Comments on EDPB Guidelines 1/2026 on Processing of Personal Data for Scientific Research Purposes: Recital 159, Article 70(1)(e) GDPR and the Ongoing Legislative Process

Introduction

The publication of these Guidelines comes at a particularly unusual moment in the development of European data protection law. For many years, the concept of scientific research within the GDPR remained largely unchanged. While practical questions arose concerning the operation of Articles 5, 6, 9 and 89 GDPR, the legislature's overall approach was reasonably clear. Scientific research was recognised as an activity of considerable social and economic value, and the Regulation sought to facilitate it through a series of specific provisions and derogations, subject to appropriate safeguards for the rights and freedoms of individuals.

The context today is markedly different. Through the Digital Omnibus proposal, the Commission has reopened discussion concerning whether the GDPR should contain a specific, clearer articulation of what constitutes scientific research and how that concept should be understood in relation to GDPR application in. The issue is therefore no longer solely one of interpretation. It has become an active subject of legislative consideration. The European Parliament and the Council are currently examining whether additional clarification is required and, if so, what form it should take.

Against that background, the decision of the European Data Protection Board to publish extensive guidance on the meaning of scientific research raises concerns that extend beyond the substance of the Guidelines themselves. Greater legal certainty would undoubtedly be welcome. Researchers, businesses, public authorities and supervisory authorities all have an interest in a predictable and coherent framework. The difficulty is that the Guidelines do not merely seek to clarify the existing legislative position. They construct a detailed framework for determining what constitutes scientific research at a time when the co-legislatures themselves are considering whether and how that question should be addressed.

The concerns set out below are therefore principally institutional in nature. They arise from the relationship between the broad concept of scientific research adopted by the legislature in Recital 159 GDPR, the interpretative role assigned to the EDPB under Article 70(1)(e) GDPR and the ongoing legislative discussions concerning the future development of that concept. Taken together, these considerations lead to the conclusion that the Guidelines should be withdrawn and reconsidered once the Digital

Omnibus negotiations have been concluded. The EDPB, as a regulatory body and not a treaty-based legislative institution, does not have the competence in EU law to assert this level of influence over a reform process that is governed by the Treaties.

Recital 159 and the Legislative Choice

Any assessment of the present Guidelines must begin with Recital 159 GDPR. Although the GDPR does not contain a formal definition of scientific research, Recital 159 remains the clearest expression of the legislature's intentions concerning the scope of the concept.

The language chosen by the legislature is striking in both its breadth and simplicity. Scientific research is to be interpreted "in a broad manner". The recital then identifies a range of activities falling within that broad understanding, including technological development and demonstration, fundamental research, applied research and privately funded research. It further links the concept to the Union objective of achieving a European Research Area under Article 179 TFEU.

These choices were neither accidental nor insignificant. They reflect a conscious legislative decision to avoid a restrictive or prescriptive understanding of scientific research. Rather than establishing a detailed set of qualifying criteria, the legislature adopted a flexible formulation capable of accommodating scientific and technological developments across a wide range of disciplines, sectors and organisational structures.

The reference to technological development is particularly important. Scientific advancement increasingly occurs through activities that do not fit comfortably within traditional academic models. Research and development undertaken by technology companies, pharmaceutical firms, industrial laboratories and emerging innovators often combines scientific inquiry with commercial objectives. The legislature plainly recognised that scientific progress frequently emerges from commercial environments and that the presence of economic incentives does not diminish the scientific character of the underlying activity.

This broader understanding is also consistent with wider Union objectives. The Treaties place considerable emphasis on research, technological development, innovation and competitiveness as set out in Title XIX (Articles 179 to 190) TFEU. The creation of a European Research Area has long been regarded as a strategic objective of the Union. Against that backdrop, it is difficult to read Recital 159 as an attempt to confine scientific research within the boundaries of a particular institutional or academic

model. The recital reflects a recognition that scientific progress occurs in many forms and that the regulatory framework should be capable of accommodating that diversity.

Equally important is what Recital 159 does not say. It does not require publication of results. It does not require peer review. It does not require formal ethical approval procedures, academic qualifications, institutional independence or adherence to particular governance structures. These omissions demonstrate that the legislators understood that the bulk of research activity, regardless of where it is conducted, follow some form of governance structures. Commercial R&D operations are typically guided by formal frameworks such as regulatory requirements in specific areas (health and pharmaceuticals), industry guidelines, internal monitoring processes, and independent institutional ethics boards. These mechanisms ensure product safety, risk management, and alignment with industry standards while balancing commercial profitability.

The omission of prescriptive definitions of scientific research in the GDPR demonstrates an open and inclusive approach focused on the nature and purpose of the activity itself. Viewed in this light, Recital 159 represents a deliberate policy choice. The legislature elected to define scientific research through breadth rather than prescription and through inclusion rather than exclusion, as this better serves the EU's treaty purposes. Any interpretation of scientific research under the GDPR should therefore begin from that premise.

