IPMPC
International Pharmaceutical & Medical Device Privacy Consortium

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IPMPC Response to the European Data Protection Board's Public Consultation on Guidelines 01/2026 on Processing of Personal Data for Scientific Research Purposes

The International Pharmaceutical and Medical Device Privacy Consortium (IPMPC) appreciates the opportunity to comment on the European Data Protection Board (EDPB) Guidelines 01/2026 on Processing of Personal Data for Scientific Research Purposes (hereinafter, 'the Guidelines'). The IPMPC supports the EDPB's efforts to promote clarity and consistent application of data protection requirements across the EU.

The IPMPC is a global privacy and digital policy organisation focused on the concerns of the pharmaceutical and medical device industries. With over 45 member companies and hundreds of member participants from around the world, the IPMPC strives to advance members' compliance with privacy, security, AI, and other digital governance obligations, with the ultimate aim of supporting innovation in health diagnostics, treatments, and disease prevention, and enabling the delivery of life-saving and quality-enhancing health care to patients.[1] For 25 years, the IPMPC has actively engaged with policy makers and data protection authorities across Europe to facilitate regulators' understanding of why and how data is processed in the pharmaceutical and medical device industries and to promote policies that align regulatory goals with members' data needs.

The medical technology and pharmaceutical industries share a long history of and commitment to advancing medical science. By turning scientific research into solutions for patients, healthcare professionals, and health systems, the medtech and pharmaceutical industries have contributed to better outcomes for patients and greater efficiency in healthcare.

A. Executive Summary

- A number of the issues addressed in the Guidelines are currently being discussed by the European Parliament and Council as part of the Commission's proposed Digital Omnibus and Biotech Act proposals. Given the significance of these issues to achieving the EU's overall research and innovation goals, it is important that legislators weigh in directly through this legislation. The EDPB should acknowledge that the Guidelines may ultimately need to be amended based on the outcomes of these legislative discussions.

[1] More information about IPMPC is available at www.ipmpc.org. Faegre Drinker Biddle & Reath LLP serves as Secretariat and Legal Counsel to the IPMPC.

- The EDPB's suggested 'key-indicative factors' for determining whether processing of personal data is for scientific research purposes introduce considerations that do not have a basis in the text of the GDPR. The core criteria for determining whether an activity qualifies as 'scientific research' are much simpler: Does the activity aim to create scientific knowledge, and does the activity follow a methodical and systematic approach, in as objective a manner as reasonably feasible, with the aim of achieving verifiable results?
- Medical research requires processing of personal health data, and with respect to the issue of lawfulness of processing, the key question is what derogation can be relied upon under Article 9(2). The 'processing for scientific research' derogation requires a basis in EU or Member State law, which presents an obstacle where this derogation has not been clearly incorporated into a European law. The EDPB must do further work to identify applicable EU and member state laws that implement or otherwise serve as a basis for the Article 9(2)(j) derogation and to explain when each law might apply.
- The Guidelines express the EDPB's view that the anonymisation of data is itself a processing operation that must meet GDPR lawfulness requirements, such as the need for a legal basis under Article 6 and for a derogation under Article 9(2) for processing of sensitive personal data. With respect to anonymisation of data for purposes of scientific research, the EDPB should affirm that Article 89(1) of the GDPR itself provides the basis in law required for the application of the derogation in Article 9(2)(j).[2]
- Obtaining the consent of the data subject to processing of personal health data in areas of medical research is one means of compliance with Article 6 and 9 requirements. Where the purpose for processing has been delimited to a field of medical research or aims, it is inappropriate to layer additional transparency requirements that are not set forth in the enacting terms of the legislation.
- The statement in the Guidelines that researchers must obtain contact details of data subjects when processing of personal data over longer periods of time in order to fulfil informational obligations conflicts with data minimisation obligations and the express language of Article 11.
- Contributing to the development of a research protocol does not in and of itself imply controllership of personal data for GDPR purposes. Only the entities that have actual control over decisions concerning the processing of personal data are controllers, and while contributing to the development of a research protocol can in some cases be an indirect indication of control, it is not dispositive.

