Centre for Information Policy Leadership
HUNTON

Response by the Centre for Information Policy Leadership to the European Data Protection Board's Public Consultation on Guidelines 1/2026 on the processing of personal data for scientific research purposes

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The Centre for Information Policy Leadership (CIPL)[1] appreciates the opportunity to comment on the European Data Protection Board's (EDPB) draft Guidelines 1/2026 on the processing of personal data for scientific research purposes (the Guidelines), adopted for public consultation.

CIPL welcomes the EDPB's contribution towards more legal certainty in an area of fundamental importance to European societal and economic progress – research. In light of persistent fragmentation in national interpretation, clear and workable guidance with respect to the processing of personal data in the context of research benefits researchers, research institutions, life sciences companies, and the many other organisations that process personal data for scientific research, whether on a public, academic, non-profit, or commercial basis. CIPL offers the comments below in a constructive spirit, with the aim of ensuring that the Guidelines *enable* responsible and beneficial research within the established framework guiding scientific research, while maintaining robust protection for data subjects. For more than twenty years, CIPL has advocated for a risk-based and accountability-driven approach to data protection, and the recommendations that follow are grounded in that approach.

Welcome key positions

CIPL welcomes a number of positions taken in the Guidelines, in particular:

- **The confirmation that the concept of scientific research includes research conducted on a commercial or for-profit basis,** including by commercial companies and start-ups, as recognised in Recital 159 GDPR. This appropriately reflects the reality that a substantial amount of valuable scientific research is conducted within, or in collaboration with, the private sector.

- **The confirmation that legitimate interest under Article 6(1)(f) GDPR is available as a legal basis for scientific research**, including research undertaken on a commercial basis, and that the societal importance of genuine scientific research carries significant weight in the balancing test. This appropriately reflects that research conducted by commercial entities can deliver substantial benefits for society as a whole.

- **The express recognition that privacy-enhancing technologies can serve as appropriate safeguards under Article 89(1) GDPR**, including synthetic data and homomorphic encryption, secure processing environments, federated databases, and codes of conduct and certification. CIPL has consistently supported the deployment and incentivisation of, privacy-enhancing and privacy-preserving

[1] The Centre for Information Policy Leadership (CIPL) is a global privacy and data policy think tank within the Hunton law firm that is financially supported by the firm, 80+ member companies that are leaders in key sectors of the global economy, and other private and public sector stakeholders through consulting and advisory projects. CIPL's mission is to engage in thought leadership and develop best practices for the responsible and beneficial use of data in the modern information age. CIPL's work facilitates constructive engagement between business leaders, data governance and security professionals, regulators, and policymakers around the world. For more information, please see CIPL's website at https://www.informationpolicycentre.com/. Nothing in this document should be construed as representing the views of any individual CIPL member company or Hunton. This document is not designed to be and should not be taken as legal advice.

technologies across the data lifecycle,[2] and welcomes their endorsement in the research context.

  - CIPL notes, however, that the benefits of these technologies can only be fully realised where identifiability is assessed in line with the relevant case law, including the Court of Justice's most recent judgment in *EDPS v SRB* (Case C-413/23 P), which confirmed a contextual, risk-based approach to identifiability. The Guidelines currently only briefly refer to such case law, as well as the pending Digital Omnibus. As discussed further below, overly restrictive interpretations of when data remains personal risks adding further complexity and ultimately disincentivising the adoption of privacy enabling measures, such as privacy-enhancing technologies, in the research context.

- **The recognition that processing operations ancillary to scientific research,** such as preparatory steps and data-management operations such as extraction, filtering, curation and categorisation**, may themselves be subject to the same treatment as the core processing.**

- The fact that the **Guidelines make an effort to give effect to the European Health Data Space (EHDS),** for example in the discussion of legal bases and appropriate safeguards. CIPL encourages the EDPB to develop this further by mapping more fully the interface between the Guidelines and the EHDS, but also other EU legislation such as the EU Biotech Act, so that controllers operating under these frameworks face coherent and non-duplicative obligations. A more harmonised and coherent approach would benefit the entirety of the research community.

