Subject: Feedback on Guidelines 1/2026 on processing of personal data for scientific research purposes

Haukeland University Hospital (Helse Bergen Health Trust) welcomes the opportunity to provide feedback on the EDPB's draft Guidelines 1/2026. As the second largest hospital in Norway, a major provider of healthcare, and a frequent participant in international clinical trials, clear and consistent guidance on the roles and responsibilities under the GDPR is essential for both legal certainty and the responsible conduct of clinical research for the hospital, sponsors and the patients.

Clarification regarding Paragraph 142: The Hospital's Role in Industry-Sponsored Trials

We would like to provide comments on the interpretation reflected in paragraph 142, which states that adhering to an already established research protocol may be indicative of a controller-processor relationship.

While we recognise the importance of identifying functional roles based on factual circumstances, we are concerned that the current formulation risks placing undue weight on adherence to an established protocol as a decisive indicator of a processor role.

The interpretation presented in the Guidelines appears to deviate from established national guidance in several Member States, including the Danish Data Protection Authority's guidance from 2023 which in our experience has been adopted by several large multinational pharmaceutical companies.[1]

[1] Extract Danish Data protection Authority page 19-20 (our English translation):

A pharmaceutical company has planned and decided on to conduct a research project/clinical trial. A hospital is required by law to conduct research. A doctor at the hospital has signed up in a data base for research institutions that want to collaborate with the pharmaceutical industry to conduct research. The pharmaceutical company is subject to pay 120% remuneration in relation to the hospital's actual expenses. The hospital secures part of the doctor's salary by the doctor entering into a research collaboration with the pharmaceutical company and complying with its obligation laid down in legislation. The pharmaceutical company writes the protocol and secures approval from relevant authorities. The doctor collects data and enters it into the pharmaceutical company's systems. The pharmaceutical company sends a copy of the entered data to the doctor, which the doctor and the hospital are obliged to keep by law.

The pharmaceutical company is an independent data controller. The doctors who carry out the research project will generally be subject to professional and legal obligations. These duties may mean that doctors will not be able to follow instructions on the processing of personal data. The hospital will therefore not be able to play a role as a data processor in connection with the research project. The hospital is therefore also an independent data controller, even though the doctor's processing of personal data is (also) carried out in accordance with a research protocol planned and established by the pharmaceutical company.

Our position is based on the following key points:

1. **Professional Independence:** Healthcare professionals are bound by strict legal and ethical obligations (e.g., professional secrecy and the duty of care) that require them to act independently in the best interest of the patient. This professional autonomy is fundamentally incompatible with the role of a "processor" who must act strictly under the instructions of a controller.
2. **Safety and Legal Duties:** Hospitals have independent legal responsibilities for patient safety and medical record-keeping that exist concurrently with the clinical trial making the hospital a controller for these specific activities regardless of the protocol's origin.
3. **The "Essential Means":** While the sponsor may define the scientific protocol, the hospital determines the essential means of how the data is gathered through its clinical expertise and infrastructure.

Recommendation: We recommend that the EDPB clarifies how national professional obligations and statutory independence of medical staff should be taken into account when determining roles in the Guidelines. Specifically, we suggest that the final Guidelines provide more detailed clarification of roles in clinical trials, to avoid different interpretations across Member States, particularly given that most large clinical trials are conducted across multiple Member States.

In line with our understanding and the recommendations of the Danish Data Protection Authority, we kindly ask that the final Guidelines explicitly clarify whether adherence to a pre-defined research protocol, in itself, is sufficient to establish a processor role, or whether the professional independence of healthcare providers may instead necessitate an independent controller or joint controller role in the context of clinical research.

Sincerely,

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on behalf of
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