Beaumont Hospital and The Royal College of Surgeons in Ireland (RCSI)- Joint Submission

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

Adopted on 15 April 2026

1. Introduction

Beaumont Hospital and the Royal College of Surgeons in Ireland welcome the opportunity to provide feedback on the European Data Protection Board on Guidelines (EDPB) 1/2026 on processing of personal data for scientific research purposes[1].

Beaumont Hospital is one of Irelands largest public hospitals founded in 1987 and is based Dublin. It is proud of its reputation both nationally and internationally as an academic teaching hospital, providing excellence in patient care, medical education, innovation and research.

Beaumont Hospital's guiding values and vision are to ensure an excellent patient experience through future-focused care, staff empowerment and well-being, education, and pioneering research. As one of Ireland's major teaching hospitals with a long tradition of academic excellence it takes pride in training doctors and nurses who will have a positive impact on the wellbeing of every patient that visits them for care. Its academic partner is the Royal College of Surgeons in Ireland (RCSI).

The Royal College of Surgeons in Ireland (RCSI) was founded in 1784 as the national training body for surgery in Ireland and has been at the forefront of healthcare education and research ever since.

Today, RCSI is an international health sciences university and is the professional training body for surgery in Ireland. It is home to students, educators, clinicians, researchers and policy leaders in a range of healthcare disciplines.

With a focus on clinical and patient-centred research, RCSI leads in discoveries which address key Irish and international health challenges. RCSI's research agenda drives scientific breakthroughs, innovations and insights in order to understand and respond to changing healthcare needs.

Beaumont Hospital and RCSI warmly welcome the EDPB Guidelines 1/2026 on processing of personal data for scientific research purposes which will help to protect individuals' fundamental rights in research. The Guidelines are a significant development for the scientific research community and provide a valuable contribution to an area of GDPR compliance which remains complex in practice, particularly in the context of health research, collaborative research, secondary use of health data and mixed-sector research collaborations.

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

In the health research context, the application of the GDPR often operates alongside Member State legal frameworks governing the processing of health data for research. In Ireland, this includes the Irish Health Research Regulations.[2]

Beaumont Hospital and RCSI's observations and feedback come from the perspective of health research.

2. Attribution of responsibility – controller, processor and joint controllership

Observation

The General Data Protection Regulation (GDPR) became applicable across all Member States on May 25, 2018[3]. The objectives of GDPR are twofold: to facilitate the free movement of personal data, including cross-border exchange, and to protect the fundamental rights and freedoms of natural persons with regard to privacy and protection of personal data (Art. 1 GDPR)[4].

An assessment of Member States application of GDPR to health data by the European Commission however found variation in interpretation of the law and national level legislation which has led to a fragmented approach across the EU[5].

Role allocation has emerged as a key pinch point in the conduct of health research. It is Beaumont Hospital and RCSI's experience that conflicting views can arise in relation to the allocation of controllership, processor and joint controllership roles, which may in turn lead to delays in the commencement of important health research. A recent Health Research Data Protection Network (HRDPN) conference held in RCSI heard of patient frustration in accessing potentially lifesaving clinical trials due to data protection delays[6]. Differing interpretation can also lead to the ultimate exclusion of institutions, and unfortunately patients as a consequence, from studies.

The correct assessment of data protection roles at the outset of a project is of vital importance from a legal, contractual and data subject rights perspective. Failing to recognise appropriate roles and comply with legal obligations (including, among others, contracts) will infringe national law as well as GPDR and is likely to result in a serious gap in the protection of personal data[7]. Narrow interpretation can create loopholes in terms of responsibility. Understandably, when disagreement arises and there is a stalemate many institutions are reluctant to proceed due to the risks involved. In addition to this a failure to put the appropriate contracts in place will lead to a lack of clarity as to where responsibility lies in the event of something going wrong or when a data subject is seeking to exercise their rights.

