Brigham and Women's Hospital
Founding Member, Mass General Brigham

HARVARD MEDICAL SCHOOL

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

European Data Protection Board

June 25, 2026

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

To whom it may concern,

The Multi-Regional Clinical Trials Center of Brigham & Women's Hospital and Harvard ("MRCT Center")[1] submits this comment in support of the European Data Protection Board ("EDPB") "Guidelines 1/2026 on processing of personal data for scientific research purposes" (the "Guidelines"),[2] adopted on 15 April 2026 for public consultation.

Background and Context

The MRCT Center is a research and policy center that addresses the ethics, conduct, oversight, and regulatory environment of international, multi-site clinical trials. It functions as an independent convener, engaging diverse stakeholders from academia, patients and patient advocacy groups, industry, non-profit organizations, national drug regulatory agencies, and others.

The MRCT Center welcomes the Guidelines as a significant and positive step toward greater regulatory clarity regarding the scientific research provisions of the European Union's General Data Protection Regulation ("GDPR"). The MRCT Center has previously engaged with the EDPB on these issues, including providing stakeholder feedback on GDPR-related challenges in clinical research and submitting comments in support of the 2021 guidelines on codes of conduct as tools for transfers. The MRCT Center commends the EDPB for addressing many core policy issues in the Guidelines and offers the following comments to strengthen the final text.

1. Areas of Support

1.1. Compatibility and Sensitive Data

The MRCT Center strongly supports the Guidelines' confirmation that further processing for scientific research purposes is presumed compatible with the initial processing purpose under

[1]The responsibility for the content of this document rests with the leadership of the MRCT Center, not with its collaborators, nor with the institutions affiliated with the authors including Brigham and Women's Hospital, Mass General Brigham, Ropes & Gray LLP, Harvard Medical School, Harvard University, and Yale Law School.

[2] https://www.edpb.europa.eu/public-consultations/guidelines-12026-on-processing-of-personal-data-for-scientific-research_en#no-back

75 Francis Street, Boston, MA 02115
Tel: 617-827-7413 | Email: bbierer@bwh.harvard.edu www.MRCTCenter.org

Article 5(1)(b) GDPR, such that the Article 6(4) compatibility test need not be separately performed. The Guidelines' clear statements regarding the presumption of compatibility will enable important secondary research with clinical trial data, which will help to advance scientific knowledge and cures for patients.

1.2. Broad Consent

The MRCT Center welcomes the clarification that broad consent is permissible for processing personal data within a defined area of scientific research, even when the specific purposes are not fully known at the time of collection, which is frequently the case for much valuable scientific research. This approach aligns with the reasonable-expectations framework familiar to U.S. organizations operating under the U.S. Health Insurance Portability and Accountability Act of 1996 and will facilitate globally harmonized consent practices in multi-regional research.

1.3. Basis for Processing in Clinical Trials

The MRCT Center welcomes the EDPB's clarification that a person's status as a patient or health care recipient does not, by itself, preclude reliance on freely given consent for the processing of personal data in clinical research. The nuanced approach to power-imbalance analysis, focusing on the actual circumstances of the particular study subject, is appropriate and will reduce uncertainty for sponsors designing consent processes. It is also fully consistent with the standards for informed consent under clinical trial regulatory regimes, which generally require consent of the individual prior to enrolment unless the individual is a minor or lacks capacity to provide consent.

1.4. Controller and Processor Roles

The MRCT Center appreciates the Guidelines' clear, research-specific explanation of controller, joint-controller, and processor roles. The focus on actual involvement in determining the purposes and essential means of processing accurately addresses the complexities of modern research. Nonetheless, the MRCT Center urges the EDPB, Member States, and supervisory authorities to promote interpretations consistent with the Guidelines' functional and research-specific approach, to avoid divergent national approaches that could undermine and obstruct cross-border and multi-institutional research collaborations.

2. Areas for Further Improvement

2.1. Interaction with the European Health Data Space

The MRCT Center welcomes the Guidelines' recognition of the European Health Data Space ("EHDS") Regulation as an integral part of the Union-law framework for processing electronic health data for scientific research. However, the Guidelines would be strengthened

by further clarification as to how the EHDS interacts with the GDPR's lawful basis and compatibility requirements for secondary research uses of electronic health data.

Specifically, the MRCT Center requests additional guidance on whether, and to what extent, an EHDS data permit or a decision by a health data access body may serve as evidence for the user's Article 6(1) lawful basis assessment, or if a separate Article 6 analysis is still required. The Guidelines should also specify which Article 9(2) derogations are expected to apply when secondary use for scientific research is authorized under the EHDS, particularly where the user relies on Article 6(1)(e) GDPR (processing necessary for the performance of a task carried out in the public interest) or 6(1)(f) GDPR (processing necessary for the purposes of legitimate interests).

Additionally, the final Guidelines should address how the EHDS secondary-use framework interacts with the GDPR's compatibility presumption – in particular, confirming that secondary use of electronic health data authorized under the EHDS benefits from the Article 5(1)(b) presumption of compatibility for further processing for scientific research, and as such, does not require additional compatibility or purpose-limitation analysis.

