Guidance on Pre-screening 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 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 this Amendment

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To facilitate the actions to be taken in the period up to an individual's enrolment in a health research study to determine whether an individual (prospective research participant) is suitable or eligible for inclusion in the study (referred to in this presentation as pre-screening actions).

Action to determine eligibility or suitability for inclusion in the research

- What was in the 2018 Health Research Regulations
- What is in the amendment
- What is envisaged by the amendment
- Steps necessary to comply with amendment

What was in the 2018 Regulations

Only healthcare staff involved in the care and treatment of individuals could access the patient records of those individuals for pre-screening purposes without explicit consent of the individuals concerned.

The Amendment

- The amendment is available to a controller where the controller already holds the personal data that is to be the subject of the action to be taken to establish suitability of eligibility of a data subject (prospective research participant) for inclusion in the substantive part of the research.

- The amendment sets out identified persons who can carry out pre-screening actions without explicit consent of the data subject or REC approval subject to specified safeguards.

- Explicit consent of the data subject and REC approval continue to be required for the substantive part of the research.

Pre-screening actions

While not defined in the Regulations, the following actions are envisaged as pre-screening actions for the purposes of the amendment:

(a) reviewing the personal data of a data subject in order to assess whether he or she might be suitable or eligible for inclusion in a health research study.

(b) analysing the pre-screening data and documenting the findings,

(c) sharing the findings (in a non-identifiable way) with others involved in the research team.

(d) approaching an individual found to be eligible or suitable to determine their interest in participation in the study see next slide.

(e) sharing the identity of the individual with the research team on a confidential basis where the individual has consented to be contacted by the research team.

Pre-Screening: approaching the Prospective research participant

While the personal data held by the controller can be accessed by any of the category of persons specified in the Amendment (see next slides), it is considered best practice that the approach to the prospective research participant to establish their interest - should always be done only by a health practitioner of the controller or an authorised person who is a health practitioner (e.g a research nurse employed by a University collaborating on the research study).

Persons specified in the Amendment who can carry out pre-screening - without consent

- **A healthcare practitioner employed by the controller (hospital, primary care centre, GP practice etc)** 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;
- **An employee of the controller (for example, a medical records clerk)** 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 were obtained for the provision of health care to those individuals); or
- **A person referred to an "authorised person"** (see next slides).

Who can be an authorised person?

The amendment specifies certain persons who can be authorised by the controller holding the personal data to carry out the pre-screening element of health research without explicit consent.

Those persons can be employees of the following organisations:

(a) an institution of higher education within the meaning of section 1(1) of the Higher Education Authority Act 1971 (No. 22 of 1971),

(b) a body or person that has as its principal activity the provision, management or development of a health practitioner, or

(c) a registered charitable organisation within the meaning of the Charities Act 2009 (No. 6 of 2009), one of whose objects is to support research and education in the health services.

The authorisation process

- For a person to become an authorised person, the controller holding the personal data must put in place a formal process for authorising a person as an authorised person for the purposes of undertaking pre-screening action.

- That process (rather than individual agreements entered into in accordance with the process) must be publicly available, including on the controller's website.

- Controllers may decide to make individual agreements available too in the interests of transparency.

The authorisation process

The controller can only appoint a named individual as an authorised person when:

(a) an agreement (called an “authorisation agreement” in this presentation) **between the controller and the individual’s employer** has been entered into (which should include sanctions for breaches of its terms); and

(b) the individual concerned agrees (in writing) to be bound by the conditions in the above agreement and whatever other policies and terms are applied by the controller in relation to the processing as long as those terms are in accordance with data protection law.

Controlled access to personal data

- An authorised person must not access or use the personal data held by the controller for any purpose other than pre-screening and cannot disclose that personal data to anyone outside of the controller organisation (including his or her employer organisation) without the explicit consent of the data subject or otherwise as required by law to so do.

- That point must be expressly referenced in the authorisation agreement and formally brought to the attention of the authorised person before he or she signs up to be an authorised person.

- The controller should have data security arrangements in place that log physical or electronic access to healthcare records.

The Transparency Requirements

- 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 where there is an "authorised person", the controller must put in place additional transparency measures to make patients aware of that fact.

- Those measures must include notices and posters on display in those public areas of the controller's organisation where individuals attend for the provision of health care (see next slide).

What must be stated on notices and posters

Notices and posters must include, at a minimum, the following information **in plain English** -

(i) that the controller has appointed an authorised person who may, without explicit consent, access and use the personal data held by the controller for the sole purpose of establishing whether an individual who has been provided with health care from the controller may be suitable or eligible for inclusion in specified health research, and

(ii) that any personal data accessed and used by an authorised person without explicit consent will be only such data that is required to assist in determining the suitability or eligibility of an individual for inclusion in the research concerned.

Policies and Processes required

- The controller (for example, hospital) intending to use the authorised person facility will need to have the required policies and processes in place (see next slide).

- **This is about the organisation holding the personal data taking documented responsibility at a corporate level for who has access to the personal information it holds.**

- **Personal arrangements between employees of the controller and individuals that they invite into the organisation on some semi-formal basis are not lawful under GDPR even if they enter into a confidentiality agreement.**

Specific policies and processes

A controller proposing to authorise a person under the amendment should, therefore, have corporate governance arrangements addressing:

- the authorisation agreement process between the controller and the employer of the authorised person,
- the process by which the controller appoints a named authorised person,
- the process by which an authorised person is authorised by the controller for specified research studies, and
- the operational oversight arrangements that the authorised person will work under which require that the authorised person must be under the direction and control of a health practitioner who is an employee of the controller.

Pre-screening outside of the amendment

For those who wish to carry out pre-screening outside of the amendment it may be done on the basis of:

(a) explicit consent of the data subject and approval of a research ethics committee,

(b) a successful application to the Health Research Consent Declaration Committee for a declaration in relation to the pre-screening stage and approval of a research ethics committee.

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.