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25 June 2026

Chair Anu Talus
Deputy Chair Jelena Virant Burnik
Deputy Chair Zdravko Vukić
European Data Protection Board (EDPB)
Rue Wiertz 60 / Wiertzstraat
601047 Bruxelles / Brussels Belgium

RE: ACRO comment submission:
Guidelines 1/2026 on processing of personal data for scientific research purposes

Dear Chair Talus, Deputy Chair Burnik, and Deputy Chair Vukić,

Founded in 2001, the Association of Clinical Research Organizations (ACRO) is non-profit trade association representing the world's leading clinical research and technology organizations, which provide specialized services that are integral to the development of drugs, biologics and medical devices that enable patients to live longer, healthier, and more productive lives. ACRO members provide a wide range of specialized services across the entire spectrum of development - from preclinical, proof of concept, and first in human studies through post-approval, pharmacovigilance, and health data research. ACRO member companies employ nearly 470,000 people worldwide and conduct research in more than 90 countries in every global region.

ACRO thanks the EDPB for the opportunity to provide these comments.

Section 3.1: "Purpose limitation (Article 5(1) GDPR)" – Paragraph 17

This section of the draft guidelines reads as follows [emphasis in original]:

> _If a controller collects personal data to process it for a specific scientific research purpose, then the research purpose is considered to be the **primary** purpose of processing. If a controller subsequently wants to process that personal data for **another** scientific research purpose that is not covered by the primary purpose, such processing is considered to be **further processing for another purpose**. If a controller initially collects and processes personal data for **non-scientific purposes**, but later on decides to process the personal data for scientific research purposes, this is considered **further processing for scientific research purposes.**_

ACRO believes the current wording could benefit from additional wording to provide clarification as outlined here:

> _If a controller collects personal data to process it for a specific scientific research purpose, then the research purpose is considered to be the **primary** purpose of processing. If a controller subsequently wants to process that personal data for another scientific research purpose that **is** covered by the primary purpose, such processing is considered to be **further processing for a compatible scientific research purpose**._

> *If a controller subsequently wants to process that personal data for **another** scientific research purpose that is <u>not</u> covered by the primary purpose, such processing is considered to be **further processing for <u>another</u> scientific research purpose**.*
>
> *If a controller initially collects and processes personal data for **non-scientific purposes**, but later on decides to process the personal data for scientific research purposes, this is considered **further processing for scientific research purposes.***

3.1.2: "Further processing when providing personal data to another controller for scientific research purposes" – Paragraph 26

This section of the draft guidelines reads:

> *If a controller (controller A) wishes to, or is obliged by Union or MS law, to provide personal data to another controller (controller B), and controller B intends to process the data for its own scientific research purposes, the provision of personal data by controller A will be considered further processing if it was not one of the primary processing purposes when the personal data was collected. When providing personal data to another controller for scientific research purposes, neither the providing (controller A) nor receiving controller (controller B) needs to undertake a compatibility assessment, pursuant to Article 6(4) GDPR.*

This situation introduces a new layer of complexity and necessitates collaboration between providing and receiving controllers, as the new (receiving) controller must meet their transparency obligations. Therefore, ACRO asks the EDPB to consider creating an appendix in the final guidelines with a table that briefly discusses some common situations and scenarios of a 'providing Controller A' and a 'receiving Controller B,' with illustrative case examples.

Section 4.1.1: "Freely given consent" – Paragraph 39

This portion of the draft guidelines reads as follows [emphasis added]:

> *If data subjects receive any kind of reimbursement or other benefit for participating in a research project, which may be regulated by Union or MS law, then controllers must determine whether the reimbursement or other forms of incentives affect the choice made by the data subjects as to whether or not they agree to the processing of their personal data. In this regard, remuneration intended to cover the income that data subjects might lose for participating in a research project, for example because they may miss out from work, would normally not affect whether consent is freely given.* ***Conversely, if the remuneration would constitute a significant part of the data subject's regular income, it is more likely that it would affect whether consent was freely given or not.***

The language here implies that we must collect more information in order to ascertain the participant's income (and, thereby, socio-economic status) to decide whether remuneration is excessive proportionally to the data subject's income.

ACRO urges the EDPB to delete Paragraph 39 from the final guidelines for three reasons:

- Paragraph 39 is unnecessary. Numerous founding principles and documents of clinical research ethics already forbid clinical trial payments and compensation that could be considered undue influence or inducements. The Belmont Report clearly outlines the required elements of voluntariness:

  > ***Voluntariness.*** *An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.*

- The concept of free and informed consent to take part in scientific research is outside the scope of EDPB guidelines and properly falls within the purview of Institutional Review Boards and medical product regulatory authorities – which would be highly unlikely to approve the collection of income information from trial participants.