The Sources of the EDPB's Approach

The difficulty with the present Guidelines does not arise because the EDPB has sought to interpret an undefined concept. Some degree of interpretation is plainly necessary. The GDPR does not contain a formal definition, and practical guidance is capable of providing considerable value to stakeholders. The issue lies in the sources from which the Guidelines derive their substantive framework.

The Guidelines introduce a series of indicative factors including methodological rigour, ethical standards, transparency, autonomy, independence and contribution to society's knowledge and wellbeing. Considered individually, many of these factors are entirely reasonable. Most people would regard them as characteristics commonly associated with good scientific practice. The question, however, is not whether they are desirable. The question is whether the indicative factors emerge from Recital 159 itself.

A review of the materials relied upon by the Guidelines suggests that many do not. Rather, they derive principally from external sources concerned with research governance, research integrity, and the organisation of scientific activity. The European Code of Conduct for Research Integrity, the OECD Frascati Manual, recommendations concerning research careers and related instruments all feature prominently in the intellectual architecture of the Guidelines.

There is nothing objectionable about these documents. They perform important functions within their respective fields. They promote transparency, integrity, accountability and public confidence in scientific research. However, they were not incorporated into the GDPR by the legislature, and they have not been used as a prominent point of reference by the Court of Justice, which has primary used Recital 159 and article 13 of the Charter of Fundamental Rights .

This distinction becomes increasingly important when examining some of the concepts introduced by the Guidelines. The emphasis placed upon autonomy and independence provides a useful example. Such concepts are familiar within academic environments and reflect long standing traditions concerning academic freedom and institutional independence. Yet many forms of scientific research take place within commercial settings where strategic priorities, intellectual property considerations and commercial objectives necessarily influence the direction of research. The legislature appears to have recognised this reality through its express inclusion of privately funded research within Recital 159 and not including any reference to the need for the research to be wholly independent, something that would not correspond to the nature and purpose of the EU treaties.

Similar observations apply to publication and transparency. The Guidelines understandably regard openness and dissemination of results as indicators of scientific activity. Yet some of the most important scientific and technological advances emerge from environments where confidentiality is unavoidable. Pharmaceutical development, advanced manufacturing, biotechnology and artificial intelligence frequently involve significant intellectual property interests. The absence of publication should not disqualify such activities from being accepted as genuine scientific research.

The cumulative effect of these additions is subtle but significant. The centre of gravity shifts from the nature and purpose of the activity towards the manner in which it is organised and governed. Scientific research begins to resemble a framework characterised by particular institutional and procedural features rather than a broad category of activities directed towards the generation and application of knowledge in support of a wide array of objectives.

This may not have been the intention of the Guidelines. Nevertheless, it is difficult to avoid the impression that the resulting framework reflects a concept of scientific research that is more closely aligned with contemporary academic governance models than with the broad legislative concept reflected in Recital 159.

The Limits of Interpretation Under Article 70(1)(e) GDPR

The foregoing discussion raises a broader question concerning the role of the EDPB within the GDPR framework and the limits of its interpretative authority. Article 70(1)(e) assigns the Board an important responsibility in promoting the consistent application of the Regulation. The value of this function is self evident. Harmonisation and consistency are essential objectives of the GDPR, and guidance plays a vital role in helping stakeholders navigate complex legal requirements.

The existence of an interpretative mandate does not, however, eliminate the distinction between interpretation and legislation. The Board is entrusted with explaining how to apply the law adopted by the legislature. It is not entrusted with supplementing legislative concepts through the introduction of substantive criteria that cannot reasonably be derived from the legislative text itself.

The boundary between interpretation and supplementation is not always easy to identify. Legislative concepts often require clarification and adaptation to practical circumstances. Nevertheless, there comes a point at which interpretation of the legislative concepts begins to assume a different character. Where guidance derives its essential content from sources external to the legislation and introduces concepts that the legislature chose not to include, legitimate questions arise concerning whether the exercise remains one of interpretation.

Those questions arise in the present case. Recital 159 adopts a broad and inclusive approach. The Guidelines establish a more structured framework informed by considerations that are not readily apparent from the text of the recital itself. While described as indicative rather than mandatory, the factors identified by the Guidelines perform an important practical function in determining which activities are more readily recognised as scientific research and which require further justification.

The resulting framework does more than explain the legislative text. It effectively introduces an additional layer of analysis. Activities that fall comfortably within the broad understanding of scientific research reflected in Recital 159 may nevertheless be assessed against criteria derived from external governance frameworks. The practical

effect is to reshape the application of the legislative concept through reference to considerations that are not found within the Regulation itself.

