Response to EDPB's Open Consultation, Guidelines 1/2026 on processing of personal data for scientific research purposes

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Executive Summary

Guidelines 1/2026 on processing of personal data for scientific research purposes, issued by the European Data Protection Board (EDPB) (henceforth: the Guidelines) represent a **significant step forward in providing a research-friendly interpretation of the GDPR**. Compared to some restrictive approaches adopted at national levels, the EDPB appears to embrace a more pragmatic understanding of how scientific research is conducted in practice and provides concrete guidance on steps to take for the processing of personal data for this pupose.

In particular, the Guidelines provide welcome clarification on several issues that have long generated uncertainty. These include the **recognition that multiple legal bases may support research activities** depending on the applicable Union and Member State legal framework; the confirmation that **broad consent may be valid where it refers to sufficiently specified areas and lines of research**, rather than to entirely undefined future uses; and further clarifications on the process of anonymisation.

The Guidelines also provide important reassurance regarding **the long-term use of research data**. They recognize that scientific research often extends beyond the duration of individual projects and that research databases may continue to be used for future research purposes, subject to appropriate safeguards. In this regard, the Guidelines rightly avoid equating scientific research with a requirement for immediate anonymisation and acknowledge that personal data may need to be retained for longitudinal research and future scientific uses, and shared to achieve these purposes among various entities and institutions.

However, some challenges remain and others have emerged. On a general level, **remaining challenges concern the interaction between the Guidelines and legal frameworks applicable to the processing of personal data for scientific research purposes at the national and European level - including the upcoming Regulation (EU) 2025/327 on the European Health Data Space (EHDS)**. While the Guidelines aim to provide a common interpretation of the GDPR with respect to scientific research across European countries, researchers operating across multiple Member States must still navigate significant differences in national frameworks governing health data research - including local ethics requirements, formulated either through legislative or, in some cases, soft law provisions - as already identified by the European Commission in the *Assessment of the EU Member States' rules on health data in the light of GDPR* in 2021 (Hansen et al., 2021). This is particularly relevant for cross-border projects involving large datasets and AI development, where vast amounts of diversified data are needed. In this regard, it is important that future national guidance and sector-specific rules remain aligned with the approach adopted by the EDPB so as to promote legal certainty and avoid the re-emergence of unnecessary barriers to processing personal data for scientific research across the EU. In addition, the forthcoming implementation of the EHDS raises important questions regarding its interaction with the GDPR. Given their timing, the EDPB Guidelines are uniquely positioned to provide anticipatory clarification on these issues before the EHDS becomes fully operational.

All considered, while we welcome the Guidelines and their research-friendly approach, we identify a **number of issues that would benefit from further clarification by the EDPB**:

1. The notion of scientific research remains difficult to operationalise in practice. Further clarification is needed on the interpretation and relative weight of the criteria proposed in the Guidelines, particularly in emerging and interdisciplinary fields such as AI, digital health, and data-intensive research, where methodological and ethical standards are still evolving.

2. The Guidelines could further clarify **how the presumption of compatibility under Article 5(1)(b) GDPR should be applied in practice**, including the role of oversight mechanisms, the relationship between compatibility and legal basis assessments, and the conditions under which data transfers between independent controllers may benefit from this presumption.

3. While the recognition of broad consent and dynamic consent is welcome, additional guidance is needed on the **allocation of responsibilities where multiple controllers rely on the same broad consent**, and on the implications for transparency and the exercise of data subject rights.

4. Further clarification would be valuable regarding the practical application of Article 14 GDPR in large-scale research projects, particularly concerning the **scope of the disproportionate effort exemption** and its relationship with the obligation to inform data subjects.

5. The approach proposed for the right to erasure may lead to inconsistent outcomes depending on the timing of requests and the size of the dataset. **Additional operational guidance would help ensure consistent application of Article 17 GDPR** and avoid perceptions of unequal treatment.

6. The EDPB should further clarify the practical content and implementation of **Article 89 safeguards in contemporary data-intensive research environments**, including federated infrastructures, AI training settings, and large-scale data platforms, by specifying how technical measures such as minimisation, pseudonymisation, and access controls should interact with organizational governance and accountability mechanisms.

7. In light of the forthcoming implementation of the EHDS, further guidance is needed on the **interaction between the GDPR research regime and the EHDS framework**, including legal bases for processing, the notion of scientific research, and the relationship between consent-based research governance and EHDS access mechanisms.