<u>Core issue: scientific research is already broadly defined in EU law</u>

Scientific research is a well-established concept in EU law and has consistently been understood in broad terms. Article 13 of the Charter of Fundamental Rights provides that scientific research shall be free of constraint, something the Guidelines themselves recognise. That breadth is reflected across the EU acquis[3] and is anchored at Treaty level in Article 179(1) TFEU, which tasks the Union with strengthening the European Research Area across all fields of research, including for industrial competitiveness. An equally broad and internationally-recognised concept of research applies in Horizon Europe, the EU's principal instrument for realising the very European Research Area.[4] Recital 159 GDPR gives direct effect to this breadth, providing that scientific research should be interpreted in a broad

[2] See CIPL, 'Privacy-Enhancing and Privacy-Preserving Technologies: Understanding the Role of PETs and PPTs in the Digital Age', (2023) and CIPL, 'Privacy-Enhancing and Privacy-Preserving Technologies in AI: Enabling Data Use and Operationalizing Privacy by Design and Default', (2025).

[3] For instance, in the definition of research in Article 3(9) of Directive (EU) 2016/801 — creative work undertaken on a systematic basis to increase the stock of knowledge and to devise new applications, a definition that contains no requirement of peer review, publication, ethical approval or independence from industry — as well as in the research and development definitions in the General Block Exemption Regulation (Regulation (EU) No 651/2014) and the 2023 Council Recommendation updating the European Charter for Researchers.

[4] The OECD Frascati Manual defines research and experimental development as creative and systematic work undertaken to increase the stock of knowledge and to devise new applications of available knowledge, comprising basic research, applied research and experimental a taxonomy that closely tracks the categories enumerated in Recital 159.

manner, including "*technological development and demonstration, fundamental research, applied research and privately funded research.*"

Against this background, CIPL is concerned that the six indicative factors introduced in section 2.1 may, in practice, narrow a concept that the EU legislator has deliberately defined in broad terms. Several of the factors — including verifiability through peer review, publication, researcher independence and qualifications, and contribution to society's wellbeing — do not appear in the legislative definition of research under EU law, and are instead drawn from external and soft-law sources.

CIPL recognises the EDPB's important role in promoting the consistent application of the GDPR but considers that in this role the EDPB should ensure that effect is given to the to the legislative intent of the GDPR as demonstrated in the broad concept of scientific research expressed by Recital 159 GDPR rather than by introducing additional qualifying and potentially limiting criteria. CIPL would also encourage the EDPB to give full effect to the balance that EU law strikes between the protection of personal data — and the freedom of scientific research (Article 13 CFREU), as envisioned by Recital 4 GDPR. CIPL notes, finally, that an unduly narrow approach risks inadvertently placing research conducted in the EU at a disadvantage relative to other jurisdictions.

We therefore encourage the EDPB to maintain the broad concept of scientific research envisioned by the legislator under Recital 159 GDPR, as well as the wider EU acquis, and reconsider whether the six indicative factors, as currently framed, should be revised so that they operationalise rather than narrow the concept of scientific research. This would also align with the EDPB Helsinki commitments to empower responsible innovation and reinforce competitiveness in Europe.

Issues for further consideration

CIPL has identified a number of areas where the Guidelines require refinement. These are set out below.

Additional issues in relation to the six-indicative factors.

1. **Any key-indicative factors should be applied as genuinely indicative, and not as sine qua non factors or as a cumulative test.**

   As referenced above, the Guidelines set out, six key-indicative factors for determining whether processing is motivated by scientific research purposes in section 2.1. The Guidelines state that activities meeting all six factors can be presumed to constitute scientific research, while activities not meeting all of them require the controller to justify and demonstrate why they should nonetheless qualify.[5] While the factors are described as indicative, this structure risks hardening in practice into sine qua non or cumulative conditions that can disadvantage legitimate research which meets the definition of scientific research under another framework. This can lead to additional exclusionary factors even though 'broad consent' was intended to be permissive.

