Comments on the Guidelines 01/2025 on Pseudonymisation

The Research Services of the Wellbeing Services County of Pirkanmaa (Finland) serves and supports researchers and cooperation partners, both locally, nationally, and internationally, at different stages of different types of research (including but not limited to clinical and biomedical research).

The Research Services provides the following comments to the Guidelines 01/2025 on Pseudonymisation for the European Data Protection Board:

In **sections 42** and **65** of the Guidelines reference to aspects to consider in relation to defining the pseudonymisation dome or designing the pseudonymisation procedure is made. The consideration referred to here (e.g. what does “with reasonable means” mean) is moderately close to the consideration of whether certain information is anonymised or not (what are “means reasonably likely to be used”, recital 26 of GDPR). Therefore, it should be noted that the contents of “reasonable means” meant in these Guidelines should not be in conflict with “reasonable means” in another context, without appropriate consideration for different circumstances. For example, as per sections 42 and 65 of these Guidelines, “reasonable means” to consider includes also illegal acts and criminal intent.

In **section 66** of the Guidelines a reference to “sufficient guarantees” is made. It should be considered whether this reference requires further clarification. In this section reference is also made to “contract or legal act”, which are referred to as supplementary acts to the sufficient guarantee. This would lead the reader of the Guidelines to understand that sufficient guarantees do not include contracts or legal acts. That raises the question of what it includes and what else is required beyond contracts or legal acts.

In **section 77** of the Guidelines, it is stated that in case the controller is unable to identify the data subject, the rights of the data subjects enumerated in Art. 11(2) or 12(2) GDPR shall not apply. However, in **section 79** the following is stated: “the controller should indicate in the information provided to data subjects according to Art. 11(2) GDPR how they can obtain the pseudonyms relating to them, and how they can be used to demonstrate their identity”. In such cases where the controller is unable to identify the data subject due to pseudonymisation, is Art. 11(2) applied? Or does the controller have an obligation to provide the data subject with sufficient information to enable the identifying of said data subject after pseudonymization (which obligation is not mentioned in Art. 11(2) referenced here)? The scope of application for the obligations set out in section 79 and the content of the information to be given is unclear. Providing information on the pseudonym might entail risks.

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In **section 81** of the Guidelines an obligation to inform data subjects of data breaches is set. However, all exceptions mentioned in Art. 34(3) to such obligation shall be applicable (not only Art 34(3)(c)).

In **section 109** reference is made to employees being vetted. It should be considered whether this reference requires further clarification. Does “vetting” an employee require some form of security inspection or some other background checking? Is it sufficient to require the employees to commit to confidentiality or to rely on obligations of confidentiality set out in law? Please also note that the persons referred to in this section might not always be employed by the controller.