

The Royal College of Surgeons in Ireland- RCSI

EDPB Consultation -Template [2026] for Data Protection Impact Assessment ('DPIA')-Version 1.0

Adopted on 10 March 2026

1. Introduction

The Royal College of Surgeons in Ireland welcomes the opportunity to provide feedback to the European Data Protection Board on the Template [2026] for Data Protection Impact Assessment ('DPIA')-Version 1.0 -adopted on 10 March 2026.

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 that allow us to understand and respond to changing healthcare needs. RCSI welcomes the EDPB Data Protection Impact Assessment template. RCSI's observations and feedback come from the perspective of health research.

2. GDPR and Health Data

Observation

The General Data Protection Regulation (GDPR) became applicable across all Member States on May 25, 2018¹. 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).

GDPR allowed Member States, through specification clauses, to adjust the application of certain aspects of the regulation to their national situation. Member States are allowed to maintain or introduce further conditions, including limitations with regard to the processing of, among others, data concerning health (Art. 9(4) GDPR).

An assessment of Member States application of GDPR to health data by the European Commission found variation in interpretation of the law and national level legislation which has led to a fragmented approach across the EU².

The study shows that Member States are extensively utilising the margin of manoeuvre afforded in GDPR. As a result, there is a significant variance of safeguards and lawful basis. Ireland's Health Research Regulations (HRR), for example, introduced additional regulatory requirements for health research in relation to governance, processes and procedures³.

Feedback

- a) In light of the Member States margin of scope with regard to health data and in the context of differing national obligations, RCSI suggests **a health sector specific DPIA template** would be useful;
- b) Failing that, RCSI suggests that it would be helpful for the EDPB DPIA template to include a specific section allowing health researchers to show the **measures/safeguards supporting compliance with national GDPR requirements**;

¹ REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

² 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](https://doi.org/10.1007/s11845-020-02331-2)

³ Kirwan, M., Mee, B., Clarke, N. et al. (2020) What GDPR and the Health Research Regulations (HRRs) mean for Ireland: "explicit consent"—a legal analysis. *Ir J Med Sci.* <https://doi.org/10.1007/s11845-020-02331-2>

- c) As discussed above there is a fragmented landscape across Member States with regard to lawful basis and the processing of health data. In large European research consortia with many partners/controllers in different jurisdictions how will **different lawful basis** be recorded in the **EDPB DPIA template**?

3. Health Research and the DPIA

Observation

A DPIA is mandatory where processing is “likely to result in a high risk to the rights and freedoms of natural persons” (Article 35(1), illustrated by Article 35(3) and complemented by Article 35(4)). The WP 29 guidelines on DPIA’s further develop the criteria set out in Article 35(3) GDPR and provide nine criteria for consideration when determining whether processing is “likely to result in a high risk”⁴. Due to the nature of health research, more often than not, data processing will involve two or more of the nine WP29 criteria - processing both special categories of personal data as defined in Article 9 and data concerning vulnerable data subjects such as patients as set out in recital 75. In consideration of this, health research, in which Europe is very active, tends to generate a high volume of DPIAs.

Health researchers can work in different setting such hospitals, universities, commercial or not for profit organisations. Wherever it takes place, it strongly relies on patients’ data created in the health sector (e.g. hospitals).

The majority of hospitals in Ireland are public and operate on a not-for-profit basis. A study exploring the impact of GDPR on researchers in Ireland identified that health researchers (in particular clinicians), in their employment capacity for the data controller, are more often than not the individuals filling in the DPIA and found them difficult and time consuming to complete⁵. This, together with the complexity of health research contexts and associated regulatory requirements, leads to misinterpretations and errors necessitating multiple DPIA’s reviews/reiterations, which, in turn significantly delays time sensitive projects and increase the workload of DPOs and clinicians, who have competing clinical work commitments.

Importantly the paper identified that clinicians undertaking DPIAs did not usually have access to the same level of legal expertise typically available in large commercial organisations, where dedicated legal teams often conduct the DPIA assessments. Consequently, many experienced difficulties navigating the legal requirements of the DPIA which often involve high risk and complex data flows. Health research also differs from many other sectors, as it operates within a broader governance framework. Ethical review is a core element of this framework and is typically conducted by a Research Ethics Committee (REC), which among other things considers privacy issues arising within a project from an ethical perspective. In many institutions, DPIAs have evolved to align closely with REC processes which have proven effective in helping researchers navigate regulatory requirements while reducing duplication.

Feedback

- a) RCSI suggests that a **specific guidance for health research when completing the EDPB DPIA template** would assist in understanding its application to this sector;
- b) RCSI suggests that **guidance** on and how the **EDPB DPIA template aligns with ethical requirements** would help to integrate the DPIA with the broader research governance process;
- c) RCSI suggests that **guidance** on how the **EDPB DPIA template’s legally technical language** applies to research would help increase understanding;
- d) RCSI notes there can be **differing interpretation** of the meaning of terms between Member States/ institutions for example joint controllership, the definition of a public or private researcher and what happens when there is a hybrid anonymised and pseudonymised data in a project. RCSI sees the need for a **Code of Conduct** to accompany the EDPB DPIA template in order to add **legal clarity and a common understanding of terms**.

⁴ WP 29 Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is “likely to result in a high risk” for the purposes of Regulation 2016/679 [ARTICLE29 - Guidelines on Data Protection Impact Assessment \(DPIA\) \(wp248rev.01\)](#)

⁵ Mee, B., Kirwan, M., Clarke, N. et al. What GDPR and the Health Research Regulations (HRRs) mean for Ireland: a research perspective. Ir J Med Sci (2020).

4. Conclusion

In conclusion RCSI sincerely values the opportunity to provide feedback on the EDPB DPIA template and warmly welcomes the introduction of a standardised template which will serve to address inconsistencies that have arisen across organisations and Member States over the past number of years. RCSI also notes that the template will be of great assistance in satisfying supervisory authorities in different jurisdictions with regard to scope, methodology and documentation required in a DPIA.

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