[2] Article 89(1) states that if the scientific research purposes for processing can be achieved by processing of anonymised data, then such purposes must be fulfilled in this manner. It logically follows that the controller must be permitted to anonymise the data for these purposes, otherwise this Article 89(1) condition could present a paradoxical "catch-22" scenario.

- The lack of harmonisation of requirements for processing of personal data in scientific research activities across the EU requires legislative intervention at the Union level. The IPMPC supports the Commission's efforts to address this through the Digital Omnibus and Biotech Act proposals.

B. Introduction

Pharmaceutical and medical device companies engage in a range of biomedical research activities with the goal of developing and deploying new drugs and medical technologies to address public health needs. Researchers at pharmaceutical and medical device companies need access to patient health data to study disease progression and the effectiveness of potential therapies. Personal health data is critical to this research. In both the recitals and operative text, the GDPR recognises the importance of privately funded biomedical research and aims to provide appropriate flexibility in the application of data protection requirements.

Example: Real-World Data

Real-world data refers to data collected outside of randomised controlled trials. In a randomised controlled trial, participants are randomly allocated to either a group receiving the drug, device, or other treatment under investigation or a group receiving standard treatment or a placebo treatment as the control, and data is pseudonymised prior to any data analysis being performed. While randomised controlled trials are generally considered the 'gold standard' for demonstrating safety and efficacy, there are inherent limitations. For example, some experimental questions do not allow for random allocation of treatments due to ethical concerns. Moreover, the population as a whole tends to be more heterogeneous than the population of individuals who participate in clinical trials. The behaviour of patients and clinicians is also more variable in the real world than in controlled, experimental settings. As a result, an 'efficacy-effectiveness gap' can occur – i.e., a gap between the 'efficacy' of a test article as measured in randomised controlled trial settings and the 'effectiveness' as measured in real-world, clinical practice.

Collection and analysis of real-world data serve a number of important research purposes. First, it enables a more robust assessment of the safety and effectiveness of a health care product in clinical practice. This includes the identification of populations for whom the product is more, or less, safe/effective. This information, in turn, informs clinical decision-making and, in some cases, can even lead to a change in product labelling (e.g., new indications, contraindications, possible side effects). Second, it enables the evaluation of the relative effectiveness of a new product as compared with other, existing products in clinical practice. This also informs clinical decision-making and can influence reimbursement decisions.

Real-world data can be obtained by conducting new studies or by utilising existing data sources. If the researcher desires to collect or use new data, experimental studies with methodologies that deviate from typical randomised controlled trials can be designed, or observational studies without any experimental interventions can be conducted in accordance with guidelines for good epidemiological practice. In many cases, however, existing data sources, such as electronic health records (EHRs) or health claims databases, may meet a researcher's needs. When utilising existing data sources, obtaining informed consent of data subjects is often impractical due to the time, cost, and effort involved.

Example: Secondary Research Using Clinical Trial Data

Scientific research is often an iterative process in which the results of one study are used to design future studies. In the course of a clinical trial, researchers may notice results that were unexpected and require further investigation. They may wish to analyse the data collected in ways that were not originally envisioned in the clinical trial protocol. More generally, as scientific understanding evolves, researchers' questions may evolve as well. Analysis of existing clinical trial datasets may enable researchers to answer these new questions without having to design and run entirely new clinical trials. This is important not only for purposes of efficiency but also to avoid exposing research participants to unnecessary risks when existing data sources could answer the scientific question.

When individuals enrol in a clinical trial, they may be informed that the data collected about them may be used in future research projects, such as research relating to the same test article or research relating to the same disease or condition in question, or more broadly to research relating to disease mechanisms generally. Such 'future research' usually cannot be described with the same level of specificity as the information in the clinical trial protocol itself because the details of the future research are unknown at the time of data collection and could be further informed by the results of the of the trial itself.

