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Health Research Regulations 2018: Context and purpose

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Purpose of the Health Research Regulations

To support health research and promote necessary and desirable public confidence in such research.

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Legal Framework

GDPR/ Data Protection Act 2018

European Convention on Human Rights and decisions of European Court on Human Rights

Irish Constitution and case law

Common law duty of confidentiality

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What's in the Health Research Regulations?

The Regulations set out suitable and specific safeguards as required under the GDPR where personal data is processed for health research, including explicit consent and REC approval

They have a definition of health research

They address the situation where the obtaining of explicit consent is not possible and provide for a Consent Declaration Committee to make decisions

The Committee will be broadly based and independent and there is an appeal mechanism

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Requirement for Consent

National and international legal frameworks that place considerable emphasis on the public interest value of confidentiality and consent when it comes to personal health information.

Anything that limits patient confidentiality and consent must itself have very strong countervailing public interest grounds.

The DPC emphasised that the requirement for explicit consent as the default position in the Regulations was a continuation of what was already the law rather than an innovation.

The requirement for consent is also very much in line with accepted international best practice in health research.

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Informed Consent and Explicit Consent

Consent is defined in Article 4 of the GDPR

Informed consent is where the person requested to give consent has been provided with as much information as he or she requires to make an informed decision and is allowed time to make the decision

Explicit consent is informed consent that has been appropriately recorded

Broad consent is also covered in the Regulations

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Clinical Trials and Biobanking

The GDPR applies to the processing of personal data associated with biobank material and the clinical trial of medicinal products.

Therefore, the Health Research Regulations also apply.

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Where the requirement to obtain consent cannot be met

For the first time in Irish law, a statutory process for a consent declaration

The Regulations set out the criteria for a decision and the information to be provided to the Consent Declaration Committee to allow it to make a decision

The Regulations provide for the operation of the consent declaration process in terms of new and ongoing health research.

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Three specific matters

Retrospective chart reviews

Research with “consent waivers” from RECs

Capacity to consent

None of the above were caused by the Regulations. However, they are being further examined.

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Conclusion/Summing Up

The Regulations set out for the first time in Irish law sound information governance principles that are in line with international best practice when it comes to the collection, use and disclosure of a patient's personal health data for health research.

The Regulations also ensure that there is certainty, consistency and clarity for those carrying out health research on what the rules are and that is a major step forward.

For data subjects, they ensure openness and transparency.