More generally, greater alignment between the Guidelines and emerging sector-specific frameworks such as the EHDS would support legal certainty, consistent implementation across Member States, and the effective conduct of scientific research in Europe.

1. Definition of scientific research

While the Guidelines provide useful indications on the notion of scientific research, important uncertainties remain regarding the practical boundaries of this concept.

The Guidelines present six key-indicative factors that should be considered, in addition to the nature, scope, context and purposes of processing, to determine if a processing activity qualifies as scientific research. These factors include adherence to methodological and ethical standards (pt. i and ii), verifiability and transparency (pt. iii), and potential to contribute to existing scientific knowledge or apply existing knowledge in novel ways (pt. vi). Yet, the application of these criteria is not straightforward, and further guidance may be needed to address the following issues:

Adherence to methodological standards. This criterion may be difficult to apply in contemporary scientific research environments, notably in the health domain, where innovation increasingly occurs across disciplinary, institutional, and sectoral boundaries. In fields such as AI, digital health, and data-intensive research, methodological standards are often continuously evolving and may be shaped by a plurality of actors, including tech companies, rather than by established scientific communities alone. As a result, **it may be difficult to rely on continously evolving methodological standards as a criterion for determining whether a given activity qualifies as "scientific research"**. Consequently, the EDPB could clarify that reference to "methodological standards" should be interpreted flexibly and contextually, taking into account the maturity of the relevant research field. Where no widely recognised standards exist, the assessment should focus on whether the activity follows a transparent and systematic methodology according to the state-of-the-art, rather than requiring adherence to pre-established disciplinary norms.

Adherence to ethical standards. The Guidelines refer to compliance with "ethical standards" as a relevant factor in determining whether data processing qualifies as scientific research and, in several examples, make reference to ethics committee review or approval. However, **ethics requirements and ethical oversight arrangements for data-based research vary considerably across Member States, particularly in the context of secondary use of routinely collected health data**. For example, observational retrospective studies may be conducted without ethics committee approval in some jurisdictions, while in others they may be subject to review by ethics committees, data access bodies, or other institutional mechanisms (Marelli et al., 2026; Sanchini et al., 2025). As a result, researchers conducting substantively similar studies may be subject to very different oversight mechanisms and requirements depending on the national legal and institutional context. The EDPB may therefore wish to clarify that references to "ethical standards" should not be interpreted as presupposing a uniform model of ethics review across the EU, nor as implying that ethics committee approval is a necessary condition for processing to qualify as scientific research under the GDPR, but rather as adherence - at minimum - to ethics requirements enshrined in national frameworks, as well as international ethics norms, where applicable.

Verifiability and transparency. The criterion of verifiability and transparency rightly emphasises that research activities should enable hypotheses, methods, data, and conclusions to be subject to scrutiny and criticism, and that research results should be shared with others, especially by publishing such results. However, the Guidelines could usefully clarify how this criterion should be interpreted in fields characterised by rapid technological development and strong industry participation. In such contexts, verifiability and transparency may be achieved through mechanisms other than traditional scientific publication and peer review, including the release of technical documentation, benchmarks, evaluation protocols, open-source code, shared datasets, standards-development activities, or other forms of dissemination that enable scrutiny and reuse by the relevant research community. The EDPB could therefore consider clarifying: (i) that the qualification of an activity as scientific research should primarily depend on its epistemological function (i.e., the systematic generation of generalisable knowledge), rather than on the specific form of dissemination adopted, and (ii) which alternative means of sharing research results with third parties satisfy the new definition of scientific research.

Potential to contribute to existing scientific knowledge or apply existing knowledge in novel ways. The Guidelines state that, in order to qualify as scientific research, an activity should display scientific merit, which may be subject to assessment, review, or approval by independent experts or committees. However, while some forms of review, such as research grant evaluations, take place before the relevant processing begins, others, such as marketing authorisation procedures, are typically conducted only after the research has been completed. It therefore remains unclear how such ex post assessments should be taken into account, or how they could support a controller's initial determination that an envisaged processing activity qualifies as scientific research under the GDPR - and further guidance could be welcome in this regard.

Finally, and more generally, the Guidelines should clarify how the criteria listed in Section 2.1 should be applied in practice, whether any hierarchy exists among them, and whether they should carry different weight when assessing whether a processing activity qualifies as scientific research. While the Guidelines acknowledge that not all criteria must necessarily be met in every case, they provide limited guidance on how each criterion should be weighed, both individually and in relation to the others. In the absence of further clarification, controllers may be left to undertake this assessment solely on the basis of the accountability principle, without sufficiently clear points of reference. This could result in divergent interpretations and inconsistent qualification practices across organisations and Member States, potentially creating legal uncertainty and undermining legitimate scientific research activities.

