To:	European Data Protection Board
From:	Health Research Data Protection Network (HRDPN)
Matter:	Submission in response to the public consultation on EDPB Guidelines 1/2026 on processing of personal data for scientific research purposes
Date:	23 June 2026

The purpose of this submission is to provide observations from the Health Research Data Protection Network (the "**HRDPN**") on the European Data Protection Board's draft Guidelines 1/2026 on processing of personal data for scientific research purposes.[1]

About the HRDPN

The HRDPN is an Irish network of data protection officers and specialists working in or supporting health research, with members drawn from the national public health body (Health Service Executive), the university sector, voluntary and statutory hospitals and other State bodies. The network exists to support consistent, lawful and ethical processing of personal data in Irish health research and previously produced its *Practical Guide on Data Protection for Health Researchers* (2022) in consultation with the Data Protection Commission (the "**DPC**"). The HRDPN welcomes the publication of the Guidelines as a substantial and overdue contribution to the framework for scientific research under the GDPR and offers the following observations in a constructive spirit.

The Irish context

Ireland has implemented a developed national framework for the processing of personal data in health research: the Health Research Regulations 2018, as amended in 2021,[2] made under section 36(2) of the Data Protection Act 2018 and reflecting Ireland's exercise of discretion under Article 9(2)(j) GDPR.[3] The HRR identifies explicit consent (or a consent declaration granted by the Health Research Consent Declaration Committee (the "**HRCDC**")) as a suitable and specific measure required when carrying out health research — in other words, as an Article 89(1)-style safeguard, rather than as the GDPR legal basis itself.[4]

Researchers in Ireland therefore operate under a dual compliance obligation: the GDPR (as elaborated by the Guidelines) on one hand and the HRR on the other. The HRDPN recognises that the EDPB cannot, in a single document of EU-wide application, address each national framework in turn. The observations below are intended to identify opportunities for clarification or expansion on the interaction between the national frameworks and the GDPR.

[1]EDPB, Guidelines 1/2026 on processing of personal data for scientific research purposes, adopted 15 April 2026 (version for public consultation) (the "**Guidelines**").
[2]Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018, S.I. No. 314/2018, as amended by the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021, S.I. No. 18/2021 (together, the "**Health Research Regulations**" or "**HRR**").
[3]Regulation (EU) 2016/679 ("**GDPR**").
[4]HRR, Regulation 3(1)(e): consent is identified as a suitable and specific measure taken to safeguard the fundamental rights and freedoms of the data subject when health research is carried out. The HRCDC consent-declaration mechanism is provided for in Regulation 5.

Specific observations and feedback

Each section below identifies the relevant provision of the Guidelines, sets out the issue and proposes feedback to the EDPB.

A. Divergence between national implementations

The single most significant gap in the Guidelines, in the HRDPN's view, concerns the management of divergence between national implementations. Articles 9(2)(j) and 89(2) GDPR permit Member States to legislate further on the processing of personal data for scientific research purposes and many have done so in materially different ways. The result, in practice, is a mosaic of national implementations that do not always sit consistently with one another and that frequently impede trans-national research — in particular projects involving universities and research consortia across several Member States and multi-site studies whose sites fall under different national rules.

The Guidelines acknowledge that the GDPR does not exhaustively harmonise the requirements for the processing of personal data for scientific research purposes,[5] but they do not provide any framework for how researchers and controllers are to operate where two or more Member States' implementations diverge, or where the application of those implementations to the same data is contested. In the HRDPN's collective experience this is not a peripheral difficulty: it is frequently the issue that determines whether a trans-national health research project can proceed at all and on what terms.

The HRDPN draws particular attention to the EDPB's own commissioned study on the secondary use of personal data for scientific research,[6] which examined this question across Member States and found no uniform approach or interpretation among them and which recommended increased dialogue between Member States' supervisory authorities. The HRDPN respectfully observes that the present Guidelines were an opportunity to act on that recommendation and do not yet do so. The HRDPN is therefore inviting the Board to give effect to the conclusion of its own research.

The HRDPN proposes that the Guidelines should acknowledge the difficulty expressly and provide a practical framework for managing it. Such a framework might address the steps a controller should take where national implementations conflict, the role of consultation between supervisory authorities, the use of the consistency mechanism under Chapter VII GDPR and the scope for joint or coordinated national guidance in recurring trans-national research scenarios.

