Justus Liebig University Giessen

Faculty of Medicine – Vice Dean for Research

European Data Protection Board

Rue Wiertz 60

B-1047 Brussels, Belgium

Giessen, June 24th 2026

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

Comments by the Faculty of Medicine, Justus Liebig University Giessen (deadline 25 June 2026)

Dear Sir or Madam,

the Faculty of Medicine of Justus Liebig University Giessen welcomes the EDPB's initiative to clarify the data protection framework for scientific research. The draft guidelines address long-standing uncertainties and provide substantial relief for academic medicine, in particular through the recognition of broad consent, the compatibility presumption for further processing, and the express inclusion of commercially funded research.

The following comments are submitted from the perspective of a research-intensive academic medical centre with a focus on clinical, clinical-experimental and translational research. This includes data-driven university medicine, Data Integration Centre infrastructures, federated research networks and multimodal biomedical research based on clinical, imaging and molecular data. They take into account both the interests of academic research and the interfaces with industrial development of medical innovations.

1. Summary of comments

We respectfully invite the Board to clarify or refine the following points in the final version of the guidelines:

- Operationalisation of the six key factors for clinical research, clinical registries and the secondary use of routine care data.
- Compatibility presumption for the further processing of routine clinical data initially collected in the healthcare context, e.g. where the initial processing is based on the treatment contract under Article 9(2)(h) GDPR and § 630a BGB.
- Concretisation of processing special categories of personal data for scientific research purposes including the term "large-scale", a workflow for the balancing test, and proportionate transparency obligations.
- Legitimate interest as a lawful ground for the use of clinical data in the development of medical AI, including industrial co-operation.

- Coherent interplay with sectoral Union law (CTR, IVDR, MDR, EHDS Regulation, AI Act) to avoid duplicate regulation.
- Express recognition of ethics committees as a safeguard under Article 89 GDPR.

2. Comments on individual sections of the guidelines

2.1 Definition of scientific research purposes (Section 3)

The introduction of six key factors (systematic methodology, ethical standards, verifiability and transparency, autonomy and independence, research objectives, contribution to the body of knowledge) is welcome. It establishes, for the first time, a workable test and draws an appropriate line between research, commercial marketing and pure quality assurance.

Recommendations

• Clinical registries and prospective observational studies should be cited in the guidelines as a clear example of research activity, provided that a published study protocol, registration (for example ClinicalTrials.gov or DRKS) and a favourable ethics opinion are in place. Without such clarification, established research infrastructures such as the German Pulmonary Hypertension Registry, the German Resuscitation Registry, ARDS/ECMO registries and outcome registries run by medical societies may face legal uncertainty.

• Secondary use of routine care data for real-world evidence should qualify as research where methodological minimum standards (a-priori hypothesis, biostatistical study design, intention to publish in peer-reviewed form) are met. The boundary to non-research market analysis must remain clear (cf. Example 3 of the guidelines) but should not capture legitimate health services research. This clarification is particularly important for Data Integration Centres and federated university medicine infrastructures, where routine care data are standardised, linked and analysed under defined governance frameworks for scientific purposes.

• Investigator-initiated trials (IITs) and academic consortia should be expressly covered, including studies conducted without a pharmaceutical sponsor. In internal medicine, perioperative medicine and intensive care medicine, IITs run through European platforms are a standard format for high-quality health services research.

2.2 Compatibility presumption for further processing (Section 4.2)

The compatibility presumption for further processing of data originally collected for other purposes is welcome. It is of considerable importance to German university medicine, where patient care and clinical research are closely interwoven at the organisational level.

Points requiring clarification

• Relationship with the lawful basis of the initial processing: the guidelines should make clear that the compatibility presumption also applies where routine clinical data were initially collected and processed in the healthcare context. This includes data generated within the treatment relationship under § 630a BGB and processed as health data under Article 9(2)(h) GDPR together with the applicable Article 6 GDPR legal basis. This should also cover subsequent processing for scientific research purposes

under Article 9(2)(j) GDPR and national research law. Otherwise, the most relevant constellation in Germany, the secondary use of clinical routine data for research remains unresolved.

- Temporal scope: the guidelines should expressly acknowledge that further processing may take place several years after the initial collection, provided that this was reasonably foreseeable and the safeguards of Article 89 GDPR are in place. This is essential for retrospective outcome analyses and biobank-based research.

2.3 Consent and broad consent (Section 4.1) and Processing special categories of personal data (Section 4.4)

The recognition of broad consent as a valid form of consent is a key achievement of the guidelines and brings European data protection law into line with established international standards (notably CIOMS and the WMA Declaration of Taipei). The additional safeguards required (independent oversight, time limitation, ongoing information, possibility of withdrawal) are appropriate.