- Finally, collection of data on the incomes of trial participants is contrary to the core tenets of data minimization – adequacy, relevance, and necessity – within the General Data Protection Regulation.

Section 4.1.2.1 "Broad consent" – Paragraph 45

Paragraph 45 states:

> *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. However, the purpose can also be delimited in view of expected outcomes of the research, for example conducting genetic research to find better medical treatment methods.*

ACRO recommends adding a new Paragraph, immediately following Paragraph 45, with the following text:

> In accordance with the accountability principle, controllers are responsible for determining and, where relevant, documenting the appropriate mechanism for obtaining and managing consent for the processing of personal data for scientific research purposes. Where the conditions for broad consent are met, and appropriate safeguards have been implemented, controllers may rely on broad consent for future research projects falling within the scope of the identified area of scientific research. Competent authorities, ethics committees and other oversight bodies should take into account the controller's assessment and the safeguards implemented, rather than presuming that separate consent must be obtained for each future research project that falls within the scope of that broad consent. This is without prejudice to any requirement under applicable Union or Member State

law to obtain a subject's specific informed consent to actively participate in a specific research study or clinical trial. The further processing of personal data within the scope of a valid broad consent should be distinguished from the recruitment or enrolment of a data subject into new scientific research.

Section 4.4.1: "Explicit consent (Article 9(2)(a) GDPR)" – Paragraph 67

Paragraph 67 states:

> *Controllers may also assess if they can rely on the explicit consent of data subjects, including Broad or dynamic consent, pursuant to Article 9(2)(a) GDPR, to process special categories of personal data for scientific research purposes. The considerations outlined in section 4.1 are also relevant when a controller considers relying on Article 9(2)(a) GDPR, as a derogation from the prohibition of processing to special categories of personal data.*

ACRO recommends adding a new paragraph, immediately after Paragraph 67, with the following text:

> Where controllers rely on Article 9(2)(a) GDPR, the requirement that consent be explicit should be assessed in light of the information provided to the data subject and the manner in which consent is obtained. Such assessment should focus on whether the data subject has been clearly informed of the nature of the personal data being processed, including any special categories of personal data, and has expressly agreed to such processing through a clear affirmative statement or action. The requirement that consent be explicit does not necessarily require a separate consent statement for each special category of personal data processed. The use of standardized consent documentation, including where required by sector-specific legislation or regulatory requirements, does not in itself preclude consent from meeting the requirement of being explicit.

Section 5.2: Provision of information when personal data are collected directly from the data subject (Article 13(1) GDPR) – Example 11: Information to data subjects whose personal data is directly collected from the data subject through a clinical trial

This example currently is written as follows:

> *A pharmaceutical company is conducting a clinical trial for a new pharmaceutical product in co-operation with a healthcare facility. In accordance with Article 28(1)(c) of the Clinical trials regulation (CTR), the informed consent of the research participants to participate in the clinical trial is required. When the research participants sign up for the trial, they are informed during an interview and given a folder that includes a form for informed consent and information about the trial, possible side effects of the pharmaceutical product, how the research data will be processed and the objectives of the trial. The folder also contains a separate section which informs about the central elements of processing of personal data, which is clearly indicated in a table of contents in the folder. In addition, data subjects are informed about the possibility of getting more detailed information through a dedicated webpage and a contact point (with an email address and a phone number) through which*

> *data subjects can pose questions, receive information or exercise their data protection rights.*

For clarity, we recommend re-writing the example in the final guidelines as follows:

> A pharmaceutical company sponsors a clinical trial conducted at a healthcare facility. In accordance with Article 28(1)(c) of the Clinical Trials Regulation, the informed consent of research participants is required. During the informed consent process, details of the clinical trial and the informed consent form is provided, discussed and explained to prospective participants during an interview with the principal investigator or appropriately qualified members of the clinical trial site staff.
>
> Through the informed consent form, participants receive information about the objectives of the trial, possible side effects of the pharmaceutical product, visits and medical procedures. The informed consent form also contains a section which informs about the central elements of processing of personal data.
>
> In addition, data subjects are informed about the possibility of getting more detailed information, posing questions, or exercising their data protection rights.
>
> The primary contact point for participants should normally be the investigator. Where appropriate, contact details for the data protection officer or other designated contact at the clinical trial site may also be provided. The clinical trial site may subsequently liaise with the sponsor where necessary to facilitate the handling of requests relating to personal data processed in the context of the clinical trial.