2.2. Consent for Data Processing in Clinical Trials

The Guidelines appropriately distinguish consent to participate in scientific research, including clinical trial informed consent, from consent relied on under the GDPR as a lawful basis for processing and, where special-category data are processed, as an Article 9(2)(a) derogation. The MRCT Center also welcomes the Guidelines' recognition that, where both forms of consent are sought at the same point in time, they may be requested in the same interface or consent form, provided the GDPR consent request is clearly distinguishable.

The MRCT Center requests that the final Guidelines clarify that, in clinical trials, the GDPR consent request may be integrated into the clinical trial consent form and that both the consent to participate in the trial and the consent to data processing may be evidenced through a participant's single signature or equivalent affirmative act on that form, provided the data-processing consent is clearly labelled, written in plain language, and separately explains the processing purposes, legal basis, withdrawal rights, and consequences of withdrawal. The MRCT Center urges the EDPB to make clear that a separate checkbox, signature block, or standalone GDPR form not be required. Mandating a separate signature or checkbox for the consent to data processing may confuse participants by suggesting that all trial-related data processing is optional and may lead to operational challenges if subjects execute one consent but not the other.

This flexible approach would reduce participant confusion, avoid unnecessary administrative burden, and align operational practice in multi-regional clinical trials. In the U.S., for example, the Health Insurance Portability and Accountability Act of 1996 permits a research authorization to be combined with consent to participate in research or with other research-

related permissions, provided the authorization elements are appropriately distinguished in the unified document.

2.3. Clinical Trials and the Right of Erasure

The Guidelines state that erasure may be denied under Article 17(3)(d) GDPR only where it "is likely to render impossible or seriously impair the achievement of the objectives" of the research, subject to safeguards and a fact-specific assessment. The MRCT Center supports the emphasis that this is a high threshold and not a categorical exemption from erasure, but considers that the final Guidelines would be improved by including examples specific to clinical trials of when erasure may seriously impair a research objective. Clinical trials are designed to generate reliable and robust evidence, and participant-level deletion may affect not only sample size, but also statistical validity, reproducibility, safety assessment, and interpretability.

This concern is especially acute when erasure requests are not random. Regulatory guidance recognizes that missing data can bias clinical trial results and that the risk of bias depends on the relationship between "missingness," treatment, and outcome. If erasure requests disproportionately come from participants with shared characteristics or outcomes — such as adverse events, treatment discontinuation, or poor response — deletion may distort efficacy or safety conclusions and undermine the representativeness of the study sample.

Clearer examples of when erasure "is likely to render impossible or seriously impair the achievement of the objectives" of the research would help sponsors, investigators, ethics committees, and supervisory authorities apply Article 17(3)(d) consistently while preserving the required case-by-case analysis and Article 89(1) safeguards.

3. Additional Clarification: Pseudonymization in Research Collaborations

The Guidelines cite the Court of Justice of the European Union ("CJEU")'s judgment in *EDPS v SRB* in relation to whether a recipient has means reasonably likely to identify a data subject. The Guidelines would be strengthened by further explaining the relative, context-specific nature of pseudonymized data as articulated by the Court. The CJEU held that pseudonymized data should not be regarded as personal data in all cases and for every person where pseudonymization can effectively prevent persons other than the controller from identifying the data subject.

The MRCT Center requests that the EDPB provide a practical pathway for research collaborations and cross-border research data sharing by which one party retains the re-identification key and another party receives robustly pseudonymized data subject to technical, organizational, legal, and contractual controls that prohibit access to that key and re-identification not reasonably likely for the recipient. This is a very common scenario in

clinical research, and thus clarifying that pseudonymized research data fall outside the scope of "personal data" for the recipient when the recipient has no reasonable means to re-identify the data, while remaining personal data for the disclosing controller where applicable, would provide significant legal certainty for multi-party research arrangements and encourage responsible data sharing in the interest of scientific advancement.

Conclusion

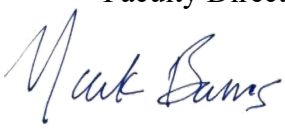
The MRCT Center commends the EDPB for this important initiative and for the substantial clarity that the Guidelines provide to the global research community. The MRCT Center strongly encourages the EDPB to finalize and adopt the Guidelines expeditiously, incorporating the clarifications requested above.

We appreciate the opportunity to provide feedback and welcome continued engagement.

Respectfully submitted,
on behalf of the MRCT Center



Barbara E Bierer, MD
Faculty Director, MRCT Center



Mark Barnes, JD, LLM
Faculty Co-Director, MRCT Center,
Partner, Ropes & Gray LLP
Visiting Lecturer, Yale Law School



David J. Peloquin, JD
Partner, Ropes & Gray LLP

75 Francis Street, Boston, MA 02115
Tel: 617-827-7413 | Email: bbierer@bwh.harvard.edu www.MRCTCenter.org