



An Coimisiún um
Chosaint Sonraí
Data Protection
Commission

Data Processing for Clinical Audit

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Data Protection Commission

National Office of Clinical Audit

GDPR & Clinical Audit Information Session

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Clinical Audit or Health Research?

“systematic review and evaluation of current practice against research based standards with a view to improving clinical care for service users”

HSE, National Quality Improvement Team

“scientific investigations that aim to test ideas, answer questions, improve treatment options and increase knowledge about human health”

New South Wales Cancer Council

Processing Special Category Data

- Legal Basis, Article 6 GDPR

“6(1)(e) necessary for the performance of a task carried out in the public interest”

- Enabling Condition, Article 9 GDPR

“9(2)(h) necessary for...the management of health or social care systems and services”

“9(2)(i) necessary for ensuring high standards of quality and safety of health care”

Principles of Data Protection

- Transparency
- Data Minimisation
- Protection of Integrity and Confidentiality
- Accountability

Ethics and Publication

- Clinical Audit not subject to HRR requirement for REC approval
- Data minimisation
 - Pseudonymisation
 - Anonymisation
- Re-identification
 - Singling Out



Health Research Regulations 2018

- Background to proposed amendments
- General exemptions to the consent requirement
- Remaining safeguards
 - Data Protection Impact Assessment
 - REC approval

Amendments to the HRR

- Retrospective Chart Review Studies
- Pre-screening for eligibility to participate in research
- Deferral of consent in emergency care situations
- Lack of Capacity to Consent
- Underpinned by ethical approval and in compliance with the principles of data protection

Role of the DPC

- Article 57 GDPR, Tasks of the Supervisory Authority
 - a) Monitor and enforce the application of the Regulation
 - b) Promote public awareness and understanding
 - c) Promote the awareness of controller and processors of their obligations

DPC Consultation functions

- Mandatory prior consultation
 - a) Data Protection Impact Assessment with Residual High Risk
 - b) Proposals for legislative measures
- Informal consultative engagement
 - a) Pre-project planning
 - b) Complex data protection queries
 - c) Representative bodies
 - d) Data Protection Officers





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Thank you.