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# Comments on the EDPB Guidelines on the Processing of Personal Data for Research Purposes

The Swedish Ethical Review Authority welcomes the ambition to clarify the rules applicable to the processing of personal data for research purposes. We recognise a significant need for clarity in order to safeguard public trust in research, as well as from the perspectives of efficiency and the rule of law. However, we have concerns regarding the guidelines.

The Swedish Ethical Review Authority is responsible for the ethical review of research involving human subjects. Such review is conducted pursuant to the Swedish Act (2004:460) on the Ethical Review of Research Involving Humans. That Act is in turn based on recognized international conventions, for example the Declaration of Helsinki.

The purpose of the Ethics Review Act is, pursuant to Section 1, to protect individual persons and respect for human dignity in research. The comments set out in this Statement are made from the perspective of that mandate and those principles.

There is an interest — both from the perspective of researchers and of research participants — in ensuring that the rules and principles applicable to research are clear and consistent, and that no divergences in different legislation are created that contribute to legal uncertainty. We encounter questions from researchers on a daily basis regarding the applicable rules which show that navigating the regulatory frameworks is already complex.

The manner in which we assess consent and various measures to reduce risk to research participants under the Ethics Review Act differs from what is proposed in the Guidelines. The Swedish Parliament has recently adopted amendments to the Ethics Review Act introducing new regulation of certain consent-based research, affecting requirements that consent be informed, voluntary, specific, and explicit.

We are concerned that the proposed Guidelines will not contribute to clarity in practical application. It is furthermore our assessment that several of the proposals operate to weaken the position and oversight rights of research participants. We elaborate on this below.

## Background

The Swedish Ethical Review Authority issues approximately 8,000 decisions per year. These cases provide us with insight into the conditions and challenges of research in Sweden.

In this context, we wish to highlight, first, that the various regulatory frameworks researchers must comply with are already complex to navigate. Researchers frequently address that they lack interpretive guidance from their own organizations. We are concerned that the Guidelines will further complicate the regulatory landscape for researchers rather than providing the intended clarification and facilitation.

Several of the proposals are premised on the ability of researchers to re-engage with research participants. This presupposes a degree of infrastructure. Here too, we are concerned that the Guidelines are built on theoretical solutions that will prove difficult to implement in practice and risk undermining the protection afforded to research participants.

## The EDPB Guidelines risk to erode the meaning of informed consent, and shift control from the individual to the researcher and the system

In practice, the EDPB Guidelines represent a shift in which the individual's right to control over their personal data is gradually replaced by a system that prioritizes research interests. This occurs not through the abolition of consent, but through a change in its function: from a concrete expression of autonomy to a general permission enabling the continued use of data over time for very broad purposes.

### 1. Broad consent

Broad consent is described and exemplified in the guidelines in a way that we find differs from today´s practice. We are concerned that a system is created in which the original consent takes on more the character of an open-ended future consent for unspecified uses of personal data.

That would mean that consent loses its function as an expression of informed self-determination. The requirement for "informed consent" is partly emptied of substance when the data subject cannot foresee how their data will subsequently be used. This represents a weakening of the individual's position rather than a neutral form of flexibility.

In practice, the fundamental question arises as to what constitutes a research purpose and what constitutes the establishment and maintenance of a research database (cf. the Act (2024:1146) on Certain Research Databases).

Under the Ethics Review Act, an ethical approval may only relate to "a specific project or a part of a project, or research defined in a comparable manner". This is somewhat different from the examples described in the guidelines, for example "medical research in the field of oncology" (45).

### 2. Transparency

The Guidelines presuppose that individuals will be informed of new purposes, while simultaneously accepting exceptions where doing so would be disproportionately burdensome, where it would risk jeopardising the research, or where contact details are unavailable. The consequence in many Swedish studies with large datasets is that individuals will in practice not be informed that their data is being used in a new manner and will therefore be unable to act by objecting or withdrawing consent. This poses a risk that the fundamental principle of transparency loses in practical significance.

## 3. Prolonged Retention

The EDPB Guidelines indicate that it is permissible to retain personal data for very long periods for future research. In practice, this means that data may circulate within research systems for decades and that new uses may continuously arise. Although the GDPR contains a storage limitation principle, this is somewhat eroded through the research exemption. For the individual, it becomes unclear when processing will actually cease — if it does — making it difficult to assess the risks involved and reducing the possibility of “leaving the system”.

## 4. The Right to Erasure

Although the GDPR confers a right to erasure, this right is restricted through the research exemption. This means that researchers may retain data notwithstanding objections and may prioritize research interests over the wishes of the individual under certain circumstances. For the individual, the possibility of regaining control in those circumstances are limited and the right becomes contingent upon an assessment of the research value. We would like to emphasize the importance of the exception being applied restrictively and not by routine.

## 5. Dynamic Consent

The EDPB Guidelines present dynamic consent as a solution; however, this model presupposes active engagement by the individual, requires technical systems and ongoing communication, and is moreover difficult to implement in relation to large datasets.

In practice, dynamic consent therefore risks being used only in limited contexts and functioning as a legitimation of an otherwise flexible system. Dynamic consent appears more as an ideal model presented in principle than as a genuine safeguard.

This Statement has been decided by the Director, Karin Nylén, following presentation by the Scientific Coordinator, Pierre Lafolie.