Guidance on Retrospective Chart Review Amendment to the Health Research Regulations January 2021

Prepared collaboratively by the
Department of Health
Health Services Executive
Health Research Board &
Health Research Consent Declaration Committee Secretariat
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.

There are also some changes to the appeals process and 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;

- 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 law.

Data Protection and Research Ethics

The opening statement in **Ethics and Data Protection** (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 be valued and respected."

Recommendation CM/Rec(2019)2 of the Committee of Ministers to Member States on the Protection of Health-related data (Council of Europe) (2019)

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)

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 this amendment

The purpose of the amendment is to facilitate low risk retrospective chart reviews that have been approved by a research ethics committee and meet specified transparency requirements.

Retrospective Chart Reviews

A retrospective chart review is a type of research design in which pre-recorded, patient-centred data are used to answer a research question. Chart review studies facilitate the rapid collection of clinical, safety, and healthcare resource utilisation data.

Retrospective chart review studies for health research purposes are mostly low risk, particularly as these are typically conducted by a healthcare practitioner working in a particular health care delivery context and by fully supervised healthcare students.

Retrospective chart reviews are carried out in a number of healthcare settings including but not limited to hospitals.

Retrospective Chart Reviews and Consent

Retrospective chart reviews, by their nature, can present real and practical challenges when it comes to obtaining explicit consent for future unknown studies.

The amendment on retrospective chart reviews addresses the consent challenge, in low risk retrospective chart review studies, through improved transparency and other safeguards.

Retrospective Chart Review for the purposes of the amendment

For the purposes of the Amendment, a ‘retrospective chart review study’ means:

-a **low risk** (see next slide) research study carried out by a controller (a controller can be a hospital, GP practice etc),

-on personal data **only** (which can include medical images), if the study is, for example, linked in any way to bio-samples then it is not covered,

-where that personal data has already been obtained by **that controller** for the purposes of the provision of health care to an individual by the controller.

Low Risk

The Health Research Regulations already require that a controller proposing to process personal for health research purposes must carry out an assessment of the data protection implications of the health research.

It is a condition of the amendment that the risk assessment must be low. A DPO should be consulted if the organisation has one. Under GDPR, the controller must be able to show how the assessment was made.

The REC considering the study must be satisfied with the assessment (see next slide).

The amendment and REC Approval

The requirement for explicit consent will not apply in relation to such a retrospective chart review study where:

- it has been approved by a REC,

- where the REC, as part of that approval, is satisfied and states in writing that the required data protection risk assessment carried out by the controller indicates a low risk to the rights and freedoms of the data subjects whose data will be accessed and used in the study.

This amendment does not affect the discretion of a REC, should it so consider it appropriate, to require that consent should be obtained for the study for reasons others than the data protection risk assessment.

Who can carry out the Retrospective Chart Review Study

As provided in the amendment, it can be carried out **only** by-

(a) a health practitioner employed by the controller or a person studying to be a health practitioner who is under the direction and control of the controller. That means that there are formal governance arrangements in place that include specifying that the controller rather than the supervising health practitioner is responsible for all data protection matters relevant to the student; or

(b) **an employee of the controller** (other than a health practitioner referred to above) **who**, in the course of his or her duties for the controller, **would ordinarily have access to the personal data of individuals held by the controller** that was obtained for the provision of health care to those individuals.

Transparency Arrangements

It is a requirement of GDPR than transparency arrangements must be put in place by the controller where personal data are processed for health research purposes.

It is a condition of the amendment that those arrangements must include notices and posters (see next slide) on display in public areas of the controller's organisation where individuals attend for the provision of health care.

Notices and Posters

They must state, at a minimum, the following in **plain English**-

(a) personal data collected by the controller for the provision of health care to an individual may be used by the controller for a retrospective chart review study but not disclosed to another person (a third party) by the controller for a retrospective chart review unless such data is anonymised,

(b) any findings from the study that are published must not identify an individual whose personal data was used in the study, and

(c) the study will be reviewed and approved by a research ethics committee prior to commencement of the study.

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 DPO.