

# **Guidance on Explicit Consent Amendment to the Health Research Regulations January 2021**

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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<sup>1</sup>** (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 data<sup>2</sup> (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](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 this Amendment**

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To formulate the requirement for explicit consent in a way more familiar to health researchers.

# Internationally accepted best practice Ethical Standards in Health Research

There are two well established basic principles:

- informed consent; and
- independent ethical oversight.

Data protection has helped highlight another established core principle:

- transparency

All three established ethical standards are found in the Health Research Regulations and are reflected in the amendment on the explicit consent requirement.

# Informed Consent in International Health Research Instruments

The requirement for informed consent in health research studies (and provision for its withdrawal) is an accepted core ethical principle that is well known to researchers and is found in international health research instruments. For example;

- WMA Declaration of Helsinki (2013) - Ethical Principles for Medical Research Involving Human Subjects
- Recommendation CM/Rec(2016) 6 of the Committee of Ministers to member States on research on biological materials of human origin
- Council for International Organizations of Medical Sciences (CIOMS). International Ethical Guidelines for Health-related Research Involving Humans. 2016.
- WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks (2016)

# Statement by the EU Commission

## (Ethics and Data Protection, November 2018)

The EU Commission has unequivocally stated the importance of consent in research:

"Informed consent is the cornerstone of research ethics. It requires you to explain to research participants what your research is about, what their participation in your project will entail and any risks that may be involved. Only after you have conveyed this information to the participants - and they have fully understood it - can you seek and obtain their express permission to include them in your project."

The Commission document goes on to say:

"You must keep records documenting the informed consent procedure, including the information sheets and consent forms provided to research participants, and the acquisition of their consent to data processing". That ensures that the informed consent becomes explicit informed consent.

# The Amendment

The amendment to the explicit consent requirement provides that explicit consent is obtained from the data subject:

- as a suitable and specific measure
- recorded and retained by the controller, and a copy of which is provided to the data subject prior to the commencement of the health research
- **in accordance with international best practice on the ethical conduct of health research (which includes informed consent, transparency and independent ethical oversight)**

→ for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof.

# Best practice in consent

As evidenced in international instruments, the best practice trend in conducting health research (including the processing of personal data that is part of the research) is strongly in favour of informed consent that:

- (i) identifies the scope of the specified research,
- (ii) provides information, in a timely manner, in an intelligible and easily accessible form, using clear and plain language.
- (iii) gives choices to individuals in terms of the areas of research that they want their information to be used in and third parties that they are willing to have their information shared or not shared with,
- (iv) allows the withdrawal of consent in a convenient way and where that is not possible explains the limits of withdrawal,
- (v) is documented by the controller in written, electronic or other format with a copy of the record of consent provided to the individual.

# Consent must always be voluntary

- Such consent must always be voluntary without any element of inappropriate pressure or undue influence on the individual to participate.
- Researchers who are involved in the care and treatment of potential participants in the research study must ensure at the time consent is being sought that the individual is expressly advised that the giving or not giving of consent for the processing of his or her personal data for research or its withdrawal will not be the cause of any adverse or reduced care and treatment by a health practitioner providing care and treatment to the data subject.

# What else is needed apart from informed consent?

The research concerned must:

- have been ethically approved by a REC,
- be underpinned by proper governance and appropriate transparency arrangements, and
- comply with other relevant data protection requirements.

# 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.