> **Feedback 1**. The EDPB is invited to expand the Guidelines to acknowledge the practical difficulties posed by divergent national implementations under Articles 9(2)(j) and 89(2) GDPR for trans-national and multi-site research and to provide a framework for managing that divergence, including the role of supervisory-authority consultation and, where appropriate, the consistency mechanism under Chapter VII GDPR. In doing so the EDPB is invited to give effect to the recommendation of its own commissioned study on the secondary use of personal data, which called for increased dialogue between Member States' supervisory authorities.

[5]Recital 159 GDPR; Guidelines, paragraph 4.
[6]EDPB, *Study on the Secondary Use of Personal Data in the Context of Scientific Research* EDPS/2019/02-04 which found no uniform approach or interpretation among Member States and recommended increased dialogue between Member States' supervisory authorities.

B. Allocation of controller and processor roles where the parties cannot agree

Section 7 of the Guidelines provides helpful guidance on the determination of controller, joint controller and processor roles.[7] In multi-party research, however, the parties involved — including, in some Member States, national supervisory authorities — not infrequently take different views on the correct allocation of those roles. The Guidelines do not address this scenario. The HRDPN has observed cases of hospitals in some Member States refusing the role of processor in a regulated trial, citing national supervisory-authority guidance, in a manner that conflicts with the EDPB's position. Guidance on the dispute-resolution pathway would be of significant practical assistance, including confirmation that role attribution is a functional question to be answered on the facts, the steps a controller should take where another party disputes its assessment and the circumstances in which consultation with the relevant supervisory authority is appropriate. The scenarios below illustrate cases where the parties could not agree on role attribution.

EXAMPLE A:

A Clinical Trial Sponsor from another EU Member state takes the position that the Sponsor and the Study Site (Hospital) are to be defined as Joint Controllers on the basis that the study site performs a number of processing activities that go beyond acting on the instructions of the Sponsor (i.e. enrols participants, obtains informed consent, collects and records study-related information, the collection of study data, monitoring and documentation of the patients' response, preparation of the findings and their transmission to the sponsor via eCRF). An Irish site, in line with EDPB guidance takes the position that the study site acts as a Processor of personal data for the purpose of health research that they have not designed the protocol and the organisation (i.e. the Sponsor) that designs the study protocol is the Controller for the purposes of the health research. This aligns with the European Data Protection Board ("EDPB") guidance.

EXAMPLE B:

A public health body holds patient data collected in the ordinary course of providing health care and treatment. A research institute approaches it seeking access to that data for a scientific research project, the purposes and methodology of which the research institute alone determines. In practice, research institutes have in a number of cases sought to designate the public health body as either a processor or a joint controller. The processor characterisation is incorrect: a public health body holds patient data pursuant to its own statutory mandate, has an independent legal relationship with the data subject and cannot receive instructions from the research institute in respect of data it holds under its own statutory functions.

The more difficult question is whether the public health body is an independent controller or a joint controller for the processing operations it carries out in facilitating the provision of data. Where its role is limited to providing data in accordance with its own independent assessment of what it is lawful to provide, independent controllership is the appropriate characterisation. Where, however, the parties together determine the relevant patient cohort, the specific data points to be extracted and the form of provision, a finding of joint

[7] Guidelines, paragraphs 132–143 (Controller, Processor and Joint controllers).

controllership for those upstream operations may have some basis in the EDPB's broad approach to joint controllership. A worked example of this may be useful.

Feedback 2. The EDPB is invited to address in section 7 of the Guidelines the circumstances in which the parties involved in research processing cannot agree on the attribution of controller, joint controller or processor roles and to provide guidance on the dispute-resolution pathway, including the role of consultation with relevant supervisory authorities.

C. Multi-site research governance: joint control and lawful bases

Two practical difficulties arise in multi-site health research, which in Ireland routinely spans a large number of participating sites across statutory hospitals, voluntary hospitals and universities.

