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

EAU Response

General comments

EAU welcomes the guidelines on processing of personal data for scientific research purposes. These provide important and much needed information necessary to support researchers in the health field. However, we still perceive a number of aspects that are not sufficiently covered when applying the guidelines through a health research lens, as health data is a very specific, and highly regulated, field.

We would like to highlight three general gaps in the current guidelines which apply to health research:

1. Lack of clarity with other horizontal and sector-specific regulations (AI Act, Medical Devices and IVD Regulations, Clinical Trials Regulation, European Health Data Space, for example)
2. Lack of harmonised approaches to handling health research across the EU. The issue is referred to in paragraph 66 of the current guidelines as an area where Member States have significant possibilities to impose further restrictions and measures for processing health data, genetic or biometric data. The 2021 Study on the Assessment of EU Member States' rules on health data (in the light of the GDPR) is a clear indication of the scope of the challenge (see here)
3. There is no acknowledgement of the overlap with ethical requirements for undertaking health research, which have previously led to ethics committees having a considerable interpretive voice to GDPR requirements.

Definition of scientific research

All of the definitions are sound and reasonable, but these will need to be clearly refined to be implementable in a health research setting.

The guideline uses the example of a clinical trial, which is still the 'gold standard' of clinical research. However, healthcare research is expanding in an important direction to a much wider range of interventional and non-interventional studies, which are frequently undertaken by both researchers and clinicians themselves, such as:

- Prospective disease registries
- Healthcare quality management research
- Real-world evidence to guide clinical practice guidelines
- Implementation science on health system capacity and feasibility.

While some examples are clear (e.g. the case study of a retail sales analysis of online customer data falling outside of scope of scientific research), many extremely important edge cases for health remain unclarified, such as in the case a health care service provider monitoring and analysing health data for quality and effectiveness purposes. This leaves a level of uncertainty in interpretation which should be clarified with more specific case studies spanning the breadth of the health research sector.

Many important discoveries emerge from real-world service improvement and learning systems. Modern health, public-sector and industrial innovation often blends research and improvement, making it a key component of medical research, particularly given the push towards real-world data use for research

purposes by the European Medicines Agency and the European Commission. Excluding all improvement activities could make GDPR rules artificial and discourage socially useful evaluation.

Scientific research as a purpose in its own right.

To avoid unnecessary fragmentation across institutional and EU borders, as well as the possible huge loss of valuable data due to unnecessary re-consenting, the EDPB should clarify that "scientific research" constitutes a broad, overarching purpose under the GDPR, where multiple projects, studies and analyses can take place. This interpretation aligns with Recital 159 GDPR, the compatibility presumption under Article 5(1)(b) GDPR, and the practical realities facing public health researchers and teams.

Consent is over-emphasised in the current guideline

Notions of consent (broad and dynamic) are over-emphasised in the guidelines. We believe they are also a departure from the sector specific opinion from EDPB in 2019 on the interplay between the clinical trials regulation and the GDPR, which was able to provide sound guidance. This differentiated between 'informed consent' and GDPR explicit consent and notes in paragraph 25 that "the EDPB considers that as an alternative to data subject's consent, the lawful grounds of processing provided under Article 6(1)(e) or 6(1)(f) are more appropriate" (link).

In the EDPB guideline, consent is implicitly framed as a default expectation, even in settings where the GDPR itself anticipates that public interest or legitimate interests are both viable and appropriate for research purposes. The guideline does not sufficiently acknowledge the impossibility of re-consent in many health research situations, that would hinder valuable data from being used, and insisting on re-contact can render further research impossible or not feasible:

- People moving health providers
- Patients lost to follow-up
- Death or people
- Lack of response/ interest of participants

Ethics committees reviewing research protocols typically do so through the lens of informed consent, which in practice often leads them to determine consent as the effective legal basis for research. This occurs partly because national guidance on the matter is limited or absent. The result is inconsistency and uncertainty across Member States. Greater legal clarity is needed at the health sector level to define the appropriate boundaries of ethical oversight in interpreting GDPR provisions.

