Tukija

Opinion
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European Data Protection Board (EDPB) public consultation: Guidelines 1/2026 on processing of personal data for scientific research purposes

Public consultation reference: 1/2026 (16 April 2026 - 25 June 2026)

Opinion of the Finnish National Medical Research Ethics Committee (Tukija)

The National Medical Research Ethics Committee (Tukija) would like to express its appreciation for the opportunity to provide input on the Guidelines and welcomes the consultation process.

Tukija endorses the EDPB Guidelines on the alignment of research and GDPR implementation, as it provides a timely and necessary clarification on data protection rules can be applied in a manner that both safeguards fundamental rights and enables high-quality scientific research. By reinforcing the interpretation of EU General Data Protection Regulation (No 2016/679, GDPR) in a research context, the Guidelines contribute to greater legal certainty for researchers and sponsors across EU Member States.

Tukija's mandate covers clinical trials under the EU Clinical Trials Regulation (No 536/2014, CTR), and accordingly, these comments focus mainly on the interaction between the GDPR and the CTR.

Comments:

1) **Introduction**

Paragraph 4

Issue:

The Guidelines state that GDPR does not comprehensively harmonise the processing of personal data for scientific research purposes, leaving substantial room for complementary Union and Member State legislation. Therefore, the application of such legislation falls outside the scope of the EDPB guidelines.

Assessment:

Tukija considers that, while the general delimitation is relevant, the introductory section does not sufficiently clarify the role of the guidelines in relation to directly applicable EU regulations and national legislation. Although the guidance addresses only the application of the GDPR in scientific research, it is nevertheless important to note that the EU also has other directly applicable regulations governing scientific research. The EDPB guidance cannot be applied without taking these other legal frameworks into account. Failure to consider the coexistence of simultaneously applicable legal regimes may lead to uncertainty and legal fragmentation, thereby creating confusion for researchers regarding the applicable requirements and their practical implementation.

Recommendation:

It should be explicitly acknowledged in the paragraph 4, that certain categories of research are governed by equally binding sector-specific EU legislation, inter alia Clinical Trials Regulation (No 536/2014, CTR), In Vitro Diagnostic Device Regulation (No 2017/746, IVDR), and Medical Device

Regulation (No 2017/745, MDR). It should be stated that in situations where the Guidelines and different regulatory frameworks interact, the applicable EU and national legislation in force prevail.

2) **2.3 Ancillary processing operations:**

Paragraphs 14–15:

Issue:

Processing operations ancillary to scientific research may fall within the notion of processing for scientific research purposes and/or overlap in incongruent way. These operations cover both preparatory activities prior to the start of a research project and processing operations related to the management of research data generated during the research.

Assessment:

Tukija considers that the scope of ancillary processing operations remains in part unclear in this section. It remains ambiguous to what extent can activities following the completion of a research project be subsumed under *ancillary processing*. In particular, the text does not address post-research activities (such as the preparation of follow-up studies based on results obtained from the initial research) and the question whether they can be considered ancillary to that research. This creates uncertainty regarding the temporal scope of ancillary processing and its application across the full lifecycle of a research project.

Recommendation:

Tukija suggests further specifying the concept of ancillary processing operations by clarifying its temporal scope across the research lifecycle. It would be beneficial to clarify whether and under what conditions activities carried out after completion of a research project, including the preparation of follow-up research based on previous results, can be classified as ancillary processing operations

3) **3.1.1 Presumption of purpose compatibility**

Paragraphs 21- 22

Issue:

Under certain conditions and with appropriate safeguards under Article 89(1) GDPR, controllers may rely on the original legal basis when further processing personal data for scientific research purposes. However, compatibility of purposes must be distinguished from the principle of lawfulness, requiring a separate assessment of whether the original legal basis remains valid for further processing. According to the Guidelines, the same legal basis can often be used, particularly where the initial processing relied on Art. 6(1)(e) public interest or Art. 6(1)(f), legitimate interests. However, this is not always possible, especially where the original basis was Art. 6(1)(a) consent or Art. 6(1)(c) legal obligation.

