

## Guidelines 1/2026 on processing of personal data for scientific research purposes

| Section                                                             | Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| <b>Section 3.2, paragraph 29, and section 4.1.2.1, paragraph 44</b> | It is stated that storage for generic scientific research purposes without specific purpose cannot be justified. Further clarification would be helpful regarding the level of specificity required when defining a research area for future projects. For example, would it be sufficient to refer broadly to the “health field,” or would it be necessary to identify a more specific field, such as “ophthalmology”? Would an even greater degree of specificity be required? Additional guidance on this point would be valuable in rapidly evolving fields such as data-driven health research, particularly in light of the broad framework for the secondary use of health data established by the European Health Data Space (EHDS) under Regulation (EU) 2025/327. |
| <b>Section 4.1, paragraph 35 and following</b>                      | This section would benefit from further clarification regarding remote consent, for example via video or telephone calls.<br>In an increasingly globalised world and a growing number of multinational clinical trials, it would be beneficial if applicable legislation and guidance kept pace with this evolution.                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Section 4.1.2.1, paragraph 48</b>                                | It is said that, regarding broad consent, controllers should make detailed information available to data subjects (for example on a webpage) on how their personal data are processed as research progresses in individual research projects. It should be clarified if this constitutes an obligation, a recommendation or whether it should be subject to a risk-based approach.                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Section 4.3., paragraph 60 and following</b>                     | Further clarification would be beneficial regarding the practical circumstances in which legitimate interests may serve as an appropriate legal basis for scientific research, particularly where informed consent is not obtained.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Section 4.4.2., paragraph 70</b>                                 | Further clarification would be beneficial regarding the distinction between making personal data publicly accessible and providing consent to its further processing for scientific research purposes. It would be helpful to explicitly reaffirm that the act of publishing personal data on social media does not imply unrestricted authorization for subsequent processing activities.                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Section 5.3., paragraph 84 and following</b>                     | The expectation that controllers should retain or re-establish contact details where future research use is                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

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|                                                         | <p>anticipated may raise challenges in relation to the principles of data minimisation and storage limitation under Article 5 of the GDPR. Further clarification would be beneficial.</p>                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>Section 8.3., paragraph 162</b></p>               | <p>It is said that the controller providing anonymised data may itself retain the personal data in a pseudonymised form. Clarification to avoid ambiguity between the concepts of anonymisation and pseudonymisation would be required, as true anonymisation is supposed to be irreversible.</p>                                                                                                                                                                                                                                                                                                              |
| <p><b>Section 8.4., paragraph 165 and following</b></p> | <p>In general, there appears to be legal uncertainty and a lack of guidance regarding the transferring of genetic data in clinical research. This guidance would be a valuable opportunity to give further clarification. For example, it could address the distinction between different types of genetic data (e.g. individual-level data or summary-level data) and their respective levels of identifiability. Further guidance would be particularly useful on the criteria under which genetic data may be transferred or considered effectively pseudonymised or, in exceptional cases, anonymised.</p> |