CONFINDUSTRIA
Dispositivi Medici

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

Confindustria Dispositivi Medici, the national association of Confindustria (General Confederation of Italian Industry) representing companies operating in the medical devices and biomedical technologies sector in its broadest sense, wishes to submit the following observations in response to the public consultation launched by the European Data Protection Board (EDPB) concerning the Guidelines 1/2026 on the processing of personal data for scientific research purposes (hereinafter, the "**Guidelines**").
The following observations are provided with a view to contributing to the interpretative and practical debate on the relationship between personal data protection and scientific research.

Paragraph 2.1 "Key-indicative factors for determining whether processing of personal data is motivated by scientific research purposes"

The Guidelines, at points 11–12, identify six relevant factors for qualifying processing as scientific research under the GDPR: (i) methodical and systematic approach; (ii) adherence to ethical standards; (iii) verifiability and transparency; (iv) autonomy and independence; (v) objectives of the research; (vi) potential to contribute to existing scientific knowledge or apply existing knowledge in novel ways.

Comment: Point 12 of the Guidelines does not clearly define whether the six identified factors constitute requirements that must all be jointly fulfilled in every case, or whether the qualification of an activity as scientific research may result from an overall and contextual assessment of the various elements.
This uncertainty has significant practical implications, as a strictly cumulative interpretation could unduly restrict the scope of the concept of scientific research, excluding activities that fully exhibit some of the characteristics identified in the Guidelines, while others may be less pronounced or take different forms depending on the specific research context.

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Paragraph 3.1. "Purpose limitation (Article 5(1) GDPR)"

The paragraph clarifies that, in the case of further processing of personal data for scientific research purposes, it is not necessary to carry out the compatibility test provided for in Article 6(4) GDPR. However, such a test must still be carried out where the primary purpose of the processing is scientific research, but the further processing is carried out for different purposes. In this respect, the EDPB has already stated that, under certain conditions and subject to appropriate safeguards pursuant to Article 89(1) GDPR, the controller may rely on the legal basis of the initial processing also for further processing of personal data for scientific research purposes. This, in any event, requires a lawfulness assessment aimed at determining whether the legal basis used for the initial processing is also suitable for the further processing.
The Guidelines note that, while in many cases the same legal basis of the initial processing may be maintained (e.g. public interest or legitimate interest), this would not be possible in other cases, particularly where the initial processing is based on consent or a legal obligation.

Comment: The wording of the paragraph could be interpreted as generally excluding the possibility of relying, for further processing for scientific research purposes, on the same consent obtained for the initial processing. Such an interpretation would risk significantly limiting the reusability of personal data already collected in the context of research or development activities.
As drafted, it could be inferred that where the initial processing is based on consent, it would never be possible to rely on the same legal basis for subsequent scientific research processing. A similar uncertainty arises with regard to processing originally based on a legal obligation, which point 22 appears equally to exclude.
This approach would deserve clarification in light of Recital 50 GDPR, also referred to by the EDPB at point 20, according to which, for further processing for scientific research purposes, "*no legal basis separate from that which allowed the collection of the personal data is required*". Taken together, points 20 and 22 may give rise to a potential interpretative tension: while point 20 seems to allow, in principle, continuity of the legal basis in the context of data

reuse for research, point 22 could be read as introducing limitations not expressly provided for in Recital 50.
Such an interpretation could create practical uncertainties with respect to legacy datasets, processing originally based on broadly informed consent, as well as data collected in compliance with legal obligations and subsequently reused for scientific research purposes (e.g. in Post-Market Surveillance and Post-Market Clinical Follow-up).
It is therefore suggested to clarify that the use of consent – as well as other original legal bases, where compatible with the applicable legal framework – is not generally excluded for further processing for scientific research purposes, but should be assessed on a case-by-case basis, in light of the original legal basis, the compatibility principle, and the safeguards laid down in Article 89(1) GDPR.

Paragraph 4.1. "Consent (Article 6(1)(a) GDPR)"
Point 38 states that: "*A controller can obtain a single consent for clinical research that involves the processing of personal data which are necessary both for the purposes of providing healthcare and conducting scientific research, since those purposes are interrelated. However, a controller cannot ask a data subject to consent to the processing of personal data for scientific research purposes as a condition for providing healthcare or other services, if those purposes for processing are not necessary for and interrelated with the conduct of scientific research*".