2. Application of the Presumption of Compatibility under Article 5(1)(b) GDPR

2.1 Section 3.1.1 clarifies that further processing for scientific research purposes benefits from the presumption of compatibility under Article 5(1)(b) GDPR and therefore does not require the compatibility assessment under Article 6(4) GDPR. At the same time, the

Guidelines indicate that controllers must assess whether the intended secondary use genuinely qualifies as scientific research and may therefore rely on this presumption.

This raises questions regarding oversight and accountability. In practice, determining whether a processing activity qualifies as scientific research may involve complex legal, methodological, and ethical assessments. However, the Guidelines do not specify whether any form of oversight is envisaged in this context, nor what role, if any, may be played by ethics committees, data access bodies, supervisory authorities, or, where relevant, authorities established under sector-specific frameworks such as the EHDS. In this respect, the EDPB could usefully clarify whether controllers are expected to document such assessments in specific forms (e.g., as part of a DPIA, data management plan, or other internal governance instruments), and whether standardised criteria or checklists could support consistent application. Greater clarity on this point would help promote a more consistent application of the presumption of compatibility across research contexts and Member States.

2.2 Moreover, paragraph 21 of the Guidelines states that "*the possibility to rely on the legal basis that the initial processing was based on* requires an *assessment of lawfulness to determine that this legal basis is also suitable* to rely on for the further processing of personal data for scientific research purposes" (emphasis added). As a result, the lawfulness and suitability of the legal basis underlying the original processing must be reassessed before the presumption of compatibility under Article 5(1)(b) GDPR can be relied upon.

This additional assessment is not expressly envisaged by the GDPR, neither in Article 6(4), which governs compatibility assessments, nor in Article 5(1)(b), which establishes the presumption of compatibility for scientific research. More importantly, it risks undermining the practical value of that presumption, namely reducing administrative burdens and facilitating the use of data for research purposes. Moreover, in operational terms, while compatibility between the original purpose and scientific research is presumed, a finding that the original legal basis is unsuitable would require the controller to identify a new legal basis and, in substance, treat the research activity as a separate primary processing operation.

To preserve a coherent framework that effectively supports scientific research, particularly where such research is understood as serving important public interests, it may be preferable to extend the presumption of compatibility to the legal basis supporting the original processing, and not solely to the compatibility of the purposes, thereby remaining closer to the original rationale of Article 5(1)(b) GDPR.

2.3 Finally, Section 3.1.2 states that the transfer of personal data from Controller A to Controller B, where Controller B intends to process the data for scientific research purposes, may constitute further processing under the GDPR but does not require a compatibility assessment under Article 6(4) GDPR. This conclusion would benefit from further clarification. Where personal data has already been processed for an initial purpose, Controller A acts as a controller in relation to the disclosure of that data, which itself constitutes a further processing operation and would ordinarily require a compatibility assessment unless it independently qualifies as scientific research. By

contrast, the scientific research activity is carried out by Controller B as an independent controller and therefore constitutes a separate primary processing activity. It is therefore unclear on what legal basis the transfer by Controller A benefits from an exemption from the compatibility assessment, or what rationale supports this conclusion. Further clarification would help controllers determine under which circumstances this exemption may legitimately be relied upon and, if applicable, how the same line of normative reasoning could be applied in similar situations..

3. Broad consent

Clarifying the possibility of relying on alternative consent models, such as broad consent and dynamic consent, is welcome. However, as regards the practical implementation of these models, Section 4.1.2.1 suggests that multiple controllers may rely on a single instance of broad consent granted for a broad area of scientific research rather than for a specific research project.

This raises practical and interpretative questions that would benefit from further clarification. In particular, it is unclear whether such controllers should be regarded as joint controllers under the GDPR and, if not, which controller is responsible for fulfilling the obligations associated with the collection of broad consent and processing the corresponding personal data. Similar questions arise where subsequent research projects are conducted independently rather than within a joint controllership arrangement.

In such cases, further guidance would be helpful as to whether additional information obligations apply, including the provision of project-specific privacy notices, the identification of the controller responsible for each research activity initiated after broad consent was collected, or the communication of changes in controller contact details whenever the original controllers that rely on broad consent become responsible for different research projects afterwards. Clarification on these aspects is important not only to enable compliance with the GDPR, but also to ensure the effective exercise of the data subjects' rights. Without a clear allocation of responsibilities, data subjects may face difficulties in identifying the controller responsible for a particular research activity, thereby undermining transparency and accountability in practice.