C. Qualification as 'Scientific Research'

The Guidelines seek to fill a gap in terms of the lack of a definition of 'scientific research' in the operative text of the GDPR. The Guidelines would make significant EU policy decisions that go far beyond 'issu[ing] guidelines, recommendations and best practices in order to encourage consistent application of [the GDPR].'[3] It is more appropriate, however, for this definitional gap to be filled through the EU legislative process by the European Parliament, the Council, and the European Commission than by the EDPB itself. For this reason, the IPMPC supports the Commission's proposal in the Digital Omnibus to incorporate a definition of 'scientific research' into the operative text of the GDPR.

The EDPB's suggested 'key-indicative factors' for determining whether processing of personal data is for scientific research purposes introduce considerations that do not appear to have a basis in the current text of the GDPR. These factors risk operating as a de facto cumulative test that effectively creates a presumption against an activity qualifying as 'scientific research' unless all six factors are met. The Guidelines are in tension with the legislators' own contextual guidance in Recital 159 that 'scientific research purposes' should be interpreted in a broad manner: 'For the purposes of this Regulation, the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research.' Paragraph 12 of the Guidelines should be revised to make unambiguously clear that the absence of one or more factors does not create a presumption against qualification as scientific research.

[3] Article 70(1)(e) GDPR.

Several factors included in the Guidelines need reconsideration and confuse legal and ethical requirements that arise under other research laws and standards from data protection compliance requirements. The IPMPC recommends that the EDPB instead consider a much simpler set of core criteria for determining whether an activity qualifies as 'scientific research':

(1) Does the activity aim to create scientific knowledge?
(2) Does the activity follow a methodical and systematic approach, in as objective a manner as reasonably feasible, with the aim of achieving verifiable results?

a. Key Factor: 'Autonomy and Independence'

The Guidelines state that one of the six key factors is whether '[t]he research activities are conducted autonomously and independently in relation to the prejudices of the scientific community and other external parties, as well as the researcher's own prejudices, in an environment free from undue pressure.' According to the Guidelines, '[t]his means that the research team has the freedom to define research questions, identify methods by which problems are solved, choose and develop scientific theories, as well as the freedom to disseminate and publish the results of their research.'[4]

While scientific research should strive for objectivity, the EDPB has instead focused the above factor on the independence and autonomy of the researchers, rather than on whether their research activities are conducted objectively. The EDPB's phrasing that such autonomy and independence is to be examined 'in relation to the prejudices of the of the scientific community and other external parties, as well as the researcher's own prejudices'[5] is indecipherable and will undoubtedly lead to confusion as to whether the focus is intended to be on the independence of the researchers or, rather, on the objectivity of their research methods. Example 3 of the Guidelines – in which the EDPB concludes that an activity is not 'scientific research' in part because '[i]t is not carried out by independent and autonomous researchers, but by marketing experts within the company' – simply highlights this lack of clarity.

Researchers, like all humans, have inherent biases, whether related to institutional affiliation, ideology, belief system, source of funding, or any other influence. Research activities are always subject to constraints, such as time, effort, and resources that are needed. Scientific research ethics standards acknowledge such biases and constraints but seek to encourage conducting research activities following a methodical and systematic approach, in as objective a manner as reasonably feasible, with the aim of achieving verifiable results. The EDPB's 'key-indicative factors' should follow a similar approach.

[4] Guidelines at ¶ 11(iv).