[5] Paragraph 12 of the Guidelines

Combined with the notion of broad consent and the recommended safeguards, this may lead to significant interpretative and operational complexity in a framework.

If the Guidelines maintains any indicative factors, CIPL recommends that the EDPB emphasise expressly that that no single factor is determinative or "key", and that an organisation is not placed at a disadvantage where it defines or evidences its research in accordance with EU law.

2. The exploratory, objective-based route under factor (i) should accommodate iterative AI research

The Guidelines recognise, in factor (i) on a *methodical and systematic approach*, that where research is exploratory or at a preliminary stage it may have a stated objective rather than a formal hypothesis. This is directly relevant to early-stage and iterative AI research and model evaluation work, where hypotheses are commonly refined as the work develops, but the Guidelines do not address that context.

CIPL recommends that the EDPB confirm expressly that the exploratory, objective-based route accommodates such iterative research, consistent with the recognition elsewhere in the Guidelines that technological development and demonstration fall within the concept of scientific research. This clarification would also help ensure that technological development, testing, validation, and demonstration activities are not inadvertently excluded from scope.

3. "Society's wellbeing" in factor (v) falls outside the EDPB's remit

The Guidelines provide, in factor (v) on *objectives of the research*, that scientific research is carried out with the aim of contributing to the growth of "society's general knowledge and wellbeing", and suggest that controllers consider reviews of the scientific merit of their projects.[6] By embedding this criterion within the test for scientific research, the Guidelines import an assessment of societal value of research into data protection law, which is a legally ambiguous concept and a judgment that sits outside the competency of a data protection authority. This framing may seem accessible when considering "scientific research" as mostly medical or clinical research, where objectives such as patient wellbeing and societal benefit are inherent to the discipline. However, as mentioned above, scientific research as defined in EU legislation is broader than that and covers technological development, applied research, privately funded research, and close-to-market innovation, which may be less obvious which may in tern lead to legal uncertainty.

This is compounded by the fact that often in the field of scientific research the hypothesis and impact can be unknown at the outset as research is often exploratory and so ultimate contribution to society value is unknown in advance. Requiring controllers to demonstrate such benefits in the context of processing personal data risks favouring established research pathways over innovative and emerging fields of inquiry.

CIPL therefore recommends that the reference to society's "wellbeing" be removed from factor (v) and that the assessment of whether research contributes to the wellbeing or

[6] Footnote 21 of the Guidelines

interests of society be left to researchers and the established ethical and scientific governance frameworks. CIPL considers that the concept of scientific research can be given effect under the GDPR by reference to the research's aim of contributing to general knowledge, without requiring data protection supervisory authorities to evaluate its broader societal value, which goes beyond their competence

4. **Consent to participate in research should be removed from the ethical-standards factor**

   The Guidelines include, within factor (ii) on *adherence to ethical standards*, "the concept of consent to participate in research," while separately and more fully addressing the distinction between consent to participate and consent as a legal basis under the GDPR in section 4.1.3. Locating consent to participate within the indicative factors introduces avoidable confusion between an ethical requirement governed by sectoral law (to consent to participate in research) and a GDPR legal basis (to consent to processing data for a specific purpose). Informed consent is a foundational ethical principle in clinical research and is already regulated under sectoral law. The current drafting could be misunderstood to elevate clinical consent to participate as an indicative factor for *all* scientific research, including applied, technological, and privately funded research, which is not in the remit of the EDPB. It may also risk suggesting that scientific research which does not have type patient-level consent is less “genuinely scientific”, which is not contrary to Recital 159 GDPR, or any other EU legislative definition of scientific research.

   CIPL recommends that the reference to consent to participate in research be removed from factor (ii) and addressed solely in section 4.1.3. At a minimum, CIPL recommends inserting “where applicable” before “the concept of consent to participate in research” so that the factor does not imply that such consent is a general feature of scientific research.