4. Obligations to inform and derogations under Article 14 GDPR

The Guidelines provide extensive guidance on the obligation to inform data subjects when personal data are not collected directly from them (Section 5.4.2). However, the practical scope of this obligation appears uncertain in light of the broad interpretation of the derogations under Article 14(5) GDPR.

In particular, the Guidelines state that situations where informing data subjects is impossible will be rare, while also indicating that informing a high number of data subjects may constitute a disproportionate effort. In many areas of scientific research, including epidemiological research, this condition is routinely met, as projects often involve

thousands of individuals. As a result, the relationship between the general obligation to inform and the availability of the derogation remains unclear.

The EDPB may therefore wish to clarify how the obligation to inform should operate in practice in large-scale scientific research projects. In addition, further clarification would be welcome as to whether the factors mentioned under the disproportionate effort exemption, such as the high number of data subjects, difficulties in obtaining contact details, and the age of the data, should be assessed cumulatively or whether any one of them may be sufficient on its own to justify reliance on the exemption. Finally, clarification on the role of alternative transparency measures (e.g., information puiblished on institutional websites) would support controllers in implementing proportionate and effective information strategies.

5. Data Subjects' Rights - Rights to Erasure

Section 6.2 provides practical guidance on the operationalisation of the right to erasure in the context of scientific research. In particular, paragraph 120 states that, in order to rely on the exception under Article 17(3)(d) GDPR, the personal data subject to an erasure request must be strictly necessary for the research purpose, with this assessment to be conducted on a case-by-case basis.

While this pragmatic approach is generally welcome, it may give rise to practical challenges. The Guidelines suggest that, in the context of large datasets, the personal data of an individual data subject will often not be considered strictly necessary and may therefore be erased. Conversely, where datasets are smaller, the deletion of even a single participant's data may jeopardise the achievement of the research objectives and justify reliance on the exception.

This approach may lead to different outcomes for data subjects whose personal data are processed under otherwise comparable conditions. For example, where a controller manages a large dataset and receives a significant number of erasure requests over time, the data of early requesters may initially be considered non-essential and deleted. As the dataset progressively shrinks, however, subsequent requests could be refused on the grounds that further deletions would compromise the research. In practice, the outcome of an erasure request could therefore depend largely on the timing of the request rather than on any material difference in the circumstances of the data subjects concerned.

The Guidelines could usefully acknowledge this potential consequence and provide further operational guidance on how controllers should approach such situations, in order to promote consistent application of Article 17 GDPR and avoid perceptions of unequal treatment among data subjects.

6. Safeguards under Article 89 of GDPR

While the Guidelines refer to the requirement for appropriate safeguards under Article 89 of the GDPR, further clarification would be valuable regarding the practical content

and implementation of such safeguards in contemporary data-intensive research environments. Indeed, Article 89 of the GDPR establishes a central but open-ended requirement to implement "appropriate safeguards" for research processing. However, the provision does not define the specific nature or implementation of such safeguards. Given the increasing complexity of data-intensive research environments, which were in their infancy when the GDPR was drafted, additional guidance from the EDPB would be essential to ensure consistent and effective implementation across Member States.

In particular, it remains unclear how safeguards such as data minimisation, pseudonymisation, and access controls should be implemented in complex research infrastructures, including federated data systems, AI training environments, and large-scale data platforms. Furthermore, the relationship between technical safeguards and organizational measures, such as governance structures, data access committees, and accountability frameworks, could be further elaborated.

The EDPB may therefore wish to provide additional guidance, possibly including examples of best practice, to ensure that the safeguards set out in Article 89 are implemented in a manner that is both effective and compatible with the practical realities of scientific research.

7. Interaction between the GDPR and the European Health Data Space (EHDS) Regulation

The Guidelines could usefully provide further clarifications on the interaction between the GDPR legal framework for scientific research and the European Health Data Space (EHDS) Regulation. In light of the forthcoming implementation of the EHDS, the Guidelines provide a timely opportunity to anticipate key interpretative questions concerning the alignment of the two frameworks. Without such clarification, there is a risk that data users may face overlapping or potentially conflicting requirements when attempting to simultaneously comply with the GDPR and the EHDS framework.

