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The Italian Society for Medical Statistics and Epidemiology (SISMEC; <https://sismec.info>) applauds EDPB's initiative to launch a public consultation on the Guidelines 1/2026, in particular for its positive impact on public health studies. We look favorably upon the clarity in the concept of scientific research (Chapter 2) and the principles for data protection outlined in Chapter 3. In this respect, paragraph 3.1.2 has the potential to enhance the interoperability of data sources from different owners, including large-scale population-based epidemiological studies carried out for scientific purposes in some Institution in which record linkage between enrolled study participants and administrative healthcare records is needed to ensure high-quality and complete follow-up. According to paragraph 3.1.1, the further processing for scientific research purposes of healthcare records (often not originally collected for scientific reasons) is presumed to be compatible with the initial purposes of processing; these data can therefore be provided to another controller (B; e.g., the initial owner of the epidemiological study) for its own scientific research purposes without further compatibility assessment (paragraph 3.1.2). Moreover, the reference to the EHDS European Health Data Space Regulation (§75) is viewed positively.

We hope that these principles will be adopted across Europe in a consistent manner, without reliance on restrictive interpretations at the State or regional level that might jeopardize homogeneous application throughout Europe. To this extent, adding to the guidelines an example related to research in the public health field might be useful.

Having set out the above general considerations, the following is a list of the main points (identified by their corresponding paragraphs in the text) which would benefit from further clarification with the aim of meeting the needs of those conducting studies in the field of public health:

- Further processing when providing personal data to another controller for scientific research purposes (§26)
- Storage limitation (§27)
- Specific Consent (§29)
- Providing healthcare and conducting scientific research, when those purposes are interrelated (§38)
- Broad consent (§40-45)
- Processing special categories of personal data for scientific research purposes (Article 9 GDPR) (§64-66).

We look forward to contribute further to the process.

Best wishes,

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