Comment: It is suggested to revise the wording of this paragraph, as it could be interpreted as conflating consent as a legal basis under the GDPR (Article 6(1)(a) and/or Article 9(2)(a)) with ethical-clinical consent to participate in clinical research.
Under the GDPR, processing for healthcare purposes is generally based on Article 9(2)(h), whereas processing for scientific research purposes may rely either on consent under Article 9(2)(a) or on a derogation under Article 9(2)(g), (i), or (j). Therefore, referring to a "*single consent*" covering both purposes risks creating interpretative uncertainty.
It would therefore be useful to clarify whether point 38 refers exclusively to the possibility of collecting, at a single operational moment, distinct and functionally autonomous expressions

of will. In any event, it should be made explicit that the legal basis for processing for healthcare purposes remains Article 9(2)(h).

Paragraph "4.1.2.1 Broad consent"

Point 43 provides that: "*A controller can obtain broad consent from data subjects when collecting and storing personal data for processing in future research projects within certain areas of scientific research. In certain cases, several controllers can rely on the same broad consent*".

Comment: The paragraph allows multiple controllers to rely on the same broad consent but does not clarify the implications of this approach for the qualification of roles and information obligations.

It should be clarified that reliance on shared consent does not automatically give rise to joint controllership, nor does it exclude independent controllership, which must be determined based on the actual determination of purposes and essential means.

It would also be useful to clarify whether consent may be collected from the outset with a view to involving additional controllers identifiable at a later stage, without prejudice to each controller's obligation to comply with Articles 13 and 14 GDPR.

An explicit alignment with the section on roles and with the examples in the Guidelines would reduce practical uncertainty.

On the same topic, point 44 provides that: "*With regard to broad consent, the EDPB has stated that the GDPR cannot be interpreted in a way that allows controllers to navigate around the key principle of specifying the purposes for which consent of the data subjects is asked. Accordingly, controllers cannot ask data subjects to consent to the processing of their personal data without any specification of the purposes for which the data will or may be processed and it is not sufficient to only state that personal data will be used for scientific research purposes. Therefore, controllers intending to process personal data for scientific research purposes on the basis of broad consent should define the purposes of future research as clearly as possible*".

Comment: The point in question requires that the purposes of future research be described "*as clearly as possible*" but does not provide useful criteria for translating this standard into operational terms.
Given that the level of specificity required constitutes a key element for the validity of broad consent, it would be appropriate to supplement the paragraph with practical examples distinguishing overly generic formulations from sufficiently specific descriptions.
Such assessment could be anchored to the ability of the data subject to understand the scientific scope within which the data may be reused (for example, therapeutic area, disciplinary field, target population, type of research or intended research infrastructure), without requiring the *ex ante* identification of each individual project.
It is also suggested to clarify the coordination with data-sharing models and with data altruism scenarios, where consent is collected to enable the reuse of data across multiple research activities carried out by the same entity or within dedicated research infrastructures.

On the same topic, point 45 provides that: "*The delimitation of the purpose should enable controllers to determine what personal data are necessary to process and make it possible for data subjects to understand what purposes of processing they are consenting to. The purpose for processing can be delimited to a certain field of research, for example medical research in the field of oncology, or sociological research in the field of criminology (…)*".

Comment: The Guidelines identify reference to a research field as a possible criterion for delimiting the purpose and refer, amongst other examples, to medical research in the field of oncology. However, this example leaves considerable room for interpretation: it is not clear what level of granularity should be regarded as sufficient for the validity of broad consent.

On the same topic, paragraph 46 provides that: "*(…) Thereafter, when the purposes of processing for individual research projects (or stages thereof) become known and before the processing is initiated, the controller should consider if the processing of personal data in those projects will be undertaken inside the boundaries of the broad consent (…).*"

Comment: The paragraph assigns a central role to the verification of consistency between each individual research project and the scope of the original broad consent, with reference to the reasonable expectations of the data subjects. This step is decisive in determining whether processing may continue on the basis of the consent already obtained or whether additional mechanisms, such as dynamic consent, should be used.
However, the Guidelines only refer in general terms to the involvement of representative groups of data subjects, without defining sufficiently structured operational criteria for carrying out such an assessment. It would therefore be useful to supplement the paragraph with methodological guidance on the main elements to be considered, such as: the relationship between the project and the originally communicated research area; the possible introduction of new categories of data or additional actors involved in the processing; the time elapsed since the initial consent, etc.
Finally, the reference in point 48 to ethical considerations relating to communication with participants would benefit from further systematisation, clarifying whether such considerations form part of the assessment of reasonable expectations or constitute an autonomous obligation, in order to avoid procedural overlaps that may hinder the practical implementation of broad consent.