7.1 Legal bases within the EHDS

Scientific research activities that process electronic health personal data will be significantly impacted by the EHDS, considering the inclusion of scientific research among the purposes for which this data can be processed for secondary use (Article 53(1)(e) EHDS). However, the interplay between the GDPR and the EHDS remains unclear, particularly regarding the identification of the appropriate legal bases and applicable derogations for the processing in question.

In particular, Recital 52 EHDS states that health data users remain responsible for identifying an appropriate legal basis under Article 6 GDPR. At the same time, the Recital provides that, where a health data user relies on Article 6(1)(e) or 6(1)(f) GDPR, the EHDS Regulation should provide the safeguards required under Article 9(2) GDPR.

In this regard, additional clarification would be welcome, first, on how the obligation to identify a legal basis under Article 6 GDPR should be interpreted where access to health data is authorised under the EHDS. This question is particularly relevant given: (i) the diversity of actors eligible to access data under the EHDS, including public research

organizations, healthcare providers, non-profit research institutes, pharmaceutical companies, and AI developers; and (ii) the heterogeneity of national legal frameworks across Member States.

Further guidance would help reduce the risk of divergent approaches to the identification of legal bases across Member States and provide greater certainty, for instance, for cross-border research projects conducted under the EHDS framework.

Second, further clarification would be valuable regarding the relationship between the EHDS and the requirements of Article 9 GDPR. Recital 52 suggests that the EHDS provides the safeguards required for the processing of special categories of personal data. However, Article 9(2)(j) GDPR requires not only appropriate safeguards, but also a basis in Union or Member State law. It remains unclear whether the EHDS framework is intended to fulfil, in whole or in part, this requirement, or whether data users must continue to identify a separate provision of Union or Member State law satisfying the conditions of Article 9(2)(j) GDPR.

These questions have significant practical implications for the implementation of the EHDS and for the conduct of scientific research based on health data across the European Union.

7.2 The Notion of Scientific Research under the GDPR and the EHDS

Further clarification on the relationship between the criteria proposed in the Guidelines for identifying scientific research under the GDPR and the concept of scientific research reflected in Article 53(1)(e) EHDS would be beneficial. The latter expressly includes among the purposes of secondary use of electronic health data scientific research activities related to the health and care sectors, including the training, testing, and evaluation of algorithms, AI systems, medical devices, in vitro diagnostic medical devices, and digital health applications.

This provision appears to encompass activities that may not necessarily satisfy all of the criteria identified in the Guidelines. For example, such activities may not always involve publication of results, formal ethical review, or a predominantly public-oriented research objective. As a result, uncertainty may arise as to whether certain activities that qualify as scientific research under the EHDS would also qualify as scientific research for the purposes of the GDPR.

The Guidelines could therefore usefully clarify the relationship between these two frameworks and explain how the criteria set out in Section 2.1 should be applied in the context of the EHDS. Such clarification would promote a more coherent and uniform interpretation of the legal framework governing the processing of health data for research purposes and support legal certainty for researchers, healthcare organisations, and other data users.

7.3 Consent and the interaction with the EHDS

The Guidelines provide welcome clarification regarding the use of broad consent in scientific research and appropriately recognise that research databases may be retained

and reused for future research projects. However, it remains unclear how this approach will interact with the governance framework established by the EHDS.

The EHDS introduces a model for secondary use of health data that is primarily based on statutory access regimes and opt-out mechanisms, rather than on consent. At the same time, existing consent-based research infrastructures, biobanks, and research databases will continue to operate alongside the EHDS. This creates the prospect of parallel governance regimes governing similar research activities.

In practice, important questions remain unresolved. For example: (i) How should broad consent obtained before the entry into application of the EHDS interact with subsequent access requests under the EHDS framework? (ii) What is the relationship between consent withdrawal and EHDS opt-out rights? (iii) And how should researchers approach data *collected* under consent-based arrangements and *accessed* through EHDS mechanisms?

The EDPB may therefore wish to provide further guidance on the interaction between consent-based research governance and the emerging EHDS framework. Such clarification would be particularly valuable in ensuring legal certainty and avoiding divergent interpretations across Member States during the implementation of the EHDS.