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[2] Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314/2018), as amended in 2019 and 2021

[3] REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

[4] REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

[5] Assessment of the EU Member States' rules on health data in the light of GDPR Specific Contract No SC 2019 70 02 in the context of the Single Framework Contract Chafea/2018/Health/03 D a7f11827-f4ca-4e4d-bd7a-c15c39664010_en

[6] HRDPN REPORT Enabling a Brighter Future for Data Protection in Clinical Research in ROI. Create an effective and streamlined ecosystem to deliver data protection while enabling health research in Ireland AD8427-HRDPN-report_2.pdf

[7] European Data Protection Board: Guidelines 07/2020 on the concepts of controller and processor in the GDPR (2.0). 2021

Section 7 of the Guidelines addresses the issue of attribution of responsibility in scientific research and which will greatly assist with supporting projects to be compliant with GDPR. The examples given are very helpful particularly for collaborative projects but are limited. The reality on the ground can be much more complex with multi-party, multi-jurisdictional research collaborations. Often there are many layers to consider and data protection roles can evolve over the course of the project.

The assessment of joint controllership in large research consortia can be particularly difficult and involve a complex assessment of multiple criteria. The threshold for joint controllership is low and can happen in a wide variety of circumstances as established by GDPR, CJEU case law[8] [9] [10]and further qualified by the EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR[11]

These multi- factorial considerations include the following:

1) Controllership exists with the joint participation of two or more entities in the determination of the purposes and means of a processing operation[12];
2) CJEU case law[13] [14] [15] shows that the threshold for the existence of a joint controllership is low;
3) There is no requirement to share responsibility equally[16];
4) There is no requirement that all parties have access to the data to be considered joint controller[17];
5) Joint controllership can arise through:
    a) a common decision where there is a common interest;
    b) converging decisions;
    c) or if there is a closely linked purpose, complementary and there is a mutual benefit from the processing activity[18].
6) Joint controllers do not have to have access to personal data or to give specific instruction/guidance in relation to the data processing to be considered a joint controller-knowledge on a general level sufficient[19];
7) Joint controllers do not need to determine all of the means. They may be involved at different stages and to different degrees and to a different extent[20];
8) One controller may provide the means of the processing and make it available to other entities. The controller who decides to make use of those means so that personal data can

[8] Case C-210/16 Wirtschaftsakademie Schleswig-Holstein. ECLI:EU:C:2018:388, 2018
[9] Case C-25/17 Jehovan todistajat. ECLI:EU:C:2018:551, 2018
[10] Case C-40/17 Fashion ID. ECLI:EU:C:2019:629, 2019
[11] European Data Protection Board: Guidelines 07/2020 on the concepts of controller and processor in the GDPR (2.0). 2021.
[12] European Data Protection Board: Guidelines 07/2020 on the concepts of controller and processor in the GDPR (2.0). 2021.
[13] Case C-210/16 Wirtschaftsakademie Schleswig-Holstein. ECLI:EU:C:2018:388, 2018
[14] Case C-25/17 Jehovan todistajat. ECLI:EU:C:2018:551, 2018
[15] Case C-40/17 Fashion ID. ECLI:EU:C:2019:629, 2019
[16] European Data Protection Board: Guidelines 07/2020 on the concepts of controller and processor in the GDPR (2.0). 2021.
[17] Case C-25/17 Jehovan todistajat. ECLI:EU:C:2018:551, 2018
[18] European Data Protection Board: Guidelines 07/2020 on the concepts of controller and processor in the GDPR (2.0). 2021.
[19] Case C-25/17 Jehovan todistajat. ECLI:EU:C:2018:551, 2018
[20] European Data Protection Board: Guidelines 07/2020 on the concepts of controller and processor in the GDPR (2.0). 2021.

be processed for a particular purpose also participates in the determination of the means of the processing[21].

The Guidelines provide useful clarification on the concept of joint controllership and correctly emphasise that responsibility must be assessed and documented where several entities are involved in scientific research. However, the example provided places particular emphasis on the research protocol as the point at which joint determination of purpose and essential means becomes visible.