The Guidelines should draw a clear distinction between ethical consent and GDPR consent. Ethical consent governs participation in research studies, whereas GDPR consent is only one of several possible legal bases for processing personal data. The Guidelines should also clarify that re-consent is not required for secondary data use where it is impossible or disproportionate, provided that Article 89 safeguards and appropriate ethical oversight are in place.

With this in mind, the Guidelines need to affirm the role of ethical committees as responsible for ethical and scientific oversight, not for determining the legal basis for processing personal data or other GDPR-specific provisions under GDPR.

Legitimate interests test for scientific research

Legitimate interest is highlighted as a possible legal basis for scientific research and the guideline mentions that "significant weight" may be attributed to the processing of personal data for scientific research purposes. However, the guideline falls short of practical implementation guidance on how this may be applied in health research. The Legitimate Interest Assessment (Purpose – necessity – balancing tests) is a concept that was mainly derived for commercial partners, but the health research landscape is much more complex.

Combined with the fragmented legal landscape for health data described above and conflicting advice from ethics committees, the absence of concrete guidance will push many studies toward consent as their default legal basis. This is at odds with the proportionate approach recommended in the EDPB's 2019 Opinion on the interplay between the Clinical Trials Regulation and the GDPR.

More practical guidance is needed on which health research studies fall within the 'reasonable expectations' of data subjects for secondary use. This is particularly important for secondary use of health system data, that is, data generated by individuals using health services, as distinct from patients enrolled in studies or trials. Guidance should clarify when legitimate interests may not be the appropriate legal basis, and when public interest or another legal basis would be more suitable.

The legitimate interest test also becomes prohibitive in many health research settings, as full anonymisation often removes the scientific value and analytical value for health research. On top of this, in many cases it also prohibits any chance of reporting significant findings to research participants - a provision of the European Health Data Space.

Pseudonymisation

Greater guidance on risk-based pseudonymisation is required. The guideline references the judgment of 4 September 2025 (C-413/23 P, EDPS v. SRB, EU:C:2025:645) EUR-Lex - 62023CJ0413 - EN - EUR-Lex, but falls short of clarifying how the concept of 'relative identifiability' (data can be personal for one actor but not another) can be reasonably and legally applied in health research settings. This guidance is of critical importance to:

- Multi-centre health studies
- Health data access platforms
- Federated health research models

These studies all fall under ethical scrutiny, with data protection impact assessments performed. They are generally processed in a secure processing environments.

Storage restrictions

Storage limitations in the guideline present a significant challenge for healthcare, where longitudinal studies and prospective registries are uniquely powerful means of understanding how diseases develop, progress, and respond to treatment over time. While paragraph 27 acknowledges that retention periods for longitudinal research may be uncertain and should be determined by the controller using defined criteria, this falls short of what is needed in practice. The ability to use data across a person's lifespan is critical to the field and far from a niche concern, yet ethics committees and institutional Data Protection Officers frequently treat longer retention periods as problematic. This pushes researchers toward shorter retention windows, even where the guidelines themselves recognise that flexibility may be warranted, and in the absence of any statutory or legal requirement to retain data for longer. This will likely stifle the large and growing body of longitudinal research that depends on real-world evidence and big data from multiple cohorts. For example, long-term

follow-up data is essential to measure the impact of screening programmes on mortality, as powerfully demonstrated by the 23-year follow-up of the European Study on Prostate Cancer Screening.

Guidelines that push researchers toward shorter retention windows risk making this kind of research impossible across the EU, with direct consequences for public health.

Conclusion

Health research operates in a complex landscape of overlapping regulations, ethical oversight, and practical constraints that distinguish it from other forms of data processing. These guidelines default toward consent and leave legitimate interest assessments underspecified. The practical effect will be to push researchers toward overly cautious interpretations that will impede valuable, life-saving research, and put the brakes on key EU initiatives with huge potential like the EHDS.

The EAU urges the EDPB to engage more directly with the realities of health research in the finalised guidelines, specifically drawing on previously published sector-specific precedents such as the 2019 Opinion on the Clinical Trials Regulation. We reiterate the need for concrete, coherent, and implementable guidance for healthcare research specifically, as it is essential to enable researchers to fulfil their obligations under the GDPR, and limit unnecessary over-reliance on consent at the expense of public health research.