Table 1 – Synoptic presentation of recommendations

TOPIC	RECOMMENDATION
Definition of scientific research	The EDPB could clarify that reference to "methodological standards" should be interpreted flexibly and contextually, taking into account the maturity of the relevant research field. Where no widely recognised standards exist, the assessment should focus on whether the activity follows a transparent and systematic methodology according to the state-of-the-art, rather than requiring adherence to pre-established disciplinary norms.
	The EDPB may wish to clarify that references to "ethical standards" should not be interpreted as presupposing a uniform model of ethics review across the EU, nor as implying that ethics committee approval is a necessary condition for processing to qualify as scientific research under the GDPR, but rather as adherence - at minimum - to ethics requirements enshrined in national frameworks, as well as international ethics norms, where applicable.
	The EDPB could consider clarifying: (i) that the qualification of an activity as scientific research should primarily depend on its epistemological function (i.e., the systematic generation of generalisable knowledge), rather than on the specific form of dissemination adopted, and (ii) which alternative means of sharing research results with third parties satisfy the new definition of scientific research.
	In general, the Guidelines should clarify how the 6 factors listed in Section 2.1 to qualify a processing activity as "scientific research" should be applied in practice, whether any hierarchy exists among them, and whether they should carry different weight when assessing whether a processing activity qualifies as scientific research.
Application Presumption of	The Guidelines indicate that controllers must assess whether the intended secondary use genuinely qualifies as scientific research and may therefore rely on the presumption of compatibility under Article 5(1)(b) GDPR. To help promote a more consistent application of

Compatibility under Article 5(1)(b) GDPR	the presumption of compatibility across research contexts and Member States, the Guidelines could clarify whether data controllers are expected to document such assessments in specific forms (e.g., as part of a DPIA, data management plan, or other internal governance instruments), and whether standardised criteria or checklists could support consistent application.
	To preserve a coherent framework that effectively supports scientific research, particularly where such research is understood as serving important public interests, it may be preferable to extend the presumption of compatibility to the legal basis supporting the original processing, and not solely to the compatibility of the purposes, thereby remaining closer to the original rationale of Article 5(1)(b) GDPR.
Broad consent	The Guidelines (Section 4.1.2.1) suggest that multiple controllers may rely on a single instance of broad consent. In this regard, questions arise where subsequent research projects are conducted independently rather than within a joint controllership arrangement. In such cases, further guidance would be helpful as to whether additional information obligations apply, including the provision of project-specific privacy notices, the identification of the controller responsible for each research activity initiated after broad consent was collected, or the communication of changes in controller contact details whenever the original controllers that rely on broad consent become responsible for different research projects afterwards.
Obligations to inform and derogations under Article 14 GDPR	• The EDPB may wish to clarify how the obligation to inform data subjects should operate in practice in large-scale scientific research projects. • Further clarification would be welcome as to whether the factors mentioned under the disproportionate effort exemption, such as the high number of data subjects, difficulties in obtaining contact details, and the age of the data, should be assessed cumulatively or whether any one of them may be sufficient on its own to justify reliance on the exemption. • Clarification on the role of alternative transparency measures (e.g., information published on institutional websites) would support controllers in implementing proportionate and effective information strategies.
Data Subjects' Rights - Rights to Erasure	The Guidelines should provide further operational guidance on how Article 17(3)(d) GDPR should be applied when erasure requests are assessed in relation to the integrity of a research dataset. In particular, they should clarify how controllers should deal with cases in which the cumulative effect of multiple erasure requests may progressively affect the feasibility of the research. Without such guidance, comparable data subjects may receive different outcomes depending mainly on when they submit their request, rather than on meaningful differences in their situation. Further clarification would therefore help ensure consistency, transparency, and equal treatment in the application of the right to erasure in scientific research.
Safeguards under Article 89 of GDPR	The EDPB may wish to provide additional guidance, possibly including examples of best practice, to ensure that the safeguards set out in Article 89 are implemented in a manner that is both effective and compatible with the practical realities of data-intensive scientific research environments.
Interaction between the GDPR and the European Health Data Space (EHDS) Regulation	• Additional clarification would be welcome on how the obligation to identify a legal basis under Article 6 GDPR should be interpreted where access to health data is authorised under the EHDS. • Further clarification would be valuable regarding the relationship between the EHDS and the requirements of Article 9 GDPR. • Further clarification on the relationship between the criteria proposed in the Guidelines for identifying scientific research under the GDPR and the concept of scientific research reflected in Article 53(1)(e) EHDS would be beneficial. • The EDPB may wish to provide further guidance on the interaction between consent-based research governance and the emerging EHDS framework. For example: (i) How should broad consent obtained before the entry into application of the EHDS interact with subsequent access requests under the EHDS framework? (ii) What is the relationship between consent withdrawal and EHDS opt-out rights? (iii) And how should researchers approach data *collected* under consent-based arrangements and *accessed* through EHDS mechanisms?

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