Joint controllers. The Guidelines correctly require, where several entities are involved in processing for scientific research, that responsibility be assessed and documented and that joint-controller arrangements be made accessible to data subjects.[8] The HRDPN endorses this. The Guidelines do not confirm whether a single master agreement — entered into by all participating sites and making the allocation of responsibilities accessible to data subjects in summary form — satisfies Article 26(1) GDPR.[9]

Feedback 3. The EDPB is invited to confirm that a single master arrangement, executed by all participating sites in a multi-site research study and making the essence of the allocation of responsibilities available to data subjects, is capable of satisfying Article 26(1) and 26(2) GDPR and to consider providing a model framework or template clauses for joint-controller arrangements in multi-site health research similar to the European Standard Contractual Clauses framework.

Co-existing lawful bases. A related difficulty arises from the co-existence of different lawful bases within a single study. Paragraph 58 of the Guidelines confirms that reliance on the performance of a task carried out in the public interest is not confined to public entities and that private entities may rely on that basis where the relevant legal act covers their activities.[10] In Irish health research, however, a single study commonly spans both public-sector and private-sector controllers. The Guidelines give no guidance on how a single research protocol operates where different controllers necessarily rely on different but compatible lawful bases for the same processing. This is precisely the kind of point on which a worked example, built on a concrete and realistic fact pattern, would be of materially greater assistance than a further statement of principle.

Feedback 4. The EDPB is invited to provide a worked example, set on a realistic multi-site fact pattern, confirming that different but compatible lawful bases may co-exist across controllers within a single research study and indicating how this should be reflected in the joint-controller arrangement.

D. Anonymisation in the hands of a third party

It would be of benefit if the EDPB could provide specific guidance on how the principles articulated by the Court of Justice in EDPS v SRB (C-413/23 P) apply in the context of scientific

[8]Guidelines, section 7 (Attribution of responsibility), paragraphs 129–144.
[9]Article 26(1) GDPR.
[10]Guidelines, paragraph 58.

and health research. In particular, the guidance should clarify how the Court's analysis of identifiability, reasonable means and the perspective of the recipient of data should be assessed in complex health research ecosystems involving sponsors, academic institutions, healthcare providers, research infrastructures and trusted third parties. Given the widespread use of coded, pseudonymised and privacy-enhancing research datasets, greater certainty is needed regarding when data should be considered personal data from the perspective of a particular organisation and how this assessment interacts with GDPR obligations and data sharing requirements/agreements. Clear guidance on the application of EDPS v SRB would promote consistent interpretation across Member States, facilitate responsible data sharing for scientific and health research and support the development of a European research environment that both protects individuals and enables high-quality research in the public interest.

> **Feedback 5**. The EDPB is invited to provide specific guidance and worked examples on how the principles articulated by the CJEU in EDPS v SRB (C-413/23 P) apply in the context of scientific research.

E. Consent: legal basis, safeguard and national mechanisms

Consent as a legal basis and as an Article 89(1) safeguard. The Guidelines' treatment of consent in section 4.1 is concerned with consent as a legal basis under Articles 6(1)(a) and 9(2)(a) GDPR.[11] Paragraph 54 of the Guidelines itself notes, correctly, that consent to participate in scientific research — which stems from ethical or legal requirements — should be distinguished from consent to the processing of personal data as a legal basis under the GDPR and that such consent may constitute an additional safeguard under Article 89 GDPR.[12] In Ireland, the national framework requires consent of the data subject as a safeguard under Article 89(1) GDPR rather than as the legal basis. The broad and dynamic consent material in section 4.1.2 is engaged quite differently depending on which role consent performs and the Guidelines do not currently make that dual role explicit. The HRDPN considers that doing so would materially reduce a real risk of inconsistent interpretation among ethics committees, controllers and researchers. This is not a request for the EDPB to address any one national instrument, but to clarify, in its general statement of principle, how the broad and dynamic consent material is to be understood where Member State law requires consent in the role of an Article 89(1) safeguard.

> **Feedback 6**. The EDPB is invited to clarify in the Guidelines whether the broad and dynamic consent material in section 4.1.2 applies to consent obtained pursuant to Article 89(1) GDPR as a safeguard, or only to consent relied on as a legal basis under Article 6(1)(a) or 9(2)(a) GDPR and to state expressly how the conditions in paragraphs 43 to 50 are to be assessed in each case.