<u>Section 5.3: "Further processing of personal data for further scientific purposes (Article 13(3) GDPR)" – Paragraph 86</u>

Paragraph 86 currently states:

> *It may be challenging for controllers to inform data subjects of further processing for scientific research purposes if they have not retained the contact details of the data subjects, for example due to pseudonymization of the personal data where identifiers or a table of correspondence are not accessible for the controller. To that end, if the controller knows at the time of collection (or when contact details are deleted because they are not necessary to process) that the personal data will be processed for scientific purposes at a later stage, then the controller should make sure that data subjects can stay informed, in accordance with Articles 12 and 13 GDPR.*

We recommend incorporating additional text for clarity, which is underlined here:

> It may be challenging for controllers to inform data subjects of further processing for scientific research purposes if they do not have access to the contact details of the data subjects, for example due to pseudonymisation of the personal data where identifiers or a table of correspondence are not accessible to that controller. In such cases, controllers should assess and document how transparency obligations will be fulfilled in practice and ensure that data subjects can remain

informed, in accordance with Articles 12 and 13 GDPR, through the controller or entity that maintains the direct relationship with the data subjects, rather than acquiring additional identifying information that is not otherwise necessary for the processing.

Section 5.3: "Further processing of personal data for further scientific purposes (Article 13(3) GDPR)" – Paragraph 88

Paragraph 88 currently states:

> *If the controller at the time of collection of the personal data did not know or anticipate that it would process personal data for scientific research purposes at a later stage, it may not have contact details of the data subjects. If the controller has identifiers, such as a name or administrative identification number, it should make reasonable efforts to acquire contact details if they are readily available and acquisition would not require a disproportionate effort.*

For greater clarity, we recommend incorporating the following additional text, which is underlined here:

> If a controller did not know or anticipate at the time of collection of the personal data that the data would later be processed for scientific research purposes, it may not have access to the contact details of the data subjects. Where the controller has identifiers, such as a name or administrative identification number, it should make reasonable efforts to acquire contact details if they are readily available and acquisition would not require a disproportionate effort.
>
> However, where the controller only processes pseudonymised data and does not have access to the identifiers or the table of correspondence necessary to identify the data subjects, it should not be required to acquire additional identifying information solely for the purpose of contacting data subjects. In such cases, controllers should consider whether the provision of information can be facilitated through another controller or entity that maintains the direct relationship with the data subjects and has access to their contact details.

Section 5.4: "Provision of information when personal data are not collected directly from the data subject (Article 14(1) GDPR)" – Paragraph 91

Paragraph 91 currently states:

> *New personal data generated in the course of a research project will fall within the scope of Article 14 of the GDPR and are not considered as collected directly from data subjects. For example, a controller may in the course of scientific research undertake data analysis which generates new personal data that is derived from the personal data provided by data subjects. This could occur where a researcher diagnoses a data subject with a psychological condition, on the basis of personal data provided by the data subject. Other situations could be where researchers generate a pseudonym or derive a data point from an identification or social security number, or add additional information about data subjects, such as their gender.*

For clarity, we recommend incorporating the following additional text, which is underlined here:

> New personal data generated in the course of a research project will fall within the scope of Article 14 of the GDPR and are not considered as collected directly from data subjects. For example, a controller may in the course of scientific research undertake data analysis which generates new personal data that is derived from the personal data provided by data subjects. This could occur where a researcher diagnoses a data subject with a psychological condition, on the basis of personal data provided by the data subject. Other situations could be where researchers generate a pseudonym or derive a data point from an identification or social security number, or add additional information about data subjects, such as their gender. However, where the generation of such data is inherent to the research activities described to the data subject and can reasonably be expected by the data subject on the basis of the information already provided, additional information may not be required. This may, for example, be the case where biological samples collected in the context of clinical research are analysed in accordance with the research protocol and new study data generated.

Section 5.4: "Provision of information when personal data are not collected directly from the data subject (Article 14(1) GDPR)" – Paragraph 94

Paragraph 94 currently states:

> If a controller or processor receives pseudonymised data from another controller to be processed for scientific research, then the data subjects should be informed about how they can exercise their rights, for example by providing the pseudonym relating to their personal data.

For clarity, we recommend adding the following addition text, as underlined here:

> If a controller or processor receives pseudonymised data from another controller to be processed for scientific research, then the data subjects should be informed about how they can exercise their rights, for example by providing the pseudonym relating to their personal data. However, controllers should not be required to acquire or have access to additional identifying information solely for the purpose of facilitating the exercise of data subject rights where such information is not otherwise necessary for the processing and where appropriate mechanisms exist to facilitate the exercise of rights through the controller that maintains the link between the pseudonym and the identity of the data subject.