However, outside of the research protocol there are other research contexts where more clarity on the assessment of data protection roles is required.

Example- research consortium

Within the context of collaborative research involving several research partners, the funding proposal identifies the key players in the project, their roles in the project as project lead or coordinator and/or work-package lead or contributor

The work-packages may be discrete pieces of work, which may or may not be interdependent, but contribute to overall aim/purpose of the project

Decision making on the direction and management of the project are joint responsibilities of a body (e.g. steering committee) which include representation of all the research partners

The research partners are funded to deliver the project to recover own costs and benefit from the peer review publications and the intellectual properties generated from the project

Therefore "purposes and means" of processing of personal data for the purpose of the collaborative project are set out in the project proposal.

Regardless of the context set out above, there are vastly differing views on the data protection role of Research partners in the project from joint controller to independent controllers or even one Party (the organisation who initiated the collaboration and coordinate the project) being the data controller and the other research partners being data processors.

Another area where there can be divergence of opinion on data protection roles is dual affiliation of researchers.

[21] European Data Protection Board: Guidelines 07/2020 on the concepts of controller and processor in the GDPR (2.0). 2021.

Example- clinical trial- dual affiliation

Academic clinical trials can also throw up complexity where there is dual affiliation. i.e. where the Chief investigator (who conceived the protocol) holds an academic appointment with the University which sponsor the Clinical Trial. There is divergence in interpretation of data protection roles of the University and the Hospital in instances where the Chief Investigator is also responsible for conducting the trial at the hospital where the Chief Investigator is employed.

Some organisations believe that the Chief investigator's roles can be separated when determining the data protection roles, thus allowing for the separation of roles of the Sponsor as data controller and the Hospital as Data Processor. Other organisations feel that Chief Investigator's role cannot be separated depending on where the Chief investigator operates and by virtue of the Chief Investigator's role in the design of the trial, both the Hospital and the University are joint data controller.

Feedback

1. Beaumont Hospital and RCSI suggest that it would be helpful to **further expand** in the Guidelines on the **criteria for the determination of joint controllership** which are broad and can happen in a wide variety of circumstances as established by GDPR, CJEU case law[22] [23] [24]and further qualified by the EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR[25] ;
2. Beaumont Hospital and RCSI would **value further examples of joint controllership** including an example based on a collaborative research consortium;
3. The inclusion of an **example of a large EU-funded research consortia** with a funding and consortium agreement would be most helpful;
4. There can be differing interpretation between Member States/ institutions on joint controllership and other terms in GDPR Beaumont Hospital and RCSI see the need for **a Code of Conduct** in order to add legal clarity and a common understanding.
5. Beaumont Hospital and RCSI see the need for **guidance on** how to deal with **deadlocks** when it comes to determining data protection roles in order to ensure that patients are not delayed or missing out on access to important research due to data protection impasses.

3. <u>Anonymity</u>

Observation

Beaumont Hospital and RCSI notes the forthcoming EDPB guidelines on anonymisation expected shortly, and welcomes the important clarity that the Guidelines on processing of personal data for scientific research purposes bring to anonymisation**.**

[22] Case C-210/16 Wirtschaftsakademie Schleswig-Holstein. ECLI:EU:C:2018:388, 2018
[23] Case C-25/17 Jehovan todistajat. ECLI:EU:C:2018:551, 2018
[24] Case C-40/17 Fashion ID. ECLI:EU:C:2019:629, 2019
[25] European Data Protection Board: Guidelines 07/2020 on the concepts of controller and processor in the GDPR (2.0). 2021.

In the context of the current Guidelines Beaumont Hospital and RCSI note some slight variance from the CJEU SRB case[26]

The Guidelines specify that legal or contractual obligations that prohibit the re-identification **can** complement technical anonymisation or pseudonymisation, in particular when data sets are shared between research partners or other recipients.