[5] Guidelines at ¶ 11(iv).

b. Key Factor: 'Objectives of the Research'

The Guidelines suggest that another factor to be considered is whether '[t]he research activities are carried out with the aim of contributing to the growth of society's general knowledge and wellbeing.'[6] This factor also invites questions as to its interpretation. For example, how is 'wellbeing' to be evaluated? Would research that leads to discoveries protected as intellectual property or trade secrets qualify? And for that matter, how is this factor intended to be different from the 'verifiability and transparency' factor and the 'potential to contribute to existing scientific knowledge or apply existing knowledge in novel ways' factor that the Guidelines separately propose? A more appropriate criterion would be simply whether the research activity aims to create scientific knowledge.

c. Key Factor: 'Adherence to Ethical Standards'

The Guidelines highlight 'adherence to ethical standards in the relevant research field' as another key indicative factor of 'scientific research'. The IPMPC agrees that adherence to ethical standards is an important element of responsible research. However, to avoid any misunderstanding, we encourage the EDPB to expressly acknowledge that this factor does not require independent ethics committee review except in situations where such independent oversight is otherwise legally required.

d. Key Factor: 'Verifiability and Transparency'

The Guidelines state that another factor is whether '[t]he results of the research are shared with other parties, for example by publication, or will be shared in the future, with due regard to legitimate limitations to access such as protection of intellectual property and trade secrets.'[7] The EDPB's acknowledgement here is welcome that the need for IP and trade secrets protections may impact sharing of results. Indeed, innovation in the pharmaceutical and medtech sectors relies upon adequate protection of intellectual property, and IP considerations play a critical role in deciding whether and when to publish the results of drug and device research. Overall, there are a number of considerations that may impact the publication or open sharing of scientific research results, including commercial considerations and costs of publication. For example, the costs of publishing research that fails to achieve its objectives may be viewed as outweighing the value of publication. – If a researcher reasonably concludes that the time and effort needed to publish the results of failed research outweigh any benefits, this decision should have no bearing on whether the underlying investigation qualifies as 'scientific research'. The legal and ethical obligations to publish research findings vary by type of research, but this is a matter for other research laws and standards, not a matter of data

[6] Guidelines at ¶ 11(vi).

[7] Guidelines at ¶ 11(iii).

protection compliance – at least not without legislators expressly incorporating this as a requirement into the text of the GDPR.

D. Lawfulness of Further Processing for Scientific Research

EU legislators recognised the importance of processing personal data for scientific research purposes and put in place a framework that was intended to facilitate the use and re-use ('further processing') of personal data for such purposes. Unfortunately, that framework has failed to fully deliver on its potential, largely because of inconsistent member state rules and interpretations, as well as an apparent fear by the EDPB that the scientific research provisions could be misused. These issues are particularly acute in the context of health research, due to the more stringent requirements that apply to processing of sensitive data.

Recital 50 of the GDPR makes clear that it was the intent of the legislators to provide that further processing of personal data for scientific research purposes is deemed both compatible with the purposes for which the personal data were initially collected and lawful in accordance with Articles 6 and 9: 'Further processing for […] scientific […] research purposes […] should be considered to be compatible lawful processing operations.'[8] To be lawful, processing of personal data must, inter alia, have a legal basis under Article 6 and, if sensitive personal data is involved, meet a condition under Article 9(2).[9] The inclusion of the word 'lawful' in Recital 50 clearly demonstrates the legislators' intent for the requirements of Articles 6 and 9 to be deemed satisfied in the context of scientific research. Nevertheless, it can be inferred from paragraph 21 of the Guidelines that the EDPB does not believe that the enacting terms, in fact, actually accomplish this. If so, the EDPB should be clearer in the Guidelines as to this disjunction so that legislators can address it in their consideration of the Digital Omnibus legislation.

In any event, a consequence of the EDPB's position is that further processing of personal health data for scientific research purposes must meet a derogation under Article 9(2). While Article 9(2)(j) facially presents the most obvious option for such a derogation, the criterion in Article 9(2)(j) that this processing must be 'based on Union or Member State law' has proven to be a significant limitation. The Guidelines should more completely set forth (i) what EU laws meet this criterion, and (ii) which member states have enacted such laws as well as details of when each law applies.[10] In addition to assisting the scientific research community in

[8] Please note that the EDPB's quotation of Article 50 in paragraph 20 of the Guidelines contains some errors.