Recommendations

- Defining "well-circumscribed areas of research": terms such as "oncological research", "cardiovascular research" or "perioperative outcomes research" should be accepted as sufficiently specific. An overly narrow reading would significantly hamper interdisciplinary consortia such as the German Medical Informatics Initiative (MII) and the Network of University Medicine (NUM).

- Definition of "large-scale" processing (Section 4.4 65.): the guidelines refer to large-scale processing of personal data without defining the term. The final version should provide either a quantitative threshold or operational criteria, building on Article 89(1) GDPR, Article 35(3)(b) GDPR and the existing EDPB guidance on Data Protection Impact Assessments.

- Balancing test for legitimate interest: the balancing test under Article 6(1)(f) GDPR in the research context should be illustrated by a worked example or a step-by-step workflow including a checklist of relevant criteria. This would help controllers and supervisory authorities apply the test consistently across Member States.

- Compatibility with national statutory permission and opt-out models: Germany increasingly relies on statutory frameworks for the secondary use of health data at federal and state level, including opt-out regimes where provided by national or state law (§ 48 LKHG Baden-Württemberg, in force since 3 December 2025; § 6 GDNG at federal level; draft legislation in further Länder). The guidelines should make clear that such national rules under Article 9(2)(j) GDPR constitute an independent legal basis that can apply alongside broad consent.

- Proportionate transparency measures: the requirement of ongoing information (web pages, newsletters, dashboards) is appropriate but should be open to proportionate implementation. For smaller research groups without dedicated communication infrastructure, fulfilment via an institutional umbrella page (for example a central research database of the university hospital) should be expressly permitted.

2.4 Training data for medical AI

The use of clinical data for the development and validation of medical AI systems is a focal point of current translational research in intensive care medicine, radiology, oncology and other disciplines. Examples include predictive models for intraoperative hypotension, haemodynamic risk stratification in pulmonary hypertension, automated ICU alarm systems, early sepsis detection, prediction of perioperative complications and multimodal AI models integrating radiological imaging, digital tissue imaging and molecular profiling data. The boundary between academic research, clinical validation and industrial product development is necessarily fluid in this area, particularly where AI systems are intended for use as CE-marked medical devices or clinical decision-support tools.

Recommendations

- Legitimate interest as a basis for AI development: the guidelines should make clear that the development of AI models for medical use – in particular software intended as a CE-marked medical device – can also be carried out by industrial partners under public-private partnerships, on the basis of Article 6(1)(f) and Article 9(2)(j) GDPR. A blanket restriction to research "in the public interest" would substantially impair the translational capacity of European university medicine.

- Coherence with the AI Act: the guidelines should clarify how GDPR requirements for scientific research interact with the data governance requirements for high-risk medical AI systems under Article 10 of Regulation (EU) 2024/1689. In particular, the GDPR and the AI Act should be interpreted coherently where clinical and biomedical datasets, including imaging and molecular data, are used for the development, validation and post-market performance monitoring of medical AI systems.

2.5 Relationship with sectoral Union law

Health research is increasingly governed by sectoral Union acts: the Clinical Trials Regulation (EU) 536/2014, the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746, the Medical Device Regulation (EU) 2017/745, the EHDS Regulation, the AI Act, the Data Act and the Data Governance Act. The guidelines should address the relationship between these acts and the GDPR in the research context to avoid conflicting requirements.

Recommendation

- A dedicated chapter in the final version of the guidelines on the coherent interplay between the GDPR and sectoral Union law would be of considerable value, in particular on the relationship between secondary use under the EHDS Regulation and research under the GDPR, and between clinical investigations under the CTR and the research privilege under Article 89 GDPR.

2.6 Role of ethics committees as a safeguard

The ethics committees established at medical faculties and state medical chambers in Germany have for decades acted as independent bodies overseeing research. They effectively perform the function that the guidelines describe under the headings of "independent oversight" and "data trustee function".

Recommendation

- The guidelines should expressly recognise ethics committees as an additional safeguard under Article 89 GDPR and acknowledge their role as independent oversight bodies in broad consent arrangements, trustee models and multi-centre consortia. Such recognition would avoid parallel approval structures and duplication of oversight.

3. Concluding remarks

The Faculty of Medicine of the Justus Liebig University Giessen acknowledges the Board's efforts to establish, through these guidelines, a balanced framework for data protection and the freedom of research. The points raised above are intended to improve the applicability of the guidelines in clinical research practice, in particular in data-driven university medicine, secondary use of routine care data, perioperative and intensive care medicine, personalised medicine, diagnostics and translational MedTech development.

We remain at your disposal for any follow-up questions or further discussion.

Yours faithfully,

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