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

Submitted by

João Miguel Alves Ferreira
[1]Institute of Pharmacology and Experimental Therapeutics & [2]Coimbra Institute for Clinical and Biomedical Research (iCBR), Faculty of Medicine, Univ Coimbra, Coimbra, Portugal; [3]Center for Innovative Biomedicine and Biotechnology (CIBB), Univ Coimbra, Coimbra, Portugal;

June 2026

General Comments

The adoption of Guidelines 1/2026 represents a significant and timely contribution to the interpretation of the GDPR in the context of scientific research.

The document provides important clarification regarding the notion of scientific research, the application of Article 5(1)(b) GDPR, the use of broad consent, the role of legitimate interests, research infrastructures, and the implementation of safeguards under Article 89 GDPR.

The effort to provide a coherent and harmonised interpretation across Member States is particularly welcome and should contribute positively to legal certainty within the European Research Area.

Nevertheless, several aspects of the Guidelines would benefit from further clarification and refinement in order to ensure that the final text remains compatible with contemporary scientific practice, emerging technological developments, and the increasing complexity of data-intensive research ecosystems.

The comments below focus on areas where additional guidance would substantially improve legal certainty, facilitate compliance, and strengthen the balance between data protection and scientific freedom.

1. The Concept of Scientific Research Should Better Reflect Contemporary Scientific Practice

The six key-indicative factors proposed by the Guidelines provide a useful analytical framework.

However, the overall approach appears predominantly based on a traditional academic model of scientific activity, characterised by:

- formal research protocols;
- institutional research environments;
- ethics committee review;
- publication-oriented dissemination;
- academically credentialed researchers.

While these elements remain highly relevant, contemporary scientific research increasingly occurs through alternative organisational structures, including:

- public-private research partnerships;
- industrial research and innovation programmes;
- translational research ecosystems;
- interdisciplinary data science initiatives;
- citizen science projects;
- open science collaborations;
- AI-enabled research environments.

The final Guidelines should explicitly clarify that the proposed factors are neither cumulative requirements nor mandatory criteria.

The qualification of scientific research should ultimately depend upon the existence of genuine scientific objectives, methodological rigour, transparency, and appropriate governance arrangements rather than the specific institutional setting in which the research is conducted.

Such clarification would reduce the risk of unintentionally excluding innovative forms of scientific inquiry that increasingly contribute to scientific advancement and societal benefit.

2. Greater Recognition of Data-Driven and Exploratory Research Is Needed

The Guidelines appear largely grounded in a traditional hypothesis-driven conception of scientific research.

Modern scientific discovery increasingly relies upon methodologies where hypotheses emerge from data exploration rather than preceding data collection and analysis.

Examples include:

- genome-wide association studies;
- large-scale population health analyses;
- biomarker discovery programmes;
- precision medicine initiatives;
- digital phenotyping;
- machine learning research;
- multimodal biomedical data integration.

These approaches often involve exploratory analyses, pattern detection, unsupervised modelling, and data-driven hypothesis generation.

The final Guidelines should explicitly recognise that exploratory and data-centric methodologies constitute legitimate forms of scientific research capable of falling within the scope of the GDPR research provisions.

Failure to provide such clarification may create unnecessary uncertainty for many contemporary research fields.

3. Ethical Oversight and Scientific Legitimacy Should Not Be Conflated

The Guidelines appropriately recognise the importance of ethical standards in scientific research.

However, ethical oversight should not be interpreted as a proxy for scientific legitimacy.

Ethical review and scientific validity address distinct questions.

A project may satisfy ethical requirements while offering limited scientific value.

Conversely, scientifically rigorous research may not necessarily require formal ethics committee approval, depending on:

- the nature of the data;
- the scientific discipline;
- national governance arrangements;
- applicable legal requirements.

Moreover, ethics review systems vary substantially across Member States and research domains.

The final Guidelines should therefore clarify that ethical review constitutes one possible governance mechanism among several approaches capable of demonstrating accountability and responsible research conduct.

Such clarification would better reflect the diversity of scientific disciplines and governance frameworks across Europe.

4. The Notion of Societal Benefit Requires Further Clarification

The Guidelines appropriately emphasise the contribution of scientific research to collective knowledge and societal welfare.

However, the concept of societal benefit remains inherently broad and potentially subjective.

Many transformative scientific discoveries originated from basic research whose practical applications were unknown at the time of investigation.

Scientific value should therefore not depend exclusively upon foreseeable societal utility.

The final Guidelines would benefit from clarifying that societal benefit may be:

- direct or indirect;
- immediate or long-term;
- foreseeable or currently unknown.