Assessment:

Tukija confirms that in the context of clinical trials conducted under the EU Clinical Trials Regulation (536/2014), sponsors frequently have an interest in conducting further research on the collected data.

Furthermore, this may have relevance in the future if Commission proposal concerning European Biotech Act (BTA)[1] will be adopted. BTA reinforces in Article 93(2)(6) that further processing of clinical trial data is compatible with the original purpose under the Clinical Trials Regulation. Article 93 establishes that sponsors must process personal data *on the basis of a legal obligation* for specified trial-related purposes, such as authorisation, conduct, safety reporting, and data retention. If adopted, this would in effect create, , a harmonised single legal basis of GDPR Art. 6(1(c) for processing personal data within clinical trials. However, under EDPB guidance (para. 22), further research may require a different legal basis, since Article 6(1)(c) may not directly extend to all future research purposes.

Recommendation:

a) Paragraph 22 should explain more thoroughly why compatibility of purpose alone does not justify continued reliance on the same legal basis and under which circumstances a different legal basis is required for further research activities. Such clarification would provide greater legal certainty for those conducting clinical research under EU regulatory frameworks, including the CTR, IVDR and MDR. This is particularly important in light of BTA and its apparent shift towards reliance on Article 6(1)(c) as the legal basis for processing.

   The paragraph should elaborate on situations where further research is considered as compatible purpose, but the legal basis for processing personal data may differ from that of the initial research. In such cases, researchers should in practise inform participants about their rights regarding i) the legal basis of processing in the primary study, and ii). any different legal basis that may apply to the further use of the data.

b) Tukija also considers that research participants should always be informed about further research. From an ethical perspective, such transparency is essential in ensuring that participants remain adequately informed about how their personal data are used beyond the scope of the initial research project. It is also consistent with the information requirements set out in Article 13 of the GDPR. Tukija thus proposes that this information prerequisite is thus dictated in Chapter 3.1.1 on purpose compatibility regarding further research.

c) Tukija also notes that compatibility with the original purpose does not, by itself, eliminate the need for additional legal grounds or justifications for further research. Compatibility cannot be interpreted as automatically exempting the processing from the need to identify and assess other applicable legal bases, safeguards, or conditions under the GDPR and other

[1] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)

relevant legal frameworks (CTR, IVDR, MDR). This notion should be dictated more clearly (than currently) in the Guidelines.

4) **4.1.1 Freely given consent**

Paragraph 37

Issue:

When conducting clinical research involving patients the controller should consider patient's mental and physical condition in assessing whether consent can be regarded as freely given. Patients may be in a vulnerable position due to illness, dependency on healthcare providers, impaired decision-making capacity, or other circumstances that may affect the voluntariness of consent. These factors may give rise to a power imbalance or create a perception that participation is linked to access to treatment or quality of care. Controllers should therefore ensure that the specific context and vulnerability of the patient are adequately considered when relying on consent pursuant to GDPR Article 6(1)(a) as legal basis for processing personal data in a clinical research setting.

Assessment:

Tukija considers that paragraph 37 discusses confusingly consent as consent to participate (in research) and consent as legal basis for processing personal data pursuant to GDPR Article 6(1)(a). These two notions of consent should be clearly distinguished from each other. Only later in Chapter 4.1.3, other legal and ethical requirements concerning consent are discussed – although, EU regulations specific to clinical research (CTR, IVDR, MDR) are not mentioned there either.

The text in Chapter 4.1.1 is confusing and potentially misleading, as it appears to conflate two distinct regulatory frameworks and concepts of consent. In other EU regulatory contexts, consent is addressed as consent to participate in research, including the conditions under which participation in a trial is ethically and scientifically permissible. By contrast, the GDPR governs the processing of personal data and treats consent solely as one of several possible legal bases for such processing. These two notions of consent serve different purposes and operate within different legal domains, and they should therefore be clearly distinguished to avoid ambiguity and conceptual overlap.

