Guidance on Deferred Consent 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

To allow deferred consent for the processing of personal data for health research in exceptional and specified circumstances where an individual is unable to give consent by reason of physical or mental incapacity and his or her vital (health) interests are engaged.

Processing of personal data only

- The Health Research Regulations and **this amendment** can apply only to the processing of personal data for health research and not extend to other aspects of participation in such research which may, for example, be governed by legislation on clinical trials.

- GDPR does not provide for anyone to give consent on behalf of a data subject where capacity to consent is in question.

Scope and application of the amendment 1

The amendment applies in exceptional circumstances, where the principal purpose of the processing or further processing of the personal data by the controller is necessary for the provision of health care to an individual and necessary to protect the vital interests of the individual.

The type of situation would be where the giving of consent to a particular treatment by the patient is not possible because of his or her physical or mental incapacity, the type of medical situation/emergency involved creates an urgency for a decision to be made on the treatment and it falls, in the circumstances, to the clinician to make the decisions in the best interests of patient care.

Scope and application of the amendment 2

In those just described circumstances:

-the personal data may also be processed by that controller for a related health research purpose on the basis of deferred consent until such time as the individual concerned has the capacity to give such consent, and

-where the health research has been approved by a research ethics committee.

Obtaining the deferred consent

Where the personal data is being processed for health research under the deferred consent process provided for in the amendment, the controller must, as soon as practicable after the individual regains decision-making capacity:

-inform the individual that the personal data is being processed for a research purpose,

-provide information on persons that the personal data has been shared with, and

-seek explicit consent for the processing from the individual.

If the deferred consent is not given

The processing for the health research must stop.

Any personal data already processed for the health research only must be erased, except where to do so would, in the words of GDPR, be likely to render impossible or seriously impair the achievement of the objectives of that processing.

Any personal data processed that is necessary for the care and treatment of the individual is not affected by a decision not to give deferred consent to the research - this protects the integrity and accuracy of the patient's healthcare records.

Applying to the HRCDC

This amendment is intended to remove the need to apply to the Health Research Consent Declaration Committee where the processing of personal data falls under the area covered by the amendment.

If you have an application that you feel is covered by this amendment awaiting consideration with the HRCDC you should contact the committee secretariat to discuss.

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.