On the same topic, points 48 and 49 list a number of safeguards to compensate for the lack of specificity of purposes in broad consent: "*(…) In addition, controllers should adopt measures that enable data subjects to receive information about the processing of their personal data, for example by subscribing to a newsletter. The modality for receiving information and its regularity should be determined in line with the wishes of the data subject, as well as legal requirements or ethical considerations for communication with participants in research projects.*" and (…)"*Safeguards may include, among others, measures for use and access controls (such as an independent data trustee), time-limited validity of consent or an independent oversight body. An oversight body may include a representative of the research participants, experts in the respective scientific research field, experts in data protection, as well as the data protection officer (DPO) (…)*".

Comment: Point 49 does not clarify whether the measures aimed at strengthening the protection of data subjects in the context of broad consent (including continuous update tools, governance mechanisms, time limits and preference management tools) should be regarded as requirements to be applied cumulatively or as examples of safeguards to be selected depending on the characteristics of the processing. Clarification on this point would be relevant from an operational perspective. A strictly cumulative reading would risk imposing, in all cases of broad consent, the adoption of additional organisational structures and tools even in research contexts already characterised by well-established governance frameworks and adequate data protection measures.

It would therefore be useful to specify that the safeguards referred to in point 49 constitute a set of tools to be applied according to a proportionality-based approach, to be tailored taking into account the nature of the research, the categories of data processed, the scale of processing, the level of risk and the governance measures already in place. In particular, in research contexts subject to specific sectoral regulations – including activities governed by the regulatory framework for medical devices and in vitro diagnostic medical devices – the existence of already structured mechanisms for oversight, ethical review and security of processing may affect the need to introduce additional layers of control.

It would also be useful to clarify that broad consent collected for scientific research purposes may legitimately support subsequent research activities carried out also by private entities or within public–private collaborative settings, provided that such activities fall within the research scope originally presented to the data subject and that the applicable requirements in terms of transparency, security and safeguards under Article 89(1) GDPR are complied with.

Such clarification would be particularly relevant in relation to biobanks, registries and research datasets managed by healthcare institutions or research infrastructures, where the reuse of data and samples by entities other than the one that collected the consent constitutes a standard practice in the development of scientific research.

Finally, the reference to the temporal validity of consent could be further clarified by specifying that the duration of broad consent should be assessed in line with the lifecycle of the research

project and with the retention period communicated to the data subject, without prejudice to the possibility of withdrawal of consent pursuant to Article 7(3) GDPR.

Paragraph 4.4.3 "Derogations under Union or Member State law (Article 9(2)(g), (i), (j) GDPR)"

Point 73 provides that: "*Controllers may rely on derogations to the prohibition of processing of special categories of data provided for by Union or MS law, pursuant to Article 9(2)(g), (i) and (j) of the GDPR, when processing personal data for scientific research purposes (…)*".

Comment: The paragraph in question should be supplemented with more detailed guidance on the requirements that provisions of Union or Member State law must meet to serve as a legal basis for processing pursuant to Article 9(2)(g), (i) and (j) GDPR.
The reference to the need for such provisions to comply with the principle of proportionality and to provide for appropriate and specific safeguards for data subjects does not, at present, make it sufficiently clear what level of legislative detail is required to render these legal bases effectively usable in practice.
The absence of operational criteria and practical examples results in significant interpretative uncertainty and may lead, in practice, to limited reliance on the derogations expressly provided for by the Regulation, with a consequent predominance of consent even in contexts in which the European legislator has provided for alternative legal bases.
It is therefore suggested that the paragraph be supplemented with illustrative examples or guiding criteria concerning the minimum elements that national or Union provision should contain.

On the same topic, point 75 provides that: "*Finally, the EDPB notes that reliance on Article 6(1)(f) GDPR in the context of medical research (such as clinical trials) also requires the application of a derogation, pursuant to Article 9(2) GDPR. One example of a provision in Union law that provides for a derogation pursuant to Article 9(2) GDPR is Article 53(1)(e) in the European Health Data Space Regulation (EHDS)*".