5. **The interpretation of "autonomy and independence" and "verifiability" must reflect commercial realities**

   The Guidelines suggest, within factors (iv) *autonomy and independence* and (iii) *verifiability,* that scientific research should be conducted free from undue pressures to define research questions, and should normally be subject to external peer review and publication. CIPL notes that these criteria are heavily modelled on traditional academic or clinical settings and pose challenges for private-sector level research, even though it is explicitly included. In commercial contexts, proprietary model development and technological advancement are legitimately and inherently part of the corporate product roadmap and in line with commercial objectives. Nevertheless, commercial enterprises also routinely contribute to scientific advancement through alternative, recognised mechanisms for achieving verifiability and transparency, such as patent disclosures, the publication of industry benchmarks, and presentations at academic or technical conferences.

   CIPL recommends that the EDPB further clarifies how these criteria can be met in a commercial setting as well, having regard to proprietary information or intellectual property concerns. CIPL also encourages the EDPB to provide illustrative examples of commercial research for further guidance

6. Section 2.1 should include an example of research conducted by researchers with a commercial background

The Guidelines further set out, in factor (iv) on *autonomy and independence*, that the relevant qualifications may be held by researchers regardless of whether they work in an academic institution, a non-profit or public body, or a for-profit organisation such as a commercial company or a start-up, and they illustrate the factors through a series of examples. None of the examples, however, clearly provide examples of genuine scientific research conducted by researchers with a commercial or company background satisfying the factors in their own right. The general absence of practical examples involving commercial research reinforces the perception of scientific research being predominantly understood as associated solely with academic institutions despite the broad and sector-neutral concept of scientific research reflected in the EU law.

CIPL recommends that section 2.1 be supplemented with an illustrative example of genuine scientific research conducted by researchers with a commercial or company background, to reinforce the inclusive concept of research and provide practical certainty for the many research-active organisations outside the academic sector. Including examples from commercial, industrial, and collaborative research environments would better reflect the reality of the modern European research ecosystem and help demonstrate that scientific research is not limited to traditional academic settings.

<u>Issues related to the rest of the guidelines.</u>

7. Section 8.3 should avoid a fixed hierarchy between anonymised, pseudonymised and identifiable data

The Guidelines establish, in section 8.3, an order of preference under which research data should in the first place be anonymised, then pseudonymised where anonymisation cannot meet the research purpose, with processing of directly identifying data permitted only where strictly necessary and proportionate. CIPL acknowledges the principle of data minimisation, which requires that the data processed be adequate, relevant and limited to what is necessary for the purpose.

However, CIPL is concerned that the Guidelines harden this purpose-bound principle into a fixed hierarchy, which raises the bar for compliance, especially within the life sciences. In many cases, whether personal data is necessary, or whether anonymisation or pseudonymisation is appropriate, will be a key part of the research design and, as such, be best determined by the researchers.

A rigid hierarchy may furthermore discourage the deployment of privacy-enhancing technologies and similar risk mitigation measures by creating the assumption that anonymisation is always preferable, irrespective of the specific research context and actual residual risks. Any assessment should also remain contextual and risk-based, and ultimately consistent with the CJEU's approach in EDPS vs SRB, which emphasises that identifiability must be assessed in light of the specific circumstances of the processing rather than through abstract assumptions.

CIPL recommends that section 8.3 is re-drafted so that it enables scientific research, consistent with the aim of providing a framework that enables the processing of personal data for scientific research, rather than raising the bar for compliance. CIPL encourages the EDPB to avoid establishing a fixed hierarchy between anonymised and pseudonymised data. The Guidelines should recognise that the appropriateness of anonymisation, pseudonymisation, or identifiable data depends on the nature of the research, the safeguards implemented, and the actual risks associated with the processing rather than on a predetermined order of preference.