For instance, in CTR, the requirements of informed consent as action to participate in a trial is regulated under Articles 28-30. Capacity to give consent is regulated under Articles 31-32 which safeguard the safety and wellbeing of participants who are underaged or lacking capacity. In certain cases, consent can also be given on behalf of another person by a legal representative. Furthermore, in clinical trials conducted under CTR, the GDPR Article 6(1)(a) is generally not considered as applicable legal basis for processing personal data, because the rights of the data subject are restricted in clinical trials.

Recommendation:

Paragraph 37 should clearly separate these two concepts in the text by consistently distinguishing between a) consent to participate in research and b) consent as a legal basis for processing personal data under Article 6(1)(a) GDPR. The former should be used in the context of ethical and regulatory requirements governing enrolment and participation in a study, while the latter should be reserved exclusively for describing the lawfulness of personal data processing under data protection law.

Chapter 4.1.1 on consent should also be clarified regarding its applicability in relation to relevant EU regulatory frameworks (CTR, IVDR, MDR) as these regulations are applicable specifically to patients consenting to take part in clinical research projects. Although the EDPB guidelines concern the application of the GDPR to the processing of personal data, it is important to notice that equally binding EU legislation applies to *consent to participate* in research.

Chapter 4.1.3 on other ethical and legal requirements should either be incorporated into Chapter 4.1.1 to improve conceptual clarity or moved to follow it as Chapter 4.1.2, as it further elaborates on the concept of freely given consent discussed in the preceding chapter. In its current structure, the relationship between these two closely related chapters is not sufficiently clear, as they are separated by several section

5) **4.1.2.1 Broad consent and 4.1.2.2 Dynamic consent**

Paragraphs 43-50, and 51-52

Issue:

A controller may obtain broad consent and dynamic consent from data subjects at the time of collecting and storing personal data intended for use in future research projects within defined areas of scientific research. This approach is applicable where the specific use of the data in individual research projects has not yet been determined at the time of collection, and where the exact processing purposes are specified only at a later stage.

Assessment:

Tukija notes that the sections on broad consent and dynamic consent are placed under the Chapter “Consent under Article 6(1)(a) GDPR.” Does the EDPB consider these types of consent to be applicable exclusively under this legal basis, or whether they may also be relevant in relation to other legal bases? In certain EU-regulated types of research, Article 6(1)(a) GDPR cannot be used as a legal basis for processing in the primary research project, and consequently broad consent and dynamic consent will, in such cases, likely need to be obtained through a separate consent mechanism. Tukija also notes that it has, in its assessment practice, reviewed research applications in which the sponsor has selected also other legal basis than GDPR Art. 6(1)(a) for broad consent. Tukija additionally notes that it does not have experience on dynamic consent in clinical trials under CTR.

Recommendation:

It shouldbe useful to explicitly state in section 4.1 the EDPB's view on whether the two consent mechanisms described in the Chapter apply solely to processing under Article 6(1)(a) GDPR or whether other legal bases are also considered applicable per sponsor's rationale.

6) **5.3 Further processing of personal data for further scientific purposes (Article 13(3) GDPR)**

Paragraphs 88-89

Issue:

According to the guidelines, the sponsor could pursue further research projects without individually contacting research participants if it is deemed as disproportionate effort. However, in such cases the sponsor should try to make every reasonable effort to inform research participants by providing public announcements of information (e.g. on a website).

Assessment:

Tukija considers that this approach is not suitable for all types of research. In particular, clinical trials on medicinal products involving medical, genomic, or biometric data raise specific concerns, as such data constitute special categories of personal data under Article 9 of the GDPR. As a general rule, the further use of such data for research purposes should not be permitted without informed consent of the research participant.

Recommendation:

In Tukija's view, this section should include a limitation; special categories of personal data cannot be subject to this type of notification-based regime. Where research involves sensitive personal data within the meaning of Article 9 GDPR, further processing for research purposes should require the explicit and informed consent of the individual concerned. Given the heightened risks associated with the use of such data, reliance on notification alone would not provide an adequate safeguard for the rights and autonomy of research participants.

