PUBLIC CONSULTATION RESPONSE

EDPB Guidelines 1/2026 on processing of personal data for scientific research purposes

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Submitted via: EDPB online feedback form ("Provide your feedback")

Respondent: Department of Medical Law, Charles University, Czech Republic (contact: sirokal@prf.cuni.cz)

Capacity: academic department specialising in medical law. This response is submitted in general terms and does not concern or identify any particular sponsor, trial or provider.

1. Scope of this response

We welcome the Guidelines and the legal certainty they bring. This response concerns Section 7 (Attribution of responsibility), in particular Section 7.1 (Controller), and its interplay with the proposed European Biotech Act. For clarity, this response uses the following terms: the sponsor is the entity that initiates, manages and finances the clinical trial; the site is the clinical trial site, that is, the health-service provider at which the trial is conducted; and the principal investigator is the physician employed by the site who is responsible for conducting the trial at that site. Both Section 7 and the Biotech Act directly affect (i) the allocation of controller and processor roles between the sponsor and the site; and (ii) the legal basis available to the site for processing personal data for clinical-trial purposes.

2. Comment 1 – The data-protection roles of the site and the principal investigator (Section 7.1)

The Guidelines establish that the controller is the entity that determines the purpose and the essential elements of the means of processing, whereas merely providing funding or being consulted in the drafting of a research protocol is not sufficient to attribute the role of controller or joint controller (paragraphs 132 and 134). For clinical trials, the Guidelines state that the sponsor is a controller (or joint controller) because it determines the purposes and means, in particular by drafting the trial protocol, even though most of the directly identifiable data is processed at the site (paragraph 136). The Guidelines further state that merely agreeing to and adhering to an already established protocol, without participating in the determination of the purposes and means, is not sufficient to create joint controllership and may be indicative of a controller–processor relationship (paragraph 142).

In commercial clinical trials, the sponsor unilaterally prepares the protocol and the case report forms and defines the methodology, scope and retention of the data. The site, and the principal investigator it employs, is engaged only after selection by the sponsor and carries out the trial in accordance with the sponsor's protocol and instructions. On the Guidelines' own functional analysis, this points towards the position of a processor.

The site and the principal investigator (employee of the site) process personal data of the same individuals for two distinct purposes:

(i) the provision of health care to the patient, for which the site is a controller and the data are recorded in the patient's medical records; and

(ii) the conduct of the clinical trial as defined by the sponsor's protocol, for which the data are recorded in the clinical trial documentation, such as the case report forms and the clinical trial master file.

These are different purposes within the meaning of Article 5(1)(b) GDPR, attracting different roles and different legal bases.

This distinction is reflected in the regulatory framework. Under Regulation (EU) No. 536/2014 the clinical trial documentation forms a distinct set of records from the patient's medical files. The clinical trial master file must at all times contain the essential documents (Article 57) and is archived by the sponsor and the investigator for at least 25 years, whereas the medical files of subjects are archived

in accordance with national law (Article 58). Under good clinical practice the trial master file is likewise maintained separately from source documents and medical records, even though the medical record may itself serve as a source document for the trial. In our view the data-protection roles should therefore be assessed per purpose. For the health-care purpose the site is a controller, typically under Article 9(2)(h) GDPR. For the trial purpose, where the site and the principal investigator merely apply the sponsor's protocol and instructions, they act for the sponsor's purpose, which in our view points towards the role of a processor. Conflating the two purposes, in particular treating the trial processing as if it were part of the site's health-care controllership under Article 9(2)(h), would not be correct, because Article 9(2)(h) covers the provision of health care, not the conduct of a clinical trial.

In our view, in such circumstances the site acts as a processor on behalf of the sponsor as controller. We politely request the EDPB to address this issue in the final Guidelines and to clarify that the site does not necessarily become a separate or joint controller merely because it (i) is the entity that physically carries out the processing of directly identifiable data; (ii) employs the principal investigator; or (iii) is subject to its own regulatory and good-clinical-practice obligations under Regulation (EU) No 536/2014. Paragraph 136 of the Guideline currently addresses only the sponsor's role. We consider that reading it together with paragraph 142 would help reduce a recurring source of uncertainty in clinical-trial agreements.

