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

The European Data Protection Board (EDPB) has published the Draft Guidelines 1/2026 of personal data for scientific research purposes (hereinafter “the Guidelines”) to provide clarity on how the GDPR applies to scientific research. The Guidelines are currently open for public consultation, with a deadline for stakeholder comments on June 25, 2026. On behalf of Västra Götalandsregionen in Sweden (hereinafter “VGR”), this submission is hereby respectfully submitted to the EDPB in response to the public consultation on the Guidelines.

VGR is a regional authority in western Sweden. Within the region there are several hospitals that provide research activities. One of the largest hospitals is Sahlgrenska University Hospital, where research is an essential part of the hospital's activities and where the hospital participates in many clinical studies within a wide range of therapy areas.

Role and responsibility

In these comments from VGR, we will focus will on the distribution of roles and responsibility that parties have in a clinical study. To clarify, clinical studies in this text also include clinical trials for medicinal products and medical devices, according to the Clinical Trials Regulation EU 536/2014 (CTR) and Medical Devices Regulation EU 2017/745 (MDR).

Before a research collaboration or assignment in clinical studies starts, our experience is that there is often uncertainty between the parties engaged in the research, about which role for personal data responsibility the parties should rightfully have under the GDPR. Parties have different interpretations of how responsibility should be distributed under the law. This differs between countries, but also between organisations within the same country, which we experience is often the case in Sweden. The room for legal interpretation leads to

long lead times to finalise the conditions that are required to conduct research studies and to agree on the necessary agreements.

Commissioned clinical research projects

One of the research scenarios, in which questions about the allocation of roles often arise, are commissioned clinical research projects, where one party has initiated, manages and funds the study, and another party is invited to participate and acts as the executing party.

It is the role of the study site that parties often disagree on – specifically whether the study site acts as a controller or as a processor. Many organisations, like Sahlgrenska University Hospital, applies the EDPB's method for allocating roles (according to EDPB Guidelines 07/2020) and reaches the conclusion that the study site is also a controller in respect of its processing of personal data. The study site's controllership may, in addition, be separate for certain processing operations and joint for others.

Other organisations refer to the example of "Clinical trials" in paragraph 68 of the EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR and argue that the study site should be regarded as a processor and the sponsor as the controller for the clinical study, since the study site has not participated in the drafting of protocol but has merely accepted a protocol designed by the sponsor.

When the EDPB's method as referred to above is applied, the outcome in commissioned clinical research projects is that a substantial part of the site's processing activities cannot be performed as processor tasks. Instead, the study site has to be seen as an independent controller for those processing activities. This is especially the case where national law attributes to the study site the power and responsibility to determine whether and under which conditions specific processing activities may take place. These implications are difficult to reconcile with an interpretation that the study site would act as a processor, as stated in the example of "Clinical trials" above.

VGR would appreciate it if the Guidelines would provide guidance on how the parties' roles should be considered concerning commissioned clinical research projects described above.

Valuable examples

It is helpful that the Guidelines contain several examples. However, VGR would highly value if there were even more examples given in the guidance in order to be able to better apply the guidance in practice. For example, a scenario from the commissioned research situation described above and guidance regarding joint controllership between research parties would be appreciated.

Freely given consent

VGR finds, that it would be valuable if the Guidelines would elaborate more upon the background to the examples on Freely given consents of patients (no. 37 and 38). We experience that consent is generally more commonly used as legal ground than public interest for public authorities outside of Sweden. It is important to validate the benefits of using consent rather than public interest from a patient perspective in conducting clinical studies.

Other topics

It would also be valuable if the Guidelines would touch upon topics such as pseudonymization and the influence of the concept of personal data following the judgment in case C-413/23 P of the EU Court of Justice 4 September 2026 (European Data Protection Supervisor v Single Resolution Board) and the use of AI as a means to re-identify individuals (i.e. pseudonymization as a security measure).

National guidance as a complement

Once the Guidelines are published, VGR sees a pertinent need for a national guideline on how actors in Sweden will comply with these guidelines considering circumstances given by national law. It is important to have a consensus on how organisations should act in these matters on a national level.

Yours Sincerely,

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