Comment: The reference to the EHDS represents a particularly relevant element for understanding the relationship between the derogations set out in Article 9(2) GDPR and the European regulatory framework governing the reuse of health data for research purposes.
However, the reference to Article 53(1)(e) EHDS does not clarify whether that provision should be construed as sufficient, in itself, to meet the requirement laid down in Article 9(2) GDPR – in conjunction with the safeguards provided for in Article 89(1) – or whether the derogation should instead be interpreted in light of the overall system of rules established by the EHDS for the secondary use of health data.
Clarification on this point would be particularly useful to distinguish between the lawfulness of processing under the GDPR and the operational conditions potentially laid down by sector-specific EU legislation.
It is therefore suggested to clarify to what extent access to the governance mechanisms provided for by the EHDS (such as authorisations, competent bodies or secure processing environments) constitutes a prerequisite for relying on the derogation, or whether it represents an additional layer of regulation applicable only in cases falling within its scope.
Furthermore, considering that point 75 refers to the context of "medical research (such as clinical trials)", it would be useful to clarify whether the same reasoning concerning the interaction between Article 6(1)(f) GDPR and the need for a derogation under Article 9(2) GDPR should be deemed applicable also to other clinical research contexts governed by Union law, including those relating to medical devices and in vitro diagnostic medical devices. Such clarification would help avoid interpreting the reference to clinical trials as limited to studies governed by Regulation (EU) No 536/2014, thereby unduly excluding clinical investigations and performance studies regulated under the sector-specific framework for medical devices.

Paragraph "6.2.2 Exceptions from the obligation to erase personal data upon request (Article 17(3) GDPR)"

With reference to points 119 and 120, these examine the application of the right to erasure (Article 17 GDPR) in the context of processing carried out for scientific research purposes. In particular, they refer to the exception provided for in Article 17(3)(d) GDPR, according to

which the right to erasure may not apply where processing is necessary for scientific research purposes and the exercise of the right is likely to significantly compromise or hinder the achievement of the research objectives, provided that the safeguards referred to in Article 89(1) GDPR are implemented. The Guidelines further clarify that this exception requires a case-by-case assessment, based on criteria of necessity and proportionality.

Comment: The approach adopted by the Guidelines appears appropriate insofar as it confirms that the application of the exception requires a concrete assessment of the impact that the erasure of data may have on the pursuit of research purposes.
However, the reference to an individualised assessment does not clarify to what extent the controller may take into account constraints and requirements already arising from the regulatory and methodological framework within which the research is carried out.
This issue is particularly relevant in research contexts subject to specific requirements in terms of data quality, integrity, traceability and retention, including those governed by the regulatory framework applicable to medical devices and in vitro diagnostic medical devices. In such situations, the erasure of individual data points may affect the methodological validity of the study, the completeness of the dataset and the reliability of the analyses carried out.
It is therefore suggested to clarify that, within the assessment required under Article 17(3)(d) GDPR, the controller may also rely on documented elements arising from the applicable regulatory framework and from the methodological structure of the research, without necessarily requiring a separate and individual justification for each erasure request, without prejudice to compliance with the accountability principle and the safeguards set out in Article 89(1) GDPR.

Paragraph 7.1 "Controller"

Point 136 of the Guidelines addresses the qualification of the research sponsor as the controller for personal data collected in the context of clinical research activities, recalling the principle that the entity which determines the purposes and essential means of processing assumes the role of controller pursuant to Article 4(7) GDPR. Healthcare institutions involved

may, depending on the specific configuration of the processing, act as joint controllers, processors or independent controllers for processing operations relating to healthcare.
At points 140–145, the Guidelines further develop the concept of joint controllership under Article 26 GDPR in research context carried out through collaborative arrangements, emphasising the need to determine roles based on the actual participation in determining the purposes and means of the processing and to regulate respective responsibilities in a transparent manner.

Comment: The approach set out in the Guidelines appears to be consistent with established principles concerning the qualification of privacy roles. However, the analysis remains necessarily general and does not address certain operational configurations that are becoming increasingly relevant in clinical research and in the generation of evidence in the field of medical devices and in vitro diagnostic medical devices.
In particular, it would be useful to provide further guidance on the criteria for defining roles in relationships between sponsors and entities providing specialised research services or technological platforms; in cases where data collected for research purposes coexists with data processed as part of healthcare activities; in models involving the use of samples and datasets from biobanks or research infrastructures; as well as in decentralised or hybrid configurations involving digital tools, connected devices and remote data collection services.
Further clarification would also be useful with regard to multicentre studies and collaborations between public and private entities, including scenarios in which data are shared or reused through research infrastructures or access models governed by sector-specific EU legislation.
It is therefore suggested to integrate the Guidelines with practical examples illustrating the criteria for distinguishing, across different operational configurations, between independent controllership, joint controllership and processing on behalf of a controller, as well as the practical implications in terms of transparency, the exercise of data subject rights and the allocation of responsibilities.