More broadly, although the Guidelines discuss clinical trials, they do not use the term "investigator" at all and refer to the "clinical trial site" only once, in paragraph 136, without classifying its data-protection role. We would therefore appriciate the EDPB to address and settle the data-protection roles of the site and the principal investigator, in particular in commercial clinical trials, where the site and the principal investigator accede to a protocol that has already been finalised unilaterally by the sponsor and merely implement it. In such cases, and consistent with paragraphs 132, 134, 142, our view is that the site and the principal investigator do not determine the purposes and essential means and act for the sponsor's purpose, with the principal investigator. Settling these roles would, in our view, reduce a significant and recurring source of legal uncertainty in clinical-trial agreements.

3. Comment 2 – Reconciling the functional test with the EDPB–EDPS Joint Opinion 3/2026 and the proposed Article 93 of Regulation (EU) No 536/2014 (European Biotech Act)

Two EDPB texts bear on the role of the site and the investigator, and in our view they would benefit from being expressly reconciled. The Guidelines apply a functional, fact-based test under which an actor that merely adheres to an already established protocol, without participating in the determination of the purposes and means, is not a joint controller and acts in a processor relationship (paragraphs 130, 132, 134 and 142). The EDPB–EDPS Joint Opinion 3/2026 on the European Biotech Act (COM(2025) 1022 final), to which the Guidelines refer at paragraphs 137 and 142, engages with a proposal that would, for the operations referred to in Article 93 of Regulation (EU) No 536/2014, characterise the actors that fund and conduct clinical trials, namely the sponsor and the investigator or the site, as controllers, with a harmonised legal basis under Article 6(1)(c) in conjunction with Article 9(2)(i) and (j) GDPR.

A direct conflict arises in the following situation. Where, on the facts of a commercial trial, the functional test leads to the conclusion that the relationship is one of controller (the sponsor) and processor (the site), the proposed Article 93 would nonetheless designate both the sponsor and the site or investigator as controllers, that is a controller–controller relationship, without distinguishing such cases. The same facts would then be classified differently depending on which instrument is applied. We note that the Joint Opinion is itself cautious on the controller question. It recommends clarifying whether those actors act as joint or as independent controllers, and it cautions against characterising individual investigators as controllers, since they act under the authority of the site, which is consistent with paragraph 137 of the Guidelines.

In our view, the functional test and the proposed statutory designation should not be left to produce divergent interpretations of the same role. We kindly ask the EDPB to address two points in the final Guidelines.

– Express reconciliation with the Joint Opinion 3/2026. Treating the site as a separate or joint controller, where on the facts it only adheres to the sponsor's finalised protocol and acts on the sponsor's instructions, is difficult to reconcile with the functional test in paragraphs 130, 132, 134 and 142. We kindly ask the EDPB to address the Joint Opinion 3/2026 expressly in the final Guidelines and to make clear how the functional test relates to the designation of controllers for Article 93 operations. This would prevent the same relationship from being classified as controller and processor under the functional test, yet as controller and controller under Article 93, and would remove the resulting uncertainty as to the role of the site.

4. Conclusion

In conclusion, we agree with the functional approach taken in the Guidelines, under which the controller is the entity that determines the purposes and the essential means of the processing, and under which a party that merely adheres to an already established protocol is not, on that basis alone, a controller (paragraphs 132, 134 and 142). Applying that approach, we are of the view that, at a clinical trial site, the provider is a controller only for the provision of health care, which is a distinct purpose with its own documentation and legal basis (Articles 57 and 58 of Regulation (EU) No 536/2014), and that for the conduct of the clinical trial, where it merely applies the sponsor's finalised protocol, it acts as a processor on behalf of the sponsor. Because the Guidelines do not classify the role of the clinical trial site and do not use the term, we kindly ask the EDPB to address and settle the roles of the site and the principal investigator, in particular in commercial trials where they accede to a protocol that has already been finalised by the sponsor.

We also kindly ask the EDPB to reconcile the Guidelines with the EDPB–EDPS Joint Opinion 3/2026. Where the functional test leads to a relationship of controller and processor, the proposed Article 93 of Regulation (EU) No 536/2014 would, without distinction, treat the same actors as two controllers, so that identical facts could be classified differently depending on which instrument applies. An express clarification of how the functional test relates to any statutory designation of controllers would remove this uncertainty.

We thank the EDPB for the opportunity to comment and remain available to provide any further input.