Section 6.2.2: "Exceptions from the obligation to erase personal data upon request (Article 17(3) GDPR)" – Paragraph 120

> *Article 17(3)(d) GDPR provides for a specific exception from the right to erasure if the processing is necessary for scientific research purposes, in accordance with Article 89(1) GDPR. In addition to assessing the strict necessity of processing of personal data in relation to the scientific research*

> *purpose, the controller must also assess the individual circumstances in each request of a data subject when applying Article 17(1)(d) GDPR. To that end, Article 17(3)(d) GDPR should only be applied in limited circumstances, as it is only when erasure is likely to render impossible or seriously impair the achievement of the scientific research purposes that it is possible for a controller to reject a request for erasure. For example, if a controller processes personal data from a large number of data subjects, requests of data subjects for erasure of their personal data may not make it impossible or seriously impair the achievement of the scientific research purposes. However, if a controller uses personal data from a small number of data subjects, where the personal data of each data subject is of significant importance for the outcome of a research project, then it is more likely that the controller is justified in relying on Article 17(3)(d) of the GDPR and reject a request for erasure. A request for erasure of personal data may also make it impossible or seriously impair the achievement of the scientific research purposes if the controller researches developments or trends over a longer period of time and the request is received while the research is still in progress.*

ACRO urges the EDPB to delete Paragraph 120 from the final guidelines, as these considerations are about science – not privacy and data protection. The right to erasure should not be conditional on the size of the study. Why should large studies provide more privacy protection than small studies? These decisions should be made by scientists as the designers of science (not by the designers of privacy) -- and, therefore, omitted from data protection guidelines.

Section 7: "Attribution of responsibility (controller and processor)" – Paragraphs 129, 130, and 131

> *129. The EDPB's Guidelines 7/2020 on the concepts of controller and processor in the GDPR provide general guidance on the attribution of responsibility when processing personal data. The following section provides additional guidance and examples relevant to the processing of personal data for scientific research purposes.*
>
> *130. The roles of controller, joint controller and processor are crucial in the application of the GDPR, since the attribution of roles determines which entity is responsible for compliance with the different provisions of the GDPR and how data subjects can exercise their rights in practice. The EDPB underlines that the determination of roles is functional and aims to allocate responsibilities according to the actual roles of the entities. Therefore, while the Guidelines provide examples and guidance to help entities determine their responsibilities under the GDPR when processing personal data for scientific research purposes, each entity must still assess and be able to demonstrate their own responsibility for the particular processing operations in which they are involved.*
>
> *131. Where personal data is processed for scientific research purposes involving several entities, it is necessary to assess and document how responsibility is allocated among the entities. The determination may be particularly relevant where multiple actors are involved in drafting scientific research protocols, such as sponsors, hospitals, private companies etc., or in the case of public-private partnerships (PPPs).*

ACRO asks the EDPB to consider bolder recommendations and a call to action for EU harmonization here. There is inconsistency, fragmented policy, and a lack of harmonization across the EU in terms of how the designation of roles of Sponsors and Sites involved in clinical trials are viewed by regulators, ethics committees, data protection authorities, and other stakeholders – leading to inefficiencies, delays and increased compliance risk for trial stakeholders.

ACRO has developed a white paper that calls for a harmonized EU approach that reduces friction, mitigates legal uncertainty, and supports timely clinical trial initiation. This white paper – titled ***"Appropriate Designations of the Roles of Sponsor and Sites in Data Processing Agreements (DPA) in Clinical Trial Agreements (CTAs)"*** – is publicly available on ACRO's website here:
https://www.acrohealth.org/resource/appropriate-designations-of-the-roles-of-sponsor-and-sites-in-data-processing-agreements-dpa-in-clinical-trial-agreements-cta/
We ask the EDPB to support the ACRO harmonization recommendations in the white paper and to incorporate them into the language of the final guidelines.

Section 8.3: "Anonymization and pseudonymization of personal data" – Paragraphs 154–161

Paragraphs 154—161 prioritize anonymization of personal data. However, anonymization is difficult to achieve in clinical research and more likely to be used in other types of research outside of clinical trials and drug development. Because pseudonymization is the standard, dominant practice in clinical research, we recommend deleting paragraphs 154—161 from the final guidelines.

Thank you for the opportunity to provide feedback on these draft guidelines.

Respectfully submitted,

Karen Noonan

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