[9] *Cf.* Recitals 40 and 51 concerning the 'lawfulness' of processing.

[10] Although footnote 115 provides '[e]xamples of Union and MS laws that are intended to provide derogations for processing of personal data for scientific research purposes,' it also states that '[t]his list is not exhaustive as to the derogation in EU or MS law that could be relevant. […] The EDPB has not reviewed nor analysed the laws referred to.' This is a missed opportunity.

identifying such laws and the associated requirements, this would assist policy makers in understanding where there may be gaps that need to be filled through additional legislation.

The IPMPC welcomes the EDPB's acknowledgement that the European Health Data Space (EHDS) is an example of an EU law that provides a derogation for the processing of health data for scientific research purposes in accordance with Article 9(2)(j) GDPR. However, an expansion of this section of the Guidelines is needed to address in which cases Article 53(1)(e) of the EHDS can be relied upon for processing of health data for scientific research purposes. For example, is this limited to health data users who have received a data permit issued pursuant to Article 68 EHDS? Is a data controller that wishes to use its own data for the same purpose that it could make data available to a third party under the EHDS, also able to rely on Article 53(1)(e) EHDS or is it disadvantaged? Further guidance here would be appreciated.

E. Lawfulness of Anonymisation

The Guidelines note that '[t]he anonymisation process itself […] is a processing operation under the GDPR that must comply with the provisions of the GDPR, including the data protection principles and the requirement of lawfulness.' There are several legal bases that controllers can potentially rely upon under Article 6 for such processing, including legitimate interests. The more interesting question is what Article 9(2) condition can be relied upon when a controller wishes to anonymise personal health data for scientific research purposes.

Article 9(2)(j) GDPR permits processing of personal health data where such processing is necessary for scientific research purposes in accordance with Article 89(1), 'based on EU or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.' In the context of anonymising personal health data for scientific research purposes, Article 89(1) GDPR itself provides the derogation for the processing of health data for scientific research purposes in accordance with Article 9(2)(j).[11] The IPMPC encourages the EDPB to expressly affirm this interpretation.

F. Consent to Processing in Future Research

The IPMPC agrees with the EDPB that there are multiple legal bases under Article 6 that scientific researchers may be able to rely upon for the processing of personal data, and, similarly, there are multiple derogations that may apply under Article 9(2) GDPR for processing of special categories of personal data like health data. In order to address misconceptions, it would be helpful if the EDPB would state even more clearly in the Guidelines that there are no preferred legal bases or Article 9(2) derogations for processing for scientific research purposes,

[11] *See supra* fn. 2.

and so any can be relied upon to the extent applicable and in accordance with Member State law.

The explicit consent of the data subject to processing for one or more specified purposes satisfies Article 6(1) and Article 9(2) requirements and thereby offers one compliance option when processing personal health data. The IPMPC understands paragraph 55 of the Guidelines as indicating that a request for a data subject to indicate consent to processing of personal data for GDPR purposes must be distinguished from a request to indicate consent to participate in the research project arising under other legal and ethical requirements, although both of these requests for consent could be contained in the same form (e.g., through the use of separate checkboxes). We ask the EDPB to confirm this understanding or to further clarify the Guidelines.

When collecting human biological samples and personal health data for future medical research purposes, researchers may consider obtaining consent to processing of personal data as a means of GDPR compliance if they can be confident that the validity of such consent will not be later challenged by supervisory authorities. It is therefore critical to have clear guidance on the level of specificity that is required in order to meet Article 6(1) and Article 9(2)(a) requirements. The IPMPC welcomes the EDPB's guidance that '[t]he purpose for processing can be delimited to a certain field of research, for example medical research in the field of oncology' or '[it] can also be delimited in view of expected outcomes of the research, for example conducting genetic research to find better medical treatment methods.'[12] We would also welcome guidance on whether an option to consent to 'any research with the aim of better understanding diseases or developing new medical tests and treatments' is sufficiently delimited.

