Examining the concept of consent from a legal perspective in health research

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Why consent and why explicit consent

- Much was made of the inclusion of a requirement for explicit consent **as a safeguard** in the Health Research Regulations
- Was the reaction to that requirement justified?
- This presentation explores why explicit consent was included and the changes made in the Amendments to the Regulations

Elements of valid consent

- Freely given/voluntary without any element of inappropriate pressure or undue influence on the data subject
- Informed
- Should be as specific as possible –can be broad but not blanket
- Capable of being withdrawn
- Capacity to consent is present
- Based on good faith principle -would the individual be surprised by who has access to his/her personal health information and the research use to which it is being put
- To make the consent ***explicit*** –it needs to be documented (and the individual should receive a copy)

Why is consent important in health research?

- Patient empowerment –people should have control over who has access to their sensitive personal health information and for what purposes
- Patient trust is at the heart of the healthcare professional/patient relationship at the level of the individual
- Best way to support health research is to enhance public confidence in such research and transparency and consent are the keys to making that happen
- Bigger debate that needs to take place about making more health information available for research on the basis of supporting the common good but that needs to be a truly genuine and open debate that respects all perspectives

Informed Consent in health research -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.

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)

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

Confidentiality and Consent –Ethical and common law

The common law duty of confidence (which derives from ethical principles) survives death (unlike data protection law which applies only to living individuals).

"Patients and their families should not have to worry about their private and personal information being disclosed without their consent. There are very limited circumstances when a doctor can disclose information without consent.“ Dr Rita Doyle, President, Medical Council, March 2021.

Supreme Court in National Irish Bank v. RTE (1988): “There is no doubt but that there exists a duty and a right of confidentiality…as…exists in…relationships such as for example doctor and patient…. There is a public interest in the maintenance of such confidentiality for the benefit of society at large.”

Health Research Regulations and Consent

- Health Research Regulations do not make consent the legal basis for processing personal data for health research.

- The legal grounds and conditions are set out in Articles 6 and 9 respectively.

- Article 9(2)(j) -processing is necessary for ……scientific or historical research purposes…… in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

- Article 9 (4) Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.

Section 36 of the Data Protection Act 2018

36. (1) Where a requirement that suitable and specific measures be taken to safeguard the fundamental rights and freedoms of data subjects in processing personal data of those subjects is imposed by this Act or regulations made under this Act, those measures may include in particular the following—(a) explicit consent of the data subject for the processing of his or her personal data for one or more specified purposes

Because it is a safeguard rather than an Article 6 ground or Article 9 condition, the January Amendment is able to frame the requirement for explicit consent in terms of international best practice on the ethical conduct of health research (which includes informed consent, transparency and independent ethical oversight)

The explicit consent safeguard can cover 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 (broad consent).

Co-existing consents

- The Constitutional right to privacy, the common law duty of confidentiality and the GDPR consent provisions sit alongside each other.
- To process personal data lawfully for health research, they must all be met.
- That’s why the consent declaration process in the Health Research Regulations is set at substantial public interest –meets common law and constitutional thresholds.
- It’s also why as a practical measure consent should be documented and recorded as per the Amendment to explicit consent in the Health Research Regulations

Capacity to consent

Health Research Regulations can apply only to the rules on the processing of personal data for health research and not extend to other aspects of participation in such research.

Section 2A(1)(a) of the Data Protection Acts 1988 & 2003 provided that if the data subject, by reason of his or her physical or mental incapacity or age, is or is likely to be unable to appreciate the nature and effect of consent, it may be given by a parent or guardian or a grandparent, uncle, aunt, brother or sister of the data subject where the giving of such consent is not prohibited by law

Article 9(2)(c) of GDPR allows processing of personal data where it is necessary to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent

GDPR does not allow anyone to give consent on behalf of another adult –problematic?

Assisted Decision-Making Capacity Act 2015

The legal concept of capacity to consent has developed over the centuries mainly under judge made law.

The Assistant Decision Making Capacity Act 2015 is the principal legislation dealing with capacity to consent in adults.

Not all provisions of that Act are commenced.

The Government Legislation Programme (Autumn 2020) refers to a Bill (in preparation) to amend the 2015 Act.

Responsibility for the Amending Bill has transferred from the Department of Justice to the Department of Department of Children, Equality, Disability, Integration and Youth

Health research and the 2015 Act

“Healthcare” is referenced in the Act (section 2) under the definition of:

“personal welfare”, in relation to a relevant person, means one or more of the following matters…..(e) healthcare”.

There is no reference to health research in the Act.

A liberal interpretation of “healthcare” in the Act might extend to health research that was directly relevant to the healthcare of the individual concerned but there is no certainty.

An amendment to the Act would be necessary to definitively include health research and define its scope.

Deferred consent amendment

The deferred consent amendment to the Health Research Regulations can apply only to situations where exceptional circumstances apply: namely,

-when the giving of consent to particular treatment and the accompanying inclusion in the research study is not possible because of the type of medical situation/emergency involved,

-the vital interests of the individual concerned are engaged, **and**

-decisions made by clinicians are made in the best interests of patient care.

What type of situations are envisaged?

The deferred consent provision would be applicable where-

(a) there is urgency caused by a life-threatening or other serious medical condition,

(b) there are reasonable scientific grounds to expect that participation of the subject in the study will have the potential to produce a clinically relevant benefit for the subject,

(c) the study relates directly to the subject's medical condition,

(d) the study poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.

Hospitals should develop a protocol for deferred consent scenarios.

Deferred Consent –Obtaining Consent

Where the personal data is being processed under this amendment for a health research purpose, the controller must, as soon as practicable, after the individual regains capacity:

-inform the individual orally and in writing that the personal data is being so processed including information regarding any person that the personal data has been shared with,

-seek explicit consent for that processing from the individual.

If the deferred consent is not given

Where the individual informs the controller that he or she does not wish the personal data to be further processed for a health research purpose the data shall not be processed for that purpose.

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

Any personal data necessary for care and treatment purposes is not affected by a decision not to give deferred consent to the research study. This is to protect the integrity and accuracy of the patient's medical records.

Applying to the HRCDC

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

Genomic Research

- There are significant—even lifesaving—benefits to sharing genomic data for healthcare and medical research.
- Large-scale genomic databases are likely to become increasingly common.
- These databases, and the underlying biobanks, give rise to substantial legal and ethical challenges particularly given their potential to facilitate discrimination or criminalisation.
- When it comes to consent –how broad can consent be and who should consent be obtained from?

Genomic Research Challenges

The area even raises basic questions about the definition of personal data associated with the data protection model.

Challenges for anonymisation of personal data.

Challenges fulfilling data subject rights and meeting obligations under the GDPR: particularly, providing information to satisfy the requirements of informed consent and ensuring complete withdrawal from research when requested.

Unclear who will enjoy subject access rights to the data held.

Is the traditional distinction between research and clinical care – with distinct processes and expectations for consent and confidentiality in each case –effective in genomic medicine

Genetic inheritance –right of veto? Findings in regard to one person could also have important medical implications for other members of their family.

What is required?

Clarity, consistency and certainty at national and international level on data protection, ethical considerations and other regulatory matters.

EDPB is considering genomic research in the context of the guidance it is preparing on health research.

Viewing consent as an ongoing process that involves discussion and dialogue rather than a one-off exercise.

Primary legislation (supplemented by codes) is needed to comprehensively regulate biobanks, genomic samples and genomic research.

Step in the right direction –National Research Ethics Committees Bill.

Most important requirement for everyone involved is an open mind when debating the issues.