudinal, register-based and multidisciplinary research.** The Guidelines should make clear that a “field of research” may be defined flexibly enough to allow future research questions, register linkages and interdisciplinary use, where these remain within the scope reasonably communicated to participants.

- **Define clearer roles and minimum standards for safeguards and secure research environments.** This would reduce duplicative assessments, improve consistency between Member States and facilitate responsible cross-border research using sensitive or register-based data.

Definition of scientific research

The guidelines seek to clarify the concept of scientific research and identify six assessment criteria:

1) systematic and methodological conduct of research
2) compliance with ethical standards
3) verifiability and transparency
4) independence and autonomy of the research
5) an objective aimed at advancing societal knowledge and well-being
6) the potential to generate new scientific knowledge or apply existing knowledge in novel ways.

It is reasonable that research is not required to meet all of these criteria perfectly, as the assessment is intended to be based on an overall evaluation. However, this holistic approach inevitably leaves considerable room for interpretation in practice. In particular, criteria 5 and 6 raise concerns from the perspective of research implementation. The objective of advancing societal knowledge and well-being, as well as the potential to generate new scientific knowledge or apply existing knowledge in novel ways, are inherently subjective assessments. Evaluating these criteria often requires expertise in the relevant field of research, methodological knowledge, and an understanding of how scientific novelty and societal relevance are determined across different disciplines.

In practice, these issues are already assessed at several stages of a research project. The societal relevance, scientific novelty, and methodological quality of research are often evaluated when research funding is awarded, during ethical reviews, through peer reviews, and during publishing of research results. For this reason, it would be important to clarify the extent to which an additional assessment of the scientific nature of research should be conducted in the context of data protection or data access decisions, and who would be responsible for carrying out such an assessment in practice.

The situation may become particularly problematic with data access requests or authorization procedures. If licensing authorities or data holders retain discretion to assess whether a research project sufficiently satisfies criteria 5 and 6, there is a risk that authorities responsible primarily for data protection or data governance may be required to evaluate the scientific substance of research itself. Such evaluations may fall outside their area of expertise. Furthermore, assessing societal benefit and scientific novelty can be difficult without in-depth knowledge of the relevant discipline. This type of discretionary authority may increase uncertainty, slow down research processes, and lead to differences in interpretation between authorities or member states.

Moreover, it is important to ensure that these criteria do not increase inequality between different research projects. If indicators such as previously obtained research funding are used as evidence of scientific legitimacy, there is a risk that externally funded projects will automatically appear more legitimate than those conducted through the core funding of universities, research institutes, or other public research organizations. Such an approach could restrict or complicate research carried out without dedicated project funding. This outcome would be problematic, as a substantial share of scientifically and socially valuable research is conducted without specific external funding.

The guidelines should therefore be clarified to ensure that assessments of scientific legitimacy do not become a new review stage in the context of data access or data protection authorizations. The assessment should focus primarily on whether the activity constitutes appropriately organized, documented, and ethically conducted research, rather than on whether a licensing authority considers the scientific novelty or societal significance of the research to be sufficient. The evaluation of scientific quality, novelty, and societal relevance should remain primarily the responsibility of the research community, peer reviews, research funders, and ethics committees. For this reason, it would be useful for the guidelines to provide concrete examples of how criteria 5 and 6 should be applied in different research contexts.

The Guidelines should make more explicit use of existing institutional markers of scientific research. Legally recognised universities, public research institutes, established research organisations and doctoral training already provide structures for assessing scientific research from other forms of data use. Where research is conducted under the responsibility of qualified researchers within such institutions, and where appropriate ethical, methodological and data protection safeguards are in place, this should create a strong presumption that the activity qualifies as scientific research. This would not remove the need to assess GDPR compliance or data subject rights, but it would reduce the risk that data protection authorities, licensing bodies or data holders are required to evaluate the scientific merit, novelty or societal value of the project.