The IPMPC disagrees, however, with the EDPB's framing that specification of purpose like the examples above requires the implementation of additional safeguards 'to compensate for the lack of purpose specification.'[13] This paradoxical statement conflicts with the structure of the GDPR and risks creating requirements for processing of personal data for scientific research purposes that are more onerous than processing for any other purposes. While we welcome examples of practices that researchers may wish to consider for purposes of enhancing transparency even further, or for purposes of compliance with other Article 5 GDPR principles, care should be taken not to frame such practices as prerequisites to the validity of consent under Articles 6 and 9.

[12] Guidelines at ¶ 45.

[13] Guidelines at ¶ 49.

G. Obligation to Inform

The Guidelines state that when a controller anticipates that it will process personal data for scientific research purposes over longer periods of time, then it should give data subjects an opportunity to voluntarily provide contact details.[14] Further, '[c]ontrollers should not knowingly delete contact details if they intend to or anticipate that they will further process personal data for scientific research purposes.'[15] The EDPB must explain how these statements comport with Article 5(1)(c) ('Personal data shall be […] limited to what is necessary in relation to the purposes for which they are processed.') and Article 11(1) ('If the purposes for which a controller processes personal data do not or do no longer require the identification of a data subject by the controller, the controller shall not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with this Regulation.')[16]

H. Roles and Responsibilities in Collaborative Research

The Guidelines state that 'active participation in the determination and the definition of a scientific research protocol, by clearly determining the purpose and essential elements of the means to achieve the objectives pursued, would normally qualify an entity as a controller for the processing of personal data within the meaning of the GDPR. However, the EDPB highlights that the fact that an organisation provides research funding or is consulted in the process of drafting a research protocol (e.g. as an independent consultant, expert, ethical committee etc.) is not in itself sufficient to attribute the role of a controller (or joint controller).'[17] The IPMPC recommends some further clarification of this paragraph.

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[14] Guidelines at ¶ 77.

[15] Guidelines at ¶ 87.

[16] The legislators were careful in Article 11 to refer to personal data that does not '*require* the identification' of data subjects. This was an attempt to distinguish identif***ied*** data from data that is merely identif***iable***. The legislators were not commenting on how the regulation applies to data rendered anonymous, as such data is already clearly out-of-scope. (*See* Recital 26.) This phrasing should also be distinguished from references to data that does not '*permit* the identification' of data subjects. (*See* Article 5(1)(e) ('Personal data shall be […] kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed.') and Article 89(1) (Processing for scientific research purposes 'shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner.').

[17] Guidelines at ¶ 134.

Collaborative research involves many partners providing scientific, technical, or methodological input, often based on specialist expertise. This input should not create a presumption that a contributor determines the purposes and essential means of processing of personal data within the meaning of the 'controller' definition in Article 4(7). Where an entity has legal responsibility for the design of the study, that entity may be presumed to be a data controller under the GDPR. Other contributors may or may not be controllers depending upon their actual control of decision-making concerning the processing of personal data.

I. Need for Further Legislation to Address Lack of Harmonisation

While the Guidelines provide a compendium of the EDPB's past statements and views on issues related to scientific research activities, they are most notable for their acknowledgement of the lack of harmonisation across the EU of standards for processing of personal data (especially personal data concerning health) for scientific research purposes. This is a problem of the GDPR itself and does not appear to be something that the EDPB can fix through guidelines alone. Instead, a legislative solution is necessary.

The amendments to the Clinical Trials Regulation contained in the Commission's proposed Biotech Act are needed to provide consistency across the EU of data protection requirements as applied to medicines research. The IPMPC strongly supports the Commission's proposed amendments. However, a similar set of amendments is needed to address medical device and IVD research.

We appreciate the opportunity to provide comments on the Guidelines. Please do not hesitate to reach out to us should any of our comments require further clarification.