8. "Manifestly made public": the additional verification steps, not the threshold, may be unworkable for research

The Guidelines, in section 4.4.2, restate the Court of Justice's threshold for the Article 9(2)(e) GDPR derogation — that the controller must establish the data subject intended, by a clear affirmative action, to make the data accessible to the general public (C-252/21; C-446/21) — which CIPL accepts as settled case law. Beyond that threshold, however, paragraphs 70 and 71 set out detailed operational steps specific to social media, including that the controller should check the platform's user settings, verify that users could only post publicly after deliberately adjusting those settings with knowledge that the data would be made public, and assess who posted the data; these steps are drawn substantially from the EDPB's own Guidelines 8/2020 on the targeting of social media users rather than from the case law. Importing operational requirements developed in the targeted-advertising context into scientific research, without accommodating the realities of research reuse of publicly available data, risks rendering the derogation unworkable for legitimate research, including AI-enabled research where such data can be foundational, and may thereby hinder research and innovation. In large-scale research environments, including AI-enabled research, reliance on Article 9(2)(e) GDPR should be capable of being assessed through proportionate and system-level measures rather than requiring case-by-case verification of individual items of content. An approach that depends on individualised verification risks rendering the derogation impractical in precisely those contexts where publicly available information is most frequently used for research purposes.

CIPL would encourage the EDPB to engage further with industry and the wider research community to develop a workable approach to reliance on Article 9(2)(e) GDPR in the scientific research context, and to retain and build on the constructive examples at Examples 9 and 10.

9. The interpretation of inferred special category data should be risk-based and workable for scientific research

The draft Guidelines indicate that special categories of data include personal data that can be used to deduce such information, and sensitive information inferred from the data processed. CIPL has serious concerns about the breadth of this formulation in the research context.

Research, by its nature, frequently involves the processing of large and heterogeneous datasets from which, through sufficiently creative multi-step aggregation or analysis, some sensitive attribute might in principle be inferred about some individuals. Treating

that theoretical possibility as sufficient to bring an entire dataset within Article 9 GDPR would effectively extend special category protection to a much broader range of research data than the Guidelines elsewhere acknowledge, and would do so without regard to whether the inference is one the researcher is actually pursuing, foresees, or has the practical means or motivation to draw.

The current approach raises concerns regarding legal certainty and practical compliance. An interpretation under which data could be treated as special category data whenever a sensitive inference is theoretically possible risks making obligations difficult to foresee and apply in practice.[7] This sits uneasily with established principles requiring a predictable legal framework and a contextual assessment of compliance responsibilities. More generally, the Guidelines appear to give insufficient weight to the contextual nature of personal data, as recognized in Breyer and SRB. In scientific research involving large volumes of publicly available information, researchers often lack both the intention and the practical means to identify individuals or derive sensitive insights about them. A proportionate approach would therefore distinguish between processing that actively seeks or is reasonably likely to generate sensitive inferences, and processing where such inferences remain incidental, speculative, or remote and instead rely on additional safeguards, like contractual obligations, to safeguard against residual risks.[8]

CIPL therefore recommends that the EDPB distinguish, for the purposes of the Guidelines, between processing where a sensitive inference is actively pursued or forms an inherent and foreseeable consequence of the processing, and processing where such an inference remains remote, speculative, or incidental to the research purpose.[9]

10. The Guidelines should not over-expand joint controllership

The Guidelines provide, in section 7.3, that where several parties jointly participate in drafting a research protocol that determines the purposes and essential means of processing, this may suffice for all of them to be considered joint controllers, even where the research and the processing of personal data are carried out by only some of them. They further provide, at paragraphs 135 and 136, that an entity may be a controller *even where it processes no personal data at all*, processes it only to a limited extent, or *processes only pseudonymised* data.

CIPL is concerned that this approach may broaden the concept of joint controllership beyond its intended scope and weaken the important connection between legal responsibility and actual decision-making authority. This may ultimately have a chilling effect on valuable research collaborations. Where parties do not genuinely determine the purposes and means of the *processing* together, the relationship may be more

[7] CIPL, ' Rethinking Sensitive Data in the Age of AI', (2025).

[8] This is also an approach suggested for anonymization means under 6(11) DMA

[9] In Lindenapotheke (C-21/23) the inference of health data was far from hypothetical: purchasing medication inherently entails a concrete link to a health condition. This is fundamentally different from scenarios where multi-step aggregation and speculative reasoning might theoretically yield some sensitive inference from general-purpose research data.

appropriately characterised as separate or independent controllership. This is consistent with the CJEU's approach which recognises that participation in processing activities may vary in nature and degree, and that responsibility should be assessed in light of the specific circumstances of each case.[10] Similarly Advocate General Bobek had observed that an overly expansive interpretation of joint controllership that could dilute accountability by extending responsibility to parties that do not exercise meaningful control.[11] Such an approach risks reducing clarity regarding which party is best placed to fulfil GDPR obligations and respond to data subjects effectively.