F. Treatment of vulnerable persons

Paragraph 36 of the Guidelines lists examples of vulnerable or disadvantaged data subjects in scientific research, naming convicted persons, pupils and unemployed or disenfranchised persons.[13] Paragraph 37 then states that the fact that a data subject is a patient receiving health care does not in itself affect the data subject's capacity to give free consent.[14]

[11] Guidelines, Section 4 (Lawfulness); Article 6(1) and Article 9 GDPR; paragraphs 32–75. The discussion of broad consent at paragraphs 43 to 50 sits within the Article 6(1)(a) consent material in section 4.1.2.1 and is extended to Article 9(2)(a) by paragraph 67.
[12] Guidelines, paragraph 54; see also paragraphs 53 and 55.
[13] Guidelines, paragraphs 36–38.
[14] Guidelines, paragraph 37, final sentence.

The HRDPN respectfully observes that this sits in tension with the Article 29 Working Party Guidelines on Data Protection Impact Assessment (WP248 rev.01), endorsed by the EDPB on 25 May 2018 and cited at footnote 60 of the Guidelines themselves, which identify patients explicitly as a category of vulnerable data subjects.[15] The Guidelines do not resolve the apparent inconsistency. In practice, the asymmetry of power between a hospital or treating clinician and a patient receiving care is a long-standing concern for ethics committees and DPOs and is not adequately addressed by the qualifying clause in paragraph 37.

A related concern arises at Example 7, which contemplates excluding from research data subjects determined not to be in a position to give free consent.[16] While the underlying caution is understandable, the result risks the systematic exclusion of vulnerable populations — including individuals with intellectual disabilities and certain ethnic or socio-economic groups — from the research that may most benefit them, with attendant consequences for healthcare equity.

> **Feedback 7**. The EDPB is invited to reconcile paragraphs 36 to 38 of the Guidelines with the categorisation of patients as vulnerable data subjects in the Article 29 Working Party Guidelines on DPIA and to amend the Guidelines to address (a) the power imbalance inherent in the patient/clinician relationship and its impact on the validity of consent and (b) the equity considerations that arise where vulnerable populations are excluded from research that may benefit them.

G. Artificial intelligence in health research

The Guidelines identify recent advances in artificial intelligence as a principal driver for issuing the guidance,[17] yet provide no operational guidance directed specifically at AI-driven scientific research. Three matters in particular remain unaddressed: the lawful basis for and safeguards applicable to, the use of patient data as training data for AI models; the attribution of controller and processor roles in federated-learning architectures, in which personal data does not leave the originating site but contributes to a shared model; and the relationship between the GDPR research framework and the AI Act, under which AI systems used in the area of health are classified as high-risk.[18] The interaction with the European Health Data Space framework adds a further dimension.[19]

The HRDPN notes that scientific research is not, of itself, subject to the substantive requirements of the AI Act in the same way as a deployed system. That qualification makes targeted guidance more useful, not less, because it is precisely at the boundary between research activity and downstream deployment that controllers and researchers most require certainty.

> **Feedback 8**. The EDPB is invited to include guidance addressing the processing of personal data in AI-driven scientific research, covering the lawful basis and safeguards applicable to the use of personal data in training AI models, the attribution of controller and

[15] Article 29 Working Party, *Guidelines on Data Protection Impact Assessment (DPIA)*, WP248 rev.01, endorsed by the EDPB on 25 May 2018; cited in Guidelines 1/2026 at footnote 60. WP248 identifies as vulnerable data subjects, inter alia, children, employees, mentally ill persons, asylum seekers, the elderly and patients.
[16] Guidelines, Example 7 and paragraph 50.
[17] Guidelines, Executive Summary.
[18] Regulation (EU) 2024/1689 (the "AI Act"), Article 6(1) and Annex I; Article 6(2) and Annex III, in particular points 5(a), (c) and (d), classifying certain AI systems used in the area of health as high-risk.
[19] Regulation (EU) 2025/327 on the European Health Data Space ("EHDS"); cross-referenced at Guidelines paragraph 75 and footnote 119.

processor roles in federated-learning architectures and the interaction between the GDPR research framework, the AI Act and the European Health Data Space framework.