Such clarification would better accommodate fundamental research and reduce interpretative uncertainty.

5. Artificial Intelligence Research Requires Dedicated Guidance

Although the Guidelines acknowledge the growing relevance of artificial intelligence, they provide limited practical guidance regarding AI-related research activities.

Given the strategic importance of AI for European scientific competitiveness, this represents a significant gap.

The final Guidelines should address:

- foundation model development;
- machine learning research;
- secondary use of datasets for AI training;
- federated learning architectures;
- synthetic data generation;
- privacy-enhancing technologies;
- continuous model improvement and adaptation.

Specific examples would greatly assist researchers, institutions, and supervisory authorities in applying GDPR principles consistently within AI-enabled research environments.

6. Broad Consent Would Benefit from Additional Operational Clarification

The recognition of broad consent constitutes one of the most valuable aspects of the Guidelines.

Nevertheless, practical uncertainty remains regarding the notion of a “certain area of scientific research”.

Additional clarification would be particularly helpful regarding:

- the required level of specificity;
- future secondary research uses;
- international research collaborations;
- public-private research partnerships;
- AI-enabled research activities.

The inclusion of practical examples and illustrative scenarios would significantly improve harmonisation across Member States.

7. The Relationship Between GDPR Research Provisions and the European Health Data Space Should Be Addressed

The Guidelines have been developed at a time when the European Health Data Space (EHDS) is expected to become a central component of the European health research landscape.

Future health research will increasingly operate within a regulatory ecosystem that includes:

- GDPR;
- EHDS;
- Data Governance Act;
- Data Act;
- AI Act.

Researchers require greater certainty regarding the interaction between these frameworks.

The final Guidelines would benefit from dedicated discussion concerning:

- secondary use permits;
- health data access bodies;
- secure processing environments;
- trusted research environments;
- interactions between EHDS safeguards and Article 89 GDPR safeguards.

Such clarification would be particularly valuable for biomedical and public health research.

8. Article 89 Safeguards Should Be Structured Through a Risk-Based Framework

The Guidelines identify a range of safeguards that may be relevant to scientific research.

However, the document provides limited assistance regarding how safeguards should be selected according to the risks associated with particular processing operations.

A structured risk-based framework would significantly improve operational applicability.

For example:

Lower-Risk Research Activities

- pseudonymisation;
- data minimisation;
- role-based access controls.

Moderate-Risk Research Activities

- secure research environments;
- controlled access mechanisms;
- governance review procedures.

Higher-Risk Research Activities

- privacy-enhancing technologies;
- federated analysis infrastructures;
- independent oversight;
- enhanced auditing and accountability measures.

Such an approach would promote proportionality while supporting harmonised implementation across Member States.

9. Research Infrastructures Should Be Viewed Beyond Traditional Repositories

The discussion concerning research infrastructures remains largely focused on databases and repositories.

Contemporary research infrastructures increasingly function as:

- federated data ecosystems;
- secure computational platforms;
- distributed analytics environments;
- trusted research environments;
- learning health systems.

The distinction between storage and processing is becoming progressively less relevant in modern research infrastructures.

The final Guidelines should acknowledge these developments and provide examples reflecting emerging computational and federated research models.

10. Stronger Recognition of Scientific Freedom as a Fundamental Right

The Guidelines appropriately emphasise the protection of personal data as a fundamental right.

However, greater attention should also be given to the freedom of scientific research, as recognised by Article 13 of the Charter of Fundamental Rights of the European Union.

The GDPR itself seeks to reconcile these two fundamental values.

Accordingly, restrictions affecting scientific research should be interpreted through a framework of necessity and proportionality that fully acknowledges the constitutional importance of scientific freedom.

A more explicit articulation of this balance would strengthen the Guidelines and better reflect the legal architecture of the European Union.

Conclusion

The Guidelines represent an important and highly valuable contribution to the governance of scientific research under the GDPR.

Further clarification regarding:

- contemporary scientific methodologies;
- artificial intelligence research;
- broad consent;
- research infrastructures;
- EHDS interoperability;
- risk-based safeguards;
- scientific freedom;

would significantly strengthen the final text.

Such refinements would enhance legal certainty, support responsible innovation, facilitate cross-border research, and ensure that the GDPR continues to provide effective protection for individuals while enabling scientific excellence and societal progress throughout the European Research Area.

The final version of the Guidelines should strive not only to regulate contemporary scientific practice but also to remain sufficiently future-proof to accommodate the evolving landscape of data-intensive and AI-enabled research.