We are also concerned that controller responsibilities may be assigned to parties that hold only pseudonymised data and have no means reasonably likely to be used to re-identify the data subjects. Consistent with the relativity of personal data the Guidelines recognise elsewhere, assigning controllership in those circumstances imposes artificial responsibilities on a party that is not, in practice, able to give effect to data subjects' rights.

Outside the formal setting of clinical trials, different actors may contribute infrastructure, expertise, or access mechanisms without determining the research purposes. A clear example is structured data access under Article 40 of the DSA: the platform determines the access mechanisms, applicable safeguards, and categories of data made available, while each researcher independently determines its own purposes and methodology. Here the parties exercise no mutual influence over one another's purposes and means; they are separate, independent controllers.

Furthermore, CIPL would like to point out, that "controller" and the "research team" are not always distinct entities. CIPL respectfully notes that, in a commercial setting where research is not conducted in conjunction with a separate legal entity, the corporate legal entity (the controller within the meaning of Article 4(7) GDPR) and the research team are one and the same.

CIPL recommends that the Guidelines do not consider joint controllership as a default, but instead confirm that controllership and joint controllership are assessed on a functional, fact-specific basis reflecting genuine control over the purposes and means of *processing*. In particular, CIPL recommends that the EDPB clarify in line with SRB, that a party which holds only pseudonymised data, and has no means reasonably likely to be used to re-identify the data subjects, should not on that basis be assigned controller or joint controller responsibilities, so that responsibility is allocated to the parties genuinely able to exercise control and to give effect to data subjects' rights.

11. The Article 14(5) transparency exceptions, in particular disproportionate effort, should be applied in a manner that genuinely accommodates the realities of scientific research

The Guidelines address, in section 5.4.2, the exceptions from the obligation to provide information under Article 14(5) GDPR, stating that the exceptions must be interpreted

[10] Case C-210/16, *Unabhängiges Landeszentrum für Datenschutz Schleswig-Holstein v Wirtschaftsakademie Schleswig-Holstein GmbH*, ECLI:EU:C:2018:388, judgment of 5 June 2018.
[11] Opinion of Advocate General Bobek in Case C-40/17, Fashion ID GmbH & Co. KG v Verbraucherzentrale NRW eV, ECLI:EU:C:2018:1039, delivered 19 December 2018, paras 91–92.

restrictively and should not be relied on routinely,[12] allowing for very few situations in which provision of information is considered impossible.[13] This framing risks being read as rendering the disproportionate-effort and impossibility exceptions practically unavailable, which would be at odds with the realities of research drawing on large registries or population datasets, older datasets with outdated contact details, and the secondary use of data not collected directly from the data subject.

CIPL recommends that the EDPB confirm that these exceptions remain available on a proportionate, contextual basis, weighing the effort involved against the impact on data subjects and taking into account the safeguards adopted under Article 89(1) GDPR and the alternative means of providing information indirectly, so that transparency is meaningful rather than burdensome without further benefits for the individual. The practical feasibility of providing information should be assessed in a realistic and contextual manner, recognising that large-scale, longitudinal, or secondary-use research may involve circumstances where individual notification would impose disproportionate efforts without corresponding benefits for data subjects.

12. Transparency expectations should not conflict with Article 11 GDPR and the principle of data minimisation

The Guidelines suggest that controllers anticipating long-term scientific research should retain contact details, or make reasonable efforts to acquire them, to facilitate transparency. CIPL is concerned that this approach introduces friction for organisations seeking to apply pseudonymisation and following the data minimisation principle as primary safeguards under Article 89(1) GDPR. In the context of long-term technological and AI research, deleting direct identifiers is a standard and necessary practice to protect individual privacy. Recommending that organisations instead actively source or retain contact details risks inadvertently incentivising the unnecessary collection or prolonged retention of personal data, which runs counter to the intent of the GDPR and Article 11 GDPR in particular.