The CJEU SRB case is more assertive in specifying that pseudonymisation could have the effect of ensuring that the data is no longer personal under two conditions: *"… **first** that **Deloitte is not in a position to lift those measures** during any processing of the comments which is carried out under its control. **Second**, those **measures must** in fact be such as to **prevent Deloitte from attributing those comments to the data subject including by recourse to other means of identification** such as cross-checking with other factors, in such a way that, for the company, the person concerned is not or is no longer identifiab*le" (*para 77)* [27].

In addition to this the Guidelines specify that data subjects **should** be informed **if personal data** is made available to other recipients and to whom it is being made available.

The CJEU however held that data subjects must be informed about recipients with whom data would be shared, "prior to the transfer of the data ….and **irrespective of whether or not those data were personal data**"(para 112).

Feedback

1. The Guidance should provide greater clarity on **transparency and anonymous data**. In the CJEU SRB case the controller must inform data subjects about the sharing of their data with 3rd parties, even if it is anonymous in the 3rd parties' hands;
2. The Guidance would benefit from providing **greater clarity** on what should be considered **mandatory contractual requirements**, such as clauses preventing re-identification, in line with CJEU SRB in order to **ensure that data is no longer personal data in the hands of a 3rd party**.

4. ***Broad Consent***

Observation

The draft Guidelines are helpful in clarifying that broad consent does not remove the requirement for purpose specification and that it is not sufficient simply to refer to 'scientific research'. The emphasis on defined research areas, reasonable expectations of data subjects, additional safeguards and the possible use of dynamic consent is welcome.

The Guidelines envisage a broad consent model that depends on ongoing transparency, later project review and in some cases re-consenting / dynamic consent, including practical mechanisms such as webpages, newsletters or other tools enabling participants to understand later uses and exercise withdrawal rights**.**

[26] Case C-413/23 P EDPS v. SRB
[27] Case C-413/23 P EDPS v. SRB

In practice, many health research PIL's and consent forms obtain broad consent for future research use but do not provide a mechanism for participants to be informed of later projects, to assess whether those projects remain within the scope of the original consent.

The example given in the Guidelines concerns broad consent for research collected by a university hospital when treating patients. In the context of research, broad consent for future research is most often captured during specific research projects.

A key question is the capture of broad consent for research that is not foreseeable at the time of the research project which may be unrelated to the original research project topic. In these instances, the potential research is explained with enhanced transparency in a high-level way specifying the field/area in as much detail as possible. This is in conjunction with the option to consent in the future and to withdraw. This approach seeks to ensure that the research falls within the reasonable expectations of the participant who would not be surprised by the processing activity and that the essence of the data subject's rights to a valid consent are served.

Recital 33 of GDPR defines "broad consent" as data subjects being allowed to give their consent to certain areas of scientific research where the purpose is not fully known at the time of data collection[28]. *: "It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to* ***certain areas of scientific research*** *when in keeping with recognised ethical standards for scientific research.* ***Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects*** *to the extent allowed by the intended purpose."*

This is an important clarification as a divergence in interpretation has emerged over the years with some institutions specifying that broad consent can only be captured for studies related to the original study topic.

Feedback

1. The Guidelines would benefit from clarifying:

a) To what **extent** project-level **transparency** is expected where controllers rely on broad consent for example would a website be **considered sufficient** or would other measure be required to complement it?;
b) What level of **safeguards** should be implemented **where no dynamic consent** model exists?
c) How the concepts of **reasonable expectations and withdrawal of consent** should operate where participants are not always routinely informed of subsequent research activities, for example would publication of all research projects on a website along with a clear mechanism for withdrawal suffice?

2. An **example of broad consent** captured **within a specific research project context** would be very useful.
3. Clarification on **broad consent** for **studies unrelated to the original study topic** would be helpful.

[28] REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

5. Conclusion

In conclusion Beaumont Hospital and RCSI sincerely values the opportunity to provide feedback on the European Data Protection Board on Guidelines (EDPB) 1/2026 on processing of personal data for scientific research purposes and warmly welcomes the Guidelines which will serve to address inconsistencies that have arisen across organisations and Member States over the past number of years.