This is particularly significant in sectors characterised by intensive research and innovation. Commercial research environments frequently combine scientific objectives with economic incentives, confidentiality obligations and proprietary methodologies. Such characteristics do not sit easily alongside certain assumptions embedded within academic governance frameworks that EDPB is seeking to embrace through the guidance. Yet they are entirely consistent with the broad understanding of scientific research reflected in Recital 159 and with the Union's wider commitment to research, innovation and technological development.

The concern is therefore not that the EDPB has sought to provide clarity. The concern is that the Guidelines risk moving beyond the interpretation of a broad legislative concept and towards the construction of a more detailed framework based on sources that the legislature itself did not adopt and disconnected from the EU's wider treaty obligations and objectives. Whether that outcome was intended is ultimately irrelevant. The question is whether such an approach is consistent with the role assigned to the Board under Article 70(1)(e). There are compelling reasons to conclude that EDPB needs to exercise more caution and restraint.

The Ongoing Legislative Process and the Need for Institutional Restraint

These concerns become particularly acute when considered in light of the ongoing Digital Omnibus negotiations. The Commission's proposal demonstrates that the meaning and scope of scientific research remains an active subject of legislative discussion. Different approaches have been advanced. Different views have emerged among Member States. The European Parliament has yet to complete its own consideration of the matter. The debate remains open and its outcome remains uncertain.

In these circumstances, the publication of a detailed interpretative framework creates an unusual institutional situation. The legislature is actively considering whether and how scientific research should be articulated within the GDPR, while the EDPB is simultaneously seeking to establish a comprehensive framework addressing the same issue.

The concern is not that the Board has expressed a view. Its expertise is both valuable and relevant and along with the EDPS the EDPB provided a joint opinion about the Digital

Omnibus as a relevant institution. The concern is that guidance issued during an ongoing legislative process may come to influence a debate that has yet to reach a conclusion. Given the authority attached to EDPB guidance, the distinction between interpretation of existing law and contribution to future policy discussions can become increasingly difficult to maintain. The concerns are elevated given the potentially significant time that will be pass before the Digital Omnibus is finally agreed by the co-legislators. What authority will organisations be looking to when pursuing scientific research under GDPR and what authority will regulators look to?

Purposely creating a high degree of uncertainty is not a prudent path for any regulator. A more prudent course would have been for the Board to await the outcome of the legislative process before developing detailed guidance. Such an approach would not have diminished its role. Rather, it would have ensured that any future guidance reflected the settled position of the co legislators and avoided the possibility of establishing an interpretative framework that may later prove inconsistent with the legislative settlement eventually reached.

There is also a practical dimension to this issue. Should the Digital Omnibus negotiations result in legislative clarification of scientific research, significant aspects of the present Guidelines may require revision. Concepts that currently appear central may become less significant, while new considerations may emerge. Waiting for the legislative process to conclude would therefore promote both legal certainty and regulatory efficiency for all stakeholders.

In a field as important as scientific research, legal certainty is undoubtedly valuable. Yet certainty is most durable when guidance follows legislation rather than anticipates it. The objective should be to provide an interpretation that reflects the final legislative settlement, not one possible outcome among several competing alternatives.

Conclusion

The present Guidelines raise issues that extend beyond the interpretation of scientific research under the GDPR. At their core, they concern the relationship between legislative choice, regulatory guidance and the institutional balance established by the Regulation itself.

Recital 159 reflects a deliberate decision by the legislature to adopt a broad understanding of scientific research. The language chosen is notably inclusive and recognises the diverse forms through which scientific advancement and innovation

occur across the European economy. The emphasis is placed upon the nature and purpose of the activity rather than upon particular governance structures or institutional characteristics.

The Guidelines adopt a more prescriptive approach. In doing so, they draw substantially upon sources originating outside the GDPR and introduce concepts that are not readily derived from Recital 159. Many of these concepts are valuable within their own fields, but they reflect policy choices that the legislature itself did not incorporate into the Regulation.

Scientific research undoubtedly deserves greater legal certainty. The EDPB has an important role to play in providing that certainty. However, the present Guidelines have been developed before the legislative debate concerning the future scope of scientific research has reached a conclusion. This gives rise to legitimate questions concerning the proper scope of guidance issued under Article 70(1)(e) GDPR.

In the circumstances, withdrawal represents the most prudent course. The EDPB should formally withdraw the Guidelines and not proceed to final adoption. The Guidelines can be reconsidered once the Digital Omnibus negotiations have concluded. Such an approach would allow future guidance to be anchored in the final legislative settlement, preserve the institutional balance of the EU treaties, and ensure that the Board's guidance remains focused on the consistent application of the law adopted by the legislature as established by the GDPR.