CIPL recommends that the EDPB clarify that controllers are not expected to retain direct identifiers, or to re-identify pseudonymous data, solely to comply with transparency obligations. Instead, CIPL encourages the EDPB to explicitly endorse scalable, alternative transparency measures — such as dedicated project websites, privacy dashboards, and proactive public communications — as safeguards where direct notification would lead to additional processing sit in tension with the data minimisation principle.

13. The Guidelines should address the interaction between scientific research under the GDPR and other EU research access frameworks.

The draft guidelines do not sufficiently address the interaction between the GDPR scientific research framework and sector-specific EU access regimes, such as Article 40 DSA. This interdependence becomes increasingly important in enabling independent research and additional clarification may be needed to ensure that controllers and researchers are not subject to duplicative or conflicting obligations.

[12] Paragraph 96 of the Guidelines
[13] Paragraph 98 of the Guidelines

CIPL recommends that the EDPB clarify how the GDPR's scientific research provisions interact with sector-specific EU data access regimes such as Article 40 DSA, and confirm that, where access is provided pursuant to a legal obligation under EU law, overlapping frameworks are interpreted coherently and proportionately so that controllers and researchers are not subject to duplicative or conflicting obligations.

14. The Guidelines do not reference the effect of national fragmentation between Member States

The Guidelines acknowledge, including at paragraph 4, that the GDPR does not exhaustively harmonise the processing of personal data for scientific research and that there is significant scope for complementary Union and Member State law, the application of which the Guidelines do not address. The resulting divergence across Member States, evident in the Article 9(2) derogations, the Article 89(2) restrictions on data subject rights, and the additional conditions permitted under Article 9(4), creates real uncertainty for controllers, and is particularly acute for cross-border and multi-site research such as consortia, biobanks, and the federated-database arrangements illustrated in Examples 22 and 25. Divergent national approaches may create legal uncertainty not only for traditional research institutions but also for private sector and collaborative research initiatives operating across multiple member states. Greater acknowledgment of these challenges would also be consistent with the broader objective of facilitating research and innovation across the European research area. This fragmentation may also discourage cross-border research collaborations and increase compliance costs without necessarily enhancing the level of protection afforded to data subjects. CIPL recognises that the harmonisation of national law is a matter for the co-legislators rather than the EDPB.

CIPL encourages the EDPB to acknowledge the practical burden of fragmentation on cross-border research and, where it can, to signpost the mechanisms that mitigate it, including codes of conduct under Article 40 GDPR, certification, and the interface with the EHDS.

15. The EDPB should exercise caution in building guidance on the still-evolving Digital Omnibus proposal.

The Guidelines refer at several points to the proposed Digital Omnibus, including in the discussion of the presumption of purpose compatibility and in the context of transparency and the provision of information. CIPL recognises the value of forward-looking guidance.

CIPL notes that a number of ongoing EU policy and legislative initiatives, including the Digital Omnibus, and proposals such as the EU Biotech Act, are closely connected to the regulation of scientific research under the GDPR. Other EDPB guidelines such as the pseudonymisation guidelines remain unfinalized. The Commission's implementing act under Article 8(2) DMA — specifying measures to ensure effective anonymisation pursuant to Article 6(11) DMA — and a delegated act under Article 40(13) DSA on technical conditions for researcher data access – should, once adopted, be easily interoperable with EDPB guidelines.

In developing the final Guidelines, it may therefore be helpful to take these developments into account to ensure long-term consistency and coherence across the evolving framework. Given that several of these initiatives remain under consideration and may continue to evolve during the legislative process, the current timing presents certain challenges. The EDPB may wish to consider whether the Guidelines would benefit from further alignment with these developments once they have reached a more settled stage, thereby providing organisations with greater certainty when designing long-term research programmes and compliance frameworks. CIPL would welcome the opportunity to discuss any of the above points further and thanks the EDPB for its work on these important Guidelines.