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To Whom It May Concern

RE: The Royal College of Surgeons in Ireland- RCSI
EDPB Consultation-Guidelines 02/2026 on Anonymisation Version 1.0
Adopted on 07 July 2026

1. Introduction

The Royal College of Surgeons in Ireland welcomes the opportunity to provide feedback on the EDPB Consultation-Guidelines 02/2026 on Anonymisation Version 1.0**.**

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 Guidelines on anonymisation, and note the important clarity that the Guidelines bring the assessment of anonymity for scientific research. Observations and feedback come from the perspective of health research.

2. Genetic and Genomic Data

Observation
Genetic and genomic data are an increasingly important part of medicine and scientific research and are critical to advancing modern healthcare.

The General Data Protection Regulation (GDPR) became applicable across all Member States on May 25, 2018[1]. Recital 34 specifies that genetic data should be defined as personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained.

Genomic data should be treated as genetic data in line with Article 4(13). Under GDPR, genetic data are special category data subject to Article 9 safeguards.

In 2021, the EDPB in response to a request from the European Commission for clarifications on the consistent application of the GDPR in health research, noted that in the interests of protecting the rights and freedoms of individual data subjects, it was strongly advised that genetic data be treated as

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

personal data and that the processing thereof be conducted with the implementation of appropriate technical and organisational measures to ensure compliance with the Regulation[2].

In addition, the recent European Data Protection Board on Guidelines (EDPB) 1/2026 on processing of personal data for scientific research purposes[3] specifies that genetic data is personal data retrieved from analysis of biological samples of human origin that is related to the inherited or acquired genetic characteristics of an individual, such as a complete genome sequence or certain genetic markers that are unique to an individual. It goes on to say that genetic data profiles are considered to be personal data by default and can only be considered anonymous in exceptional circumstances, following a thorough analysis that takes the specific genetic configuration, and how common it is in the population, into account.

There is general consensus that genomic data—i.e., more or less the entire genome of an individual—can never be truly anonymised however the potential for anonymisation is not as clear with respect to incomplete genomes[4][5].

The Guidelines do not explore the complex issues involved in processing genetic and genomic data and in what circumstances, if ever, such data could be considered anonymous. This topic is of enormous importance on multiple fronts in terms of the preservation of the rights of data subject, the legal consequence for institutions, and also in the classification of such data in light of the European Health Data Space.

Example-whole genome sequencing
A university biobank shares whole genome sequences with hospital researchers who are investigating the prevalence of a rare genetic lung disease in the general population. The university removes all identifiers before sharing. Contractual arrangements are put in place preventing the hospital from reidentifying the data. Can the sequences ever be considered anonymous for the hospital?

Feedback

- **a)** RCSI respectfully suggests that **specific examples** relating to **genetic and genomic data** in the **health research** context would be particularly helpful;
- b) RCSI notes there can be **differing interpretation** between Member States/ institutions on anonymisation. RCSI sees the need for **a Code of Conduct** to accompany the EDPB Guidelines on anonymisation in order to add **legal clarity and a common understanding.**

3. Conclusion

In conclusion RCSI sincerely values the opportunity to provide feedback on the EDPB Guidelines on Anonymisation and warmly welcomes the introduction of these Guidelines which will further serve to protect the rights and freedoms of data subjects. RCSI also notes that the Guidelines will be of great assistance in terms of standardisation of the process and procedure around anonymisation assessments.

Dónall King
Data Protection Officer
30th October 2026

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[2] EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research Adopted on 2 February 2021- para 50 edpb_replyec_questionnaireresearch_final.pdf

[3] https://www.edpb.europa.eu/public-consultations/guidelines-12026-on-processing-of-personal-data-for-scientific-research_en#no-back para 165

[4] Johanna Rahnasto, Genetic data are not always personal—disaggregating the identifiability and sensitivity of genetic data, *Journal of Law and the Biosciences*, Volume 10, Issue 2, July-December 2023, lsad029, https://doi.org/10.1093/jlb/lsad029

[5] Kieran C. O'Doherty et al., *Toward Better Governance of Human Genomic Data*, 53 Nat. Genet. 2, 2–5 (2021).