UCD School of Medicine Response to the European Data Protection Board Public Consultation on Guidelines 1/2026 on Processing of Personal Data for Scientific Research Purposes

Introduction

The UCD School of Medicine welcomes the opportunity to contribute to the European Data Protection Board (EDPB) public consultation on Guidelines 1/2026 on the processing of personal data for scientific research purposes.

UCD School of Medicine is a leading academic clinical and translational research centre supporting investigator-led clinical research, clinical trials, translational research, and collaborative studies involving healthcare providers, universities, public bodies, industry partners and patient communities. As a centre operating at the intersection of research, healthcare delivery, ethics, and regulatory compliance, we strongly support efforts to provide greater clarity regarding the application of the General Data Protection Regulation (GDPR) to scientific research.

We welcome the EDPB's recognition of the importance of scientific research as a societal good and its commitment to providing a practical framework that enables responsible research while safeguarding the rights and freedoms of data subjects. In particular, we welcome the Guidelines' acknowledgement of the public value of scientific research, the recognition of broad consent, the confirmation of the presumption of compatibility for further processing for scientific research purposes, and the recognition that both public-interest and legitimate-interest legal bases may support research activities.

Our comments focus on areas where additional clarification would assist researchers, research institutions, ethics committees, sponsors and data protection professionals in applying the GDPR consistently across the European Research Area.

1. Broad Consent and Future Research Uses

We welcome the Guidelines' recognition that broad consent may be appropriate where future research purposes cannot be fully specified at the time personal data are collected.

This approach reflects the practical realities of many forms of health research, including biobanking, longitudinal cohort studies, rare disease research, precision medicine initiatives and research infrastructures designed to support multiple future studies. The ability to collect data and biological samples for future ethically governed research is essential to maximising the societal value of research participation and avoiding unnecessary duplication of data collection activities.

We recommend that the final Guidelines include additional practical examples illustrating the use of broad consent in:

- Biobanks and genomic research programmes;

- Longitudinal population cohorts;
- Secondary use of clinical trial data;
- Research infrastructures supporting multiple future projects; and
- Cross-border collaborative research initiatives.

Greater practical guidance would support harmonised implementation across Member States and reduce uncertainty for researchers and ethics committees.

2. Distinguishing GDPR Consent from Research Participation Consent

The Guidelines appropriately recognise the distinction between consent as a legal basis under the GDPR and informed consent to participate in research required under ethical and regulatory frameworks.

In practice, confusion between these concepts remains widespread, particularly in clinical research settings. Researchers, ethics committees and participants often assume that informed consent to participate in research necessarily constitutes the GDPR legal basis for processing personal data, despite the availability of alternative legal bases such as public interest or legitimate interests.

We recommend that the final Guidelines further emphasise that:

- Ethical consent and GDPR consent serve different purposes;
- Research participation consent should not automatically be equated with GDPR consent;
- The choice of GDPR legal basis should be determined separately from ethical requirements; and
- The use of public-interest or other legal bases does not diminish the importance of obtaining informed consent to participate in research.

Additional examples from clinical trials and health research would be particularly helpful.

3. Recognition of Public Interest and Legitimate Interests as Legal Bases

The UCD School of Medicine welcomes the Guidelines' acknowledgement that scientific research may constitute a legitimate interest and that public-interest legal bases may be available to both public and private organisations engaged in research.

This clarification reflects the increasingly collaborative nature of modern health research, where universities, healthcare providers, charities, public authorities and commercial partners frequently work together to address significant societal challenges.

We encourage the EDPB to provide further practical examples illustrating the use of Articles 6(1)(e) and 6(1)(f) in research settings, particularly in:

- Investigator-led research;
- Public-private partnerships;
- Research infrastructures;
- Secondary use of healthcare data; and

- Collaborative European research programmes.

Such examples would promote consistency across Member States.

4. Application of the Six Key-Indicative Factors for Scientific Research

The proposed six-factor framework for determining whether processing is undertaken for scientific research purposes is a valuable contribution and provides useful guidance for controllers.

However, we are concerned that these factors may inadvertently be interpreted as cumulative requirements rather than indicative criteria. Scientific research frequently involves exploratory, pilot, feasibility or methodological work that may not satisfy all factors at the outset of a project.

For example:

- Early-stage exploratory studies may not yet have clearly defined hypotheses;
- Methodology-development projects may focus on validating new approaches rather than generating immediate knowledge outputs;
- Patient-led and community-based research initiatives may operate outside traditional academic structures;
- Emerging interdisciplinary fields may not yet have established publication pathways or review mechanisms.

We therefore recommend that the final Guidelines clearly emphasise that the six factors are indicative rather than mandatory criteria and that genuine scientific research should not be excluded solely because one or more factors are not fully developed at an early stage.