Reuse of personal data in research

The guidelines also address the further use of personal data. In accordance with the GDPR, the further processing of personal data for scientific research purposes is generally presumed to be compatible with the original purpose for which the data was collected. Researchers are therefore not required to conduct a separate compatibility assessment when personal data are subsequently used for scientific research purposes. The lawfulness of data-processing must still be assessed, but in most cases the same legal basis that applied to the original processing may also be used for the subsequent research use.

This is one of the most significant and research-positive clarifications contained in the guidelines. It is particularly important for long-term research, where datasets may be needed to address new research questions years or even decades after their original collection. The guidelines also facilitate longer retention periods for personal data intended

for research purposes, provided that future research uses are reasonably foreseeable and appropriate safeguards are in place.

This approach is highly welcome because the accumulation of knowledge is a fundamental principle of scientific research. Current interpretations and applications of the GDPR can, in some instances, lead to situations where the further use or long-term retention of research data is restricted in ways that do not optimally support the accumulation of scientific knowledge, the re-evaluation of previous findings, or the development of new research questions. From this perspective, the guidelines make an important contribution to strengthening the conditions for the responsible reuse of research data.

Broad and dynamic consent

The guidelines also address situations in which the precise purposes of research are not yet known at the time data is collected. In such cases, researchers may rely on so-called broad consent, whereby data subjects consent to the use of their personal data in a broader manner within a research field.

This is a highly positive development from the perspective of research. A clearer acceptance of broad consent could facilitate research designs that combine multiple sources of data, such as survey responses and register data. In practice, data linkage may currently be difficult if researchers cannot specify all potential registers or data sources at the time survey data is collected. In many cases, however, research participants have been informed more generally that their data may be linked with administrative records for scientific research purposes. The guidelines should support a predictable and legally sound interpretation of such situations.

The guidelines also highlight the possibility of using dynamic consent, under which research participants are asked to provide consent separately for new phases of research or additional projects. It is appropriate that the guidelines permit a combination of broad and dynamic consent. At the same time, it is important to recognize that dynamic consent is not a practical or methodologically neutral solution in every research setting. Its implementation may significantly increase the administrative burden associated with research and may also place a burden on participants through repeated consent requests. Furthermore, in longitudinal studies, repeated requests for consent may contribute to selective attrition and thereby reduce the representativeness of research data.

For this reason, it would be beneficial to clarify the circumstances in which dynamic consent is considered necessary. One reasonable starting point would be to require dynamic consent particularly when a new phase of research, a new data linkage, or a new purpose of use differs substantially from what participants were informed about during the original consent and information process. By contrast, where subsequent use remains clearly within the same field of research, within the scope of the original information provided, and subject to appropriate safeguards, broad consent should generally be considered sufficient.

The guidelines rightly emphasize that consent cannot be entirely open-ended or undefined. Research fields and purposes of use must be specified with sufficient clarity. However, it is equally important to ensure that these requirements do not become excessively restrictive in light of the nature of scientific research. New research questions emerging from long-term research, data linkages and relevant data sources cannot always be precisely anticipated at the time of data collection. The guidelines should therefore provide more concrete examples of what constitutes a sufficiently specific, yet sufficiently flexible, definition of research fields and purposes of use.

Data subject rights in research

The guidelines further clarify the rights of data subjects in the research context. As a general rule, data subjects have the right to request the erasure of their personal data. However, exceptions may apply where erasure would seriously impair the achieving research objectives or undermine the reliability of research results. Similarly, the right to object to processing may be restricted where research is carried out in the public interest or pursuant to a statutory task assigned to a public authority.

This clarification is particularly important for scientific research as it clearly distinguishes research from activities such as marketing or commercial profiling. In research, the purpose of processing personal data is not to influence specific individuals but to generate broader scientific knowledge. It is therefore appropriate that the application of data subject rights takes into account the specific nature of research, the reliability of research datasets, and the reproducibility of scientific findings.

Safeguards and secure research environments

The processing of personal data for research purposes requires appropriate safeguards. As a general principle, research should rely on anonymized or pseudonymized data whenever the objectives of the research allow for it. Deviations from this principle should therefore be sufficiently justified.