7) **5.4.2.6 The personal data must remain confidential subject to an obligation of professional secrecy regulated by Union or MS law, including a statutory obligation of secrecy (Article14(5)(d) GDPR)**

Paragraph 105

Issue:

Legal requirements may prevent researchers from disclosing information in order to protect research integrity. This is particularly relevant where a participant discloses sensitive personal data about a third party, the disclosure of which could strain their relationship or even place the participant at risk.

Assessment:

Information relating to third parties does not necessarily constitute personal data within the meaning of Article 4(1) GDPR, provided that the information cannot be directly or indirectly linked to an identified or identifiable natural person. In this respect, relational references such as “sibling” or “spouse” do not, in themselves, automatically amount to personal data concerning a third party, unless they can be associated with a specific and identifiable individual in the given context. The guidance may create a misleading impression that such relational information would always constitute personal data.

An assessment of this kind could also lead to misinterpretation in another context, for example where an individual provides anonymised information about a third party, and the sponsor would nevertheless consider such information to fall within the scope of its notification obligations as personal data. For instance, in medical research, information on diseases occurring within a family can be collected in a way that does not enable the identification of individual persons. This can be achieved by recording such data in non-specific form or focusing on general family history patterns rather than identifiable relatives. When information does not allow direct or indirect identification of specific individuals and therefore, does not constitute personal data under GDPR. The assessment must thus be carried out on a case-by-case basis, considering the surrounding information and the overall context in which such (relational) terms are used.

Recommendation:

This section should clarify that the provision on third parties applies to situations in which a third party *is directly or indirectly identifiable*, and their data therefore constitute personal data within the meaning of Article 4(1) GDPR. In such cases, the obligation to inform the third party under Article 14 may be exempted, provided that specific reasons (which are further specified in the section) are met.

8) 8 Appropriate safeguards (Article 89(1) of the GDPR)

Paragraphs 168 and 170

Issue:

Appropriate safeguards may include, but are not limited to, pseudonymisation, ethical review/approval, strict purpose limitation, federated storage with access provided through secure processing environments, and robust role-based access controls.

Assessment:

Tukija notes that a favourable opinion from an ethics committee can only function as a safeguard insofar as the committee is able to assess a specific and defined research protocol. This is important because the ethical review is conducted based on a clearly defined research design, including its objectives, data processing activities, and intended uses. As a result, the scope of the committee’s assessment is necessarily limited to that individual project and cannot automatically extend to undefined future research activities.

In cases of broad consent for future use, the ethics committee's opinion is necessarily limited to evaluating whether the sponsor has complied with its information obligations under Article 13 GDPR towards the data subject, rather than providing substantive approval or oversight of all potential future uses of the data.

Recommendation:

It should be explicitly stated that an ethical review is inherently tied to a specific research protocol. Making this limitation clear helps avoid the misconception that ethical approval provides a blanket endorsement for future uses of data beyond the scope of the original research purpose

Concluding remarks

The EDPB Guidelines describe a wide range of scientific research activities and the processing of personal data within them. However, it would be beneficial in some Chapters to more specifically target those categories of research that are also explicitly regulated under EU sectoral research legislation. A more focused approach in these areas would help ensure greater legal clarity and consistency in the application of the relevant EU legislation, in cases where different but equally applicable regulations interact.

The GDPR and applicable EU research regulations must be interpreted and applied together as a single, coherent legal framework. They are equally binding and operate in parallel within their respective scopes. Compliance therefore requires a coordinated assessment of GDPR requirements alongside sector-specific research legislation under CTR, MDR and IVDR. These frameworks are intended to be complementary rather than hierarchical, and together they define the conditions for lawful research involving personal data. A fragmented or siloed approach risks legal uncertainty, inconsistencies, and unnecessary barriers to research.

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