Trinity Roundtable: Amendments to the Health Research Regulations - What researchers need to know

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Purpose of presentation

- Put the Amendments made by Minister for Health (January 2021) to the Health Research Regulations in context
- Outline the reasons for, limits on and key themes of the Amendments
- Go through the Amendments

The Legal Framework for processing personal data in health research

International

European Convention on Human Rights

Charter of Fundamental Rights

EU GDPR

National

Constitutional

Common Law

Data Protection Act 2018

Health Research Regulations

Transparently, Fairly and Lawfully

- Core data protection principles (Article 5 GDPR)
- Lawfully (in a GDPR context) means that the processing of personal data must not only be compliant with data protection law but also with other relevant law.
- That's why consent declaration process is set at substantial public interest –meets common law and constitutional thresholds.
- Ethics Committees –how much of the law do they need to know?

Key theme of Amendments: Governance

- Governance is the key theme of the amendments.
- Obligations in data protection law on data controllers and data processors –organisational entities.
- Employees and agents of data controllers do not exist or operate in a vacuum from the organisation.
- Universities and other academic institutions need to be particularly aware of the governance issue when collaborating with a hospital or a commercial body.

The Amendments

There are five substantive amendments-

- action to determine eligibility or suitability for inclusion in the research
- low risk 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.

Some things we couldn’t do in the amendments

- The Health Research Regulation derive from GDPR. They can deal with (i) personal data and (ii) the interplay between personal data and biomaterial but they cannot address issues related to biomaterial per se.

- We are aware of the issues in relation to capacity to consent (and tried to push as far as we could) but the substantive issues go beyond the scope of the Regulations.

- We had hoped to include an amendment to provide that the disclosure of pseudonymised personal data for research purposes to a researcher would be regarded as anonymised (in the context of the disclosing data controller) if the recipient data controller formally undertook not try to identify the individuals involved but that was not acceptable.

Pre-screening

Amendment covers actions taken in terms of **transparently** processing personal data **(already held)** to establish whether an individual is suitable or eligible for inclusion in study.

It sets out who can process that personal data without explicit consent and REC approval (which are both needed for the substantive part of the study).

1. Health practitioner who is employee of data controller/healthcare student under the direction and control of controller.

2. Other employees of controller who would in course of his/her duties have access to health records.

3. “authorised person” –a person who is not an employee of the data controller.

Pre-Screening: Authorised Person

An “authorised person” must be an employee of one 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.

Formal corporate governance arrangements and higher levels of transparency are required.

Pre-screening Actions

The following actions are viewed as pre-screening actions for the purposes of the amendment:

(a) reviewing the personal data of a data subject.

(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 –this should be done only by a health practitioner.

(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.

Low Risk Retrospective Chart Review

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

-a **low risk** research study carried out by a controller (which includes a health professional employed by the controller or a person studying to be a health practitioner who is under the direction and control of the controller or another employee who would normally have access to the personal data as part of his or her employment duties),

-on personal data **only** (which can include medical images and already recorded person-identifiable information on bio-samples),

-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 (which effectively means that the controller must be a health services provider),

-where appropriate transparency arrangements have been put in place.

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/risk of the study.

It is a condition of the amendment that the risk assessment must be low. A DPO should be consulted and can help in determining what is low risk. Under GDPR, the controller must be able to show how the assessment was made.

REC approval is required and the REC considering the study must be satisfied with the risk assessment.

Informed Consent –EU Data Protection Directive

We considered the situation where health researchers had obtained informed consent for the processing of personal data for health research during the time of, and in accordance with, the EU Data Protection Directive (1995 -2018).

That consent could include legitimate broad informed consent but not blanket consent.

The amendment, is a good faith measure, to provide that such consent is to be regarded as continuing to be a valid safeguard.

When does the amendment apply?

This amendment applies to a controller who is carrying out health research that commenced prior to 8 August 2018 and 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 the consent has not been withdrawn;

(b) 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);

(c) meets other applicable GDPR and Health Research Regulations requirements.

Explicit Consent -reframed

There are two well established internationally accepted best practice principles in carrying out health research: informed consent and independent ethical oversight.

Data protection has brought to the fore another core principle: transparency

All three principles are found in the Health Research Regulations and are now expressly reflected in the amendment on the explicit consent requirement.

Such consent must always be voluntary/freely given without any element of inappropriate pressure or undue influence on the individual to participate and must be recorded.

Consent: EDPB Guidance

- EDPB is preparing guidance on health research.
- EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research (Adopted on 2 February 2021 –where consent in not legal basis, it must be **a safeguard** reflecting Ireland's position.
- EDPB Stakeholder Event on processing of personal data for scientific research purposes (30 April)
- The DoH will consider EDPB outputs to see if changes to the Health Research Regulations are warranted.

Deferred consent in certain care and treatment situation

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

The amendment is about situations where the individual concerned lacks the capacity to consent and his/her vital interests are engaged from a care and treatment perspective.

The consent of the individual must be obtained when he or she regains capacity to consent.

Concept of capacity to consent is complex and scope of what we could do was limited.

Assisted Decision-Making Capacity Act 2015 covers “healthcare” but not “health research”.

Final points

- We will continue to listen and engage with those involved in health research and others with an interest in health research.
- We will engage with the Department of Children, Equality, Disability, Integration and Youth on the Assisted Decision-Making Capacity Act.
- Genomics will obviously be an increasingly important area in both research and in data protection.
- We remain very much committed to the view that strengthening public confidence in health research is everyone's responsibility.