Key safeguards include:

- secure processing environments
- ethical oversight
- pseudonymization and anonymization of data
- safeguards relating to the publication of research findings
- privacy-enhancing technologies (PETs), such as homomorphic encryption and synthetic data.

This emphasis is justified and aligns closely with the needs of register-based research and research involving sensitive personal data. At the same time, the guidelines leave several practical questions unanswered. First, it would be important to clarify who is responsible for assessing the adequacy of safeguards in practice and according to what criteria such assessments should be conducted. Responsibility may lie with research organizations,

data holders, ethics committees, data protection officers, or licensing authorities, but the roles of these actors are not always clearly defined. Unclear allocation of responsibilities may increase administrative burdens and result in the same safeguards being evaluated multiple times according to different standards.

Second, the safeguards relating to the publication of research findings require further clarification. It is clear that publication practices should prevent the identification of individuals through small subgroups, rare events, or combinations of background characteristics. Simultaneously, it is important to recognize the growing importance of open science principles and the FAIR principles, which seek to enhance the findability, accessibility, interoperability, and reusability of research data, methods, and results. The guidelines would therefore benefit from a more explicit discussion of how data protection requirements, safeguards for research results, and principles of open science can be reconciled in practice.

Key Policy Implications

The guidelines suggest that the European Union is moving toward a framework that supports more flexible use of research data. Key themes include:

- facilitating the reuse of personal data for scientific research
- expanding opportunities to utilize broad consent models
- emphasizing the importance of secure research environments
- recognizing the societal value of scientific research in GDPR interpretation
- supporting the development of research infrastructures and research registers.

Overall, the guidelines indicate a clear objective of balancing data protection with research competitiveness, enabling the full potential of scientific research to be realized while safeguarding fundamental rights.

Additional Observations on the Guidelines

The guidelines recognize research infrastructures and research registers as essential components of the research ecosystem. This is an important and welcome starting point, particularly for register-based, longitudinal, and population-level research. However, the guidelines provide only limited guidance regarding actual authorization and data access procedures. Clarifying GDPR interpretation alone may therefore be insufficient if national authorization processes, data access procedures, and data governance frameworks remain fragmented, slow, and inconsistent. From the perspective of practical research implementation, these processes often constitute the most significant bottlenecks.

The guidelines place considerable emphasis on data security. While this emphasis is justified, important practical questions remain unanswered. In particular, it is unclear what should be considered a sufficiently secure research environment and how secure environments across different countries can be assessed according to comparable standards. To facilitate European research collaboration, it may be beneficial to consider

common minimum standards for secure research environments. Such standards could strengthen trust in the responsible use of data, reduce duplicative assessments, and facilitate cross-border register-based and population-level research.

Broad consent represents an important and research-positive approach. Based on the guidelines, it appears particularly well suited to longitudinal research, arguably more so than many previous and more restrictive interpretations of the GDPR. In longitudinal studies, future research questions often cannot be specified precisely at the time data is collected, yet subsequent use of the data is essential for the accumulation of scientific knowledge, the development of new research questions, and producing socially valuable insights.

A key question concerns how narrowly or broadly the concept of a “field of research” should be defined in the context of broad consent. A too narrow interpretation may create obstacles for new projects that require the combining of multiple disciplines. Research questions situated at the intersection of medicine, demography, social sciences, and economics, for example, may be both scientifically and socially significant, yet may not fit neatly within a single predefined research field. For this reason, the guidelines should explicitly clarify that the concept of a research field may be interpreted with sufficient flexibility, particularly in multidisciplinary research environments and projects.

Taken as a whole, the guidelines appear supportive of research. However, they may not necessarily reduce the administrative burden associated with research activities. Assessment obligations, documentation requirements, and risk assessments remain substantial and may in some cases even increase. A particular risk arises if authorities or data holders begin to scrutinize more closely whether a project qualifies as “scientific research” under the guidelines. In such a scenario, assessments of data protection compliance and data governance could be accompanied by a new layer of substantive evaluation of the scientific content of research itself. This could slow down research projects, increase uncertainty, and create additional barriers to conducting scientific research.