

**Guidance on Informed Consent
obtained in the time of EU Directive
Amendment 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 Protection¹** (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.”

- The **Recommendation CM/Rec(2019)2** of the Committee of Ministers to Member States on the **Protection of Health-related data² (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-data-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 Amendment

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To recognise that many health researchers, obtained informed consent, including legitimate broad informed consent, for the processing of personal data during the time of, and in accordance with, the EU Data Protection Directive and, as a good faith measure - to provide that such consent is to be regarded as continuing to be valid.

Consent obtained during the time of the EU Data Protection Directive

- The EU Data Protection Directive dates from 1995 and came into effect in Ireland in 2003 (Data Protection Act 2003) and continued in effect up until 25 May 2018 (when replaced by GDPR). The Amendment applies from the first date and that will benefit biobanking.
- Informed consent was required for the processing of personal data for health research purposes under the Directive and the Data Protection Acts 1998 & 2003.

What is required for the Amendment to apply

This amendment applies to a controller who is carrying out health research that commenced prior to 8 August 2018.

It provides that explicit consent is not required where that controller:

- (a) has obtained the consent of the data subject, before 25 May 2018, to his or her personal data being processed or further processed for the purpose of the specified health research and
- (b) the consent has not been withdrawn; and
- (c) has a valid and lawful basis for the processing of the personal data in Article 6 of the GDPR and meets one of the conditions in Article 9(2).

Controllers relying on consent as lawful basis

Where the lawful basis used by the controller for processing personal data for health research purposes in Article 6 of GDPR is consent and the condition relied on in Article 9 is explicit consent then such consent/explicit consent must always be in accordance with the definition of consent in Article 4 and the conditions for consent in Article 7.

Broad Consent

- The amendment applies to informed consent obtained for specified health research which could have been obtained either in relation to (i) a particular area or (ii) more generally in that area or a related area of health research or part thereof.
- Accordingly, it allows for the consent obtained to cover broad consent in the same way that broad consent can apply to new research.
- The amendment does not cover blanket consent as such consent was not in accordance with the EU Directive.

Applications to the HRCDC

- This amendment may be of particular relevance to controllers who have a re-consenting application awaiting consideration by the Consent Declaration Committee.
- They should consider the amendment and then contact the Secretariat to the Committee to establish whether their application now needs to proceed.

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.