We would also welcome confirmation that the framework accommodates the enabling and methodological activities on which modern research increasingly depends, such as the construction and operation of research data infrastructures, the curation, mapping and harmonisation of data to common standards and ontologies, and the development of data-analytical tooling and methods. Such activities may be essential to scientific research even where they are not themselves hypothesis-driven and may not on their own yield peer-reviewed outputs.

5. Trusted Research Environments and Privacy-Enhancing Technologies

The Guidelines appropriately recognise secure processing environments, pseudonymisation and privacy-enhancing technologies as important safeguards under Article 89 GDPR.

The UCD School of Medicine strongly supports this approach. Increasingly, health research relies on trusted research environments, secure data access platforms, federated analysis models, synthetic data approaches and other privacy-enhancing technologies that enable valuable research while minimising privacy risks.

We recommend that the final Guidelines provide additional discussion and examples of:

- Trusted Research Environments (TREs);
- Secure Data Environments (SDEs);

- Federated learning and federated analytics;
- Privacy-enhancing technologies;
- Data safe havens; and
- Controlled access research infrastructures.

Explicit recognition of these approaches as examples of good practice would encourage innovation while maintaining robust protections for data subjects.

6. Transparency in Long-Term and Secondary Research Uses

We support the emphasis placed on transparency and participant information throughout the research lifecycle.

However, many research projects continue over extended periods and involve secondary uses of data that may not have been fully specified at the time of original collection. In some cases, participants may no longer be contactable, while in others data may be held within established research infrastructures supporting multiple approved studies.

We therefore encourage the EDPB to provide additional guidance regarding proportionate approaches to transparency in long-term research, including circumstances where:

- Individual re-contact is impracticable;
- Research extends over many years;
- Data are reused within established governance frameworks;
- Research is conducted through national or European research infrastructures; or
- Participants have access to ongoing information through websites, participant portals or transparency registers.

Greater clarity regarding acceptable transparency mechanisms would assist institutions in meeting GDPR obligations while maintaining the feasibility of valuable research.

7. Application of Data Subject Rights in Clinical Research

The discussion of the right to erasure and right to object is welcomed. However, further practical guidance would be beneficial for regulated health research.

Clinical trials and other regulated studies are subject to legal and scientific obligations relating to data integrity, audit trails, pharmacovigilance, safety reporting and Good Clinical Practice (GCP) requirements. In such contexts, deletion of data may compromise participant safety, scientific validity or regulatory compliance.

We recommend that the final Guidelines include additional examples addressing:

- Clinical trials conducted under the Clinical Trials Regulation;
- Pharmacovigilance activities;
- Research involving long-term follow-up;
- Safety reporting obligations; and
- Regulatory record retention requirements.

Such examples would provide greater certainty for both researchers and participants.

8. Secondary Use of Health Data and the Presumption of Compatibility

The UCD School of Medicine strongly welcomes the Guidelines' confirmation that further processing for scientific research purposes benefits from the GDPR presumption of compatibility.

This clarification is particularly important in health research, where valuable public-interest research often depends on the responsible secondary use of healthcare, registry and clinical trial data.

We encourage the EDPB to further develop this section through practical examples involving:

- Secondary use of electronic health records;
- Disease registries;
- Clinical trial datasets;
- Biobank-linked health data; and
- Population health research.

Clear guidance in these areas would support responsible data reuse while maintaining robust safeguards and public trust.

9. International and Cross-Border Research Collaboration

Scientific research increasingly depends on collaboration across institutions, sectors and national boundaries. European research programmes, multinational clinical trials and international research consortia rely upon appropriate mechanisms for sharing and analysing personal data across jurisdictions.

UCD School of Medicine encourages the EDPB to provide additional clarification regarding the application of the Guidelines in cross-border collaborative research settings, including:

- Academic collaborations;
- Public-private partnerships;
- European research infrastructures;
- International research consortia; and
- Multinational clinical studies.

Such clarification would support the objectives of the European Research Area while maintaining high standards of data protection.

Conclusion

The UCD School of Medicine welcomes the publication of Guidelines 1/2026 and supports the EDPB's efforts to provide greater legal certainty regarding the processing of personal data for scientific research purposes.

Overall, the Guidelines represent a positive and balanced approach that recognises both the fundamental importance of data protection and the significant societal value of scientific research. We particularly welcome the recognition of broad consent, the presumption of compatibility for scientific research purposes, the role of legitimate interests and public interest legal bases, and the emphasis on proportionate safeguards.

We encourage the EDPB to build on these strengths by providing additional practical guidance relating to health research, clinical trials, biobanking, trusted research environments, long-term studies, secondary use of health data and international collaboration.

A harmonised and research-enabling interpretation of the GDPR is essential to maintaining Europe's leadership in scientific research while preserving public trust and protecting the rights of research participants.