Guidance on Appeals and Technical Amendments to the Health Research Regulations January 2021

Prepared collaboratively by the

Department of Health
Health Services Executive
Health Research Board &
Secretariat to Health Research Consent Declaration Committee
in consultation with
The Data Protection Commission

Who is this presentation for?

- This presentation is for those who carry out, fund or otherwise are involved in health research, including the institutions that researchers are employed in, research ethics committees and DPOs, so that they can better understand the amendments made to the Health Research Regulations.

- It is also for the public whose support for health research is essential so that they can see that their rights have been considered and respected throughout the amendment process.

- The presentation is for guidance purposes, it should not be construed as offering a legal interpretation.

The Amendments

The Minister for Health has made amendments (January 2021) to the Health Research Regulations 2018. There are five substantive amendments;

- action to determine eligibility or suitability for inclusion in the research,
- retrospective chart reviews,
- deferred consent situations,
- informed consent obtained during the time of the EU Data Protection Directive,
- explicit consent in the context of international best practice in health research.
- the appeals process and other technical amendments.

The text of the amendments can be found in the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021.

Reason for the Amendments

At the time the Health Research Regulations were made (August 2018), the Department:

- identified retrospective chart reviews, pre-screening and capacity to consent as areas that it would examine further; and

- undertook to monitor the Regulations and engage with stakeholders to identify genuine and meaningful challenges that can impact on health research and health researchers.

This process involved considerable work, including extensive consultation with the Data Protection Commission to prepare amendments that are fully consistent with the GDPR.

The Amendments have been prepared and drafted on the basis of legal advice to ensure consistency with the GDPR and other relevant national and EU laws.

Data Protection and Research Ethics

- The opening statement in **Ethics and Data Protection**[1] (EU Commission, November 2018) is:

  "Data protection is both a central issue for research ethics in Europe and a fundamental human right. It is intimately linked to autonomy and human dignity, and the principle that everyone should bevalued and respected."

- The **Recommendation CM/Rec(2019)2** of the Committee of Ministers to Member States on the **Protection of Health-related data**[2] **(Council of Europe) (2019)** is:

  "15.7 The conditions in which health-related data are processed for scientific research must be assessed, where necessary, by the competent independent body (for example, an ethics committee)"

1. https://ec.europa.eu/info/sites/info/files/5._h2020_ethics_and_data_protection_0.pdf
2. https://edoc.coe.int/en/international-law/7969-protection-of-health-related-date-recommendation-cmrec20192.html#

Important General Points

- The Health Research Regulations and the amendments are one element of the ethical and legislative framework that applies to the processing of personal data for health research purposes.

- All the applicable elements of the framework must be complied with by the controller in any case where the amendments are to be used.

- Controllers (which encompass researchers acting under a data controller and/or controllers) should always engage with their DPOs as early as possible in any research study.

Purpose of the Amendments

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- To enhance the appeals process

- To clarify and bring consistency to related provisions in the Regulations

Appeals Process (1)

- Consistent with the diversity of expertise, skills and background of the HRCDC, the size of an appeal panel will be increased from the current 3 to not less than 5 and not more than 7.

- As the appeal panel has to be set up separately for each appeal so the time allowed to do so properly is being increased from 40 to 60 working days.

- An appeal panel will not stand dissolved until 30 working days after it has made its decision so that it can provide formal clarification on any matters arising from the decision.

Appeals Process (2)

- To improve the working of the appeal process, the appellant will forward written information (including any documentation) relevant to the appeal within 30 working days of the establishment of the appeal panel.
- Given its expertise, the secretariat of the HRCDC will provide the administrative support that an appeal panel needs.
- To ensure, in the interests of fairness, that the appeal panel can hear the view of parties other than the appellant, it will be the case that a panel must request the observations of the HRCDC and that it can seek the views of other relevant persons.

Technical Amendments

The opportunity is also being taken to make two technical and clarification amendments:

- The HRRs provides that the HRCDC may revoke a declaration where it is satisfied that the conditions imposed by it are not being met. For consistency, an amendment will ensure that the HRCDC can also revoke where conditions imposed by an appeal panel are not being met.

- It is being made clear that consultations carried out by persons seeking a consent declaration should encompass not only potential data subjects but also patients and the public.

Final Slide

We hope you have found this guidance on the amendments helpful.

Information on the Health Research Regulations generally continues to be available on the websites of the Health Research Board and the Health Research Consent Declaration Committee.

If you have a specific data protection question on a particular research study, you should always consult with your organisation's Data Protection Officer.