The Guild's contribution to the Guidelines 1/2026 on processing of personal data for scientific research purposes

The Guild welcomes the opportunity to provide comments to the European Data Protection Board's public consultation on the Guidelines 1/2026 on processing of personal data for scientific research purposes, henceforth called 'the guideline'. The processing of personal data for research purposes constitutes a fundamental aspect of research activities. In the context of clinical and health research, it is important to recognise that data is provided by individuals who entrust research teams, within the framework of research projects or research infrastructures, with the overarching goal of producing knowledge that serves the public interest.

The Guild is concerned about the European Data Protection Board's responsiveness to requests from the Commission and calls from the research community. Given that the GDPR, together with other data legislation, is currently under revision as part of the Digital Omnibus VII, in which the Commission aims to define scientific research, subject to inter-institutional negotiations between the European Parliament and the Council, The Guild is cautious about the guidelines' timeliness and applicability.

Below, The Guild provides targeted feedback on the Guidelines to ensure they are fit for purpose for the community across the full research spectrum.

1. **Definition of scientific research (paragraphs 6 and 11)**

The guideline does not consider the Commission's Digital Omnibus proposal, which aims to define scientific research as 'any research which can also support innovation, such as technological development and demonstration. These actions shall contribute to existing scientific knowledge or apply existing knowledge in novel ways, be carried out with the aim of contributing to the growth of society´s general knowledge and wellbeing and adhere to ethical standards in the relevant research area. This does not exclude that the research may also aim to further a commercial interest.' To remain relevant and applicable as soon as the guidelines are available, including the reference in paragraph 11, this development should be considered. Otherwise, the guidelines will become outdated as soon as the digital omnibus package is adopted.

2. **Strengthening key indicative factors (paragraph 11)**

The Guild notes that the point on "verifiability and transparency" should be strengthened by outlining requirements needed to ensure that the data processing is driven by research purposes. At the same time, the point on "autonomy and independence" should also consider whether a declaration of potential conflicts of interest is available.

3. **Not meeting the factors presumed to constitute scientific research (paragraph 12)**

The Guild welcomes the identification of the six key-indicative factors outlined in paragraph 11. However, paragraph 12 does not sufficiently clarify how those factors should be applied where a research activity does not meet all six. In particular, it remains unclear whether the factors are cumulative or equivalent, whether some should be given greater weight than others, and whether one factor may compensate for the absence or partial fulfilment of another.

To promote harmonised application across Member States, the Guidelines should distinguish between indispensable or core factors and supporting or context-dependent factors, and clarify how partial fulfilment should be assessed and how factors should be weighed against one another. This would reduce the risk of divergent national interpretations without introducing a fixed minimum number of factors. For example, Member State A might deem research scientific if the researcher meets 3 out of 6 factors, while Member State B might require meeting 4 out of 6 factors.

4. **Negative examples (example 3)**

The Guild appreciates the EDPB's intention to include so-called negative examples, as this can provide a more nuanced review for principal investigators and the broader research team, and reduce the number of research project proposals that are potentially declined due to unlawful processing of personal data.

5. **Research data infrastructure and the role of data labs (paragraph 13)**

While only adjacent to the scope of the guidelines, the EDPB should, with the support of the European Commission, clarify whether AI Factories are considered a research data infrastructure. In addition, as outlined in the European Commission's Data Union Strategy, Data Labs, which are currently part of the AI Factory initiative, can be used to conduct pseudonymisation. Therefore, it should be clarified how Data Labs' pseudonymisation services align with the requirements of the GDPR and sectoral legislation, such as the European Health Data Space (EHDS) Regulation**.**

6. **Purpose limitation and its link with the EHDS Regulation (paragraph 17)**

As with health research, researchers, such as those working at university hospitals, are bound by obligations under the GDPR and, when applicable, the EHDS Regulation, regarding the link between the primary use of health data and its secondary use. Paragraph 17 could be improved by including references to purpose limitations and highlighting the interaction between the GDPR and the EHDS Regulation.

7. **Potential changes regarding further processing of personal data concerning health, genetic or biometric data regarding the EHDS Regulation (paragraph 25)**

As under the EHDS Regulation, Article 51(1)(f), health data holders have to make, among others, human genetic, epigenomic and genomic data available for secondary use, the paragraph would benefit from including a footnote specifying the provision to ensure researchers consulting the present guidelines are aware of the additional provisions.

8. **Cases when one controller is obliged by Union or Member State law to provide personal data to another controller (paragraph 26)**

The paragraph notes that there are conditions when one controller is obliged by Union or Member State law to provide personal data to another controller. The Guild would like to highlight that, although this case may be uncommon, the section would benefit from an example illustrating a hypothetical scenario. Furthermore, where personal data is provided to another controller for research purposes, the presumption of compatibility should still require an assessment of the guarantees attached to the transfer and further processing.

9. **Informing data subjects (paragraph 28)**

While controllers are permitted to store personal data for specific research, even after the initial purposes are fulfilled, including when research results lead to future projects requiring further data processing, The Guild seeks clarification on whether, in such cases, data subjects must be informed.

10. **Purpose limitations and foreseeable future research activities (paragraph 29)**

While storing data for general research without a clear purpose is not justified by Article 5(1)(e) in the GDPR, and the fact that future research activities should be foreseeable within the research field, the section would benefit from an example illustrating a hypothetical scenario.

11. **Further clarification on respective roles and responsibilities (paragraph 38)**

Regarding clinical research, The Guild notes that the guidelines should provide clearer guidance on the respective roles and responsibilities of the sponsor, investigator, hospitals, and universities, as they operate under different legal entities in certain instances.

12. **Validity of decisions of ethics committees in the event of multi-country research projects (Example 8)**

The example describes in detail the processing of personal data for research purposes based on broad consent. However, The Guild seeks clarification on a hypothetical scenario in which using patient data for a specific research project requires review and approval by multiple independent ethics committees, for example, when data subjects are in different Member States. How should a researcher proceed if the ethics committee in country A gives their approval, whereas the ethics committee in country B declines the proposal?

13. **Additional examples under section 4.1.3 (paragraphs 53 – 55)**

The Guild would like to note that the topic of consent to participate in research, when required by ethical or legal requirements that do not stem from the GDPR, would benefit from a hypothetical example.

14. **Additional example under section 4.4.3 (paragraph 75)**

The Guild welcomes reference to the EHDS Regulation, as the legislation will have a significant impact on how health research will be conducted in the future. As such, an example should be introduced illustrating the derogation.

15. **Introduction of proportionality principles (paragraph 79)**

The Guild appreciates the nuances and layered approach mentioned in the paragraph. However, it should also reflect on proportionality, as researchers' efforts to ensure that data subjects can stay informed on the processing of their personal data need to be proportionate to the main research activity.

16. **Requirements on keeping personal data confidential, subject to an obligation of professional secrecy, and its relation to the EHDS Regulation (paragraph 106)**

The Guild seeks clarification on how the concepts laid out in paragraph 106 would need to be applied in practice when researchers must also consider the opt-out requirements under the EHDS Regulation, as outlined in Article 71(1), as well as the Member State's right to override the opt-out under Article 71(4).

17. **Additional information on the choice of software to be used (paragraph 132)**

The paragraph notes that non-essential aspects of processing, such as the practical aspects of implementation, including the choice of software to be used, may be left to the processor. The Guild seeks

guidance on the processes to follow if the processor decides to use software that the data controller has been discouraged from using due to the data controller's employment in the public sector. For example, if the processor operates under Microsoft, however, the controller, such as a researcher, is employed by a public sector body, the researcher must follow the governmental decisions.