H. Statutory data, data-subject rights and participant information

Statutory data collection and the rights of erasure and objection. Certain Irish health research relies on personal data that national statute requires to be collected and reported — most notably data submitted to the National Cancer Registry of Ireland.[20] Where the legal basis is therefore a statutory obligation under Article 6(1)(c) GDPR, the interaction with the rights of erasure and objection in Articles 17 and 21 GDPR is largely beyond doubt as a matter of interpretation, but the Guidelines do not specifically address it.[21] An express acknowledgement would assist controllers operating registries on a statutory footing in responding to data-subject requests with confidence.

> **Feedback 9**. The EDPB is invited to confirm in the Guidelines that, where processing is necessary for compliance with a legal obligation under Article 6(1)(c) GDPR, the exception in Article 17(3)(b) GDPR applies so that the right to erasure cannot be exercised to defeat that obligation and that Article 21 GDPR does not apply to processing on that basis, the right to object being available only in respect of processing under Article 6(1)(e) or (f) GDPR.

Participant information. A practical point on participant information also merits attention. Participant Information Leaflets in health research are becoming progressively longer and more complex, in part through the inclusion of data-protection content, to the point where their length may itself impair rather than assist data subjects' understanding. Guidance on the level of information actually needed to meet the other relevant legal and ethical obligations (e.g. Clinical Trials Regulation, Good Clinical Practice, etc.) — illustrated by worked examples of compliant, proportionate participant information across different research scenarios — would be of real practical value to research teams and ethics committees alike.[22]

> **Feedback 10**. The EDPB is invited to provide a template and guidance, illustrated by worked examples across a range of research scenarios, on the level of information required to satisfy the transparency obligations in the research context, with a view to enabling proportionate participant information that supports rather than overwhelms data subjects' understanding.

I. Newly generated personal data

Paragraph 91 brings new personal data generated in the course of a research project within Article 14 GDPR.[23] The HRDPN would welcome guidance on whether new research findings of this kind — typically generated incrementally as a study progresses — trigger a fresh Article 14 notification obligation each time and if so, the practical limits of that obligation.

> **Feedback 11**. The HRDPN suggests the EDPB consider revising paragraph 91 to clarify the potential application of Article 14 GDPR to new research findings.

[20] Health (Provision of Information) Act 1997; see also other national disease and condition registries operating on a statutory basis.
[21] Articles 17(3)(b) GDPR and 21(1) GDPR; Guidelines paragraphs 111–128 in particular paragraphs 122 and 124.
[22] Articles 13 and 14 GDPR; Guidelines, section 5 (Obligations to inform).
[23] Guidelines, paragraph 91.

Specific drafting observations on the text of the Guidelines

In addition to the substantive feedback above, the HRDPN offers the following drafting observations on the text of the Guidelines, in case they are of assistance in finalising the document.

- **Paragraph 11 — circular definition.** The use of the word "research" in the key-indicative factors at paragraph 11 is problematic. Using the very word the EDPB is trying to clarify creates a circular definition as the reader must already understand the word in order to understand the explanation. A good definition should clarify meaning by using simpler, independent terms, whereas a self-referential definition provides little or no new information and fails to make the concept more understandable. The HRDPN suggests the EDPB consider revising paragraph 11 to use independent terms.
- **Paragraph 13 — application to registries.** It is unclear from these paragraphs and Example 4 whether “research data infrastructure” includes registries operated for healthcare purposes by a hospital but subsequently used for health research.[24] Given significant divergence across European Reference Network registries in governance and role attribution, more detailed guidance on the position of registries — including those operated for healthcare purposes that come to be used for research — would be welcome.
- **Paragraph 27 — retention period example.** It would be of practical assistance if the Guidelines provided an illustrative example of the kind of considerations that justify a defined retention period for personal data processed for scientific research purposes.

Concluding observations

The HRDPN welcomes the Guidelines and the EDPB’s engagement with what is a complex and rapidly developing area. These observations are offered in a constructive and practitioner-led spirit.

Statement on the use of Artificial Intelligence

This submission is based on the substantive feedback and positions provided by the authors. Generative AI tools were used to collate, structure and synthesise the contributions into a coherent consultation response. All content was subsequently reviewed and approved by the authors.

[24] Guidelines, section 2.2 (Research data infrastructures), paragraph 13 and Example 4.