Data Protection Law in the Republic of Ireland in the context of Research

European Data Protection Law

GDPR 2016

Age:

Capacity: *does not address capacity*

Concepts:

- Personal Data / Special Category Data
- Transparency
- Data Controllers / Joint Controllers / Processors
- Data Privacy Impact Assessments (DPIAs)
- Data Processing Agreements
- Data Protection Principles
- Data Subject Rights
- Data Protection by Design / Default
- Accountability

Definitions:

Scientific Research not defined
High Risk Processing not defined - see DPIAs
Processing on a large scale not defined - see DPIAs

Safeguards: **Art 89 + scientific research - additional safeguards**

Subject to: **GDPR & Research - See Recitals 33, 50, 52, 53, 62, 65, 113, 156, 157, 159, 160, 161, 162**

and: **GDPR & Research - See Articles - Art 5, 1 (b), 1 (e), Art 9 2 (j), Art 14 5(b), Art 17 3(d), Art 21 (6), Art 89 1-4**

Consent: Consent' is a legal basis for processing in Art 6 1 (a); 'Explicit Consent' is also a condition of processing special category data in Art 9 2 (a); 'Explicit Consent' is a condition of 'automated processing' in Art 22 2 (c)

Subject to: Art 7 (1)(2)(3)(4) - conditions of consent

and: **GDPR & Consent - See Recitals 32, 33, 38, 40, 42, 43, 50, 51, 54, 65, 68, 71, 111, 112, 155, 161, 171,**

and: **GDPR & Consent - See Articles - Art 4 11 , Art 6 1 (a), 4, Art 7 1-4, Art 8 2, Art 9 2 (a), Art 13 2 (c), Art 14 2 (d), Art 17 1 (b), Art 18 (2), Art 20 1 (b), Art 22 1 (c), Art 49 1 (a), 1 (f), Art 83 5 (a)**

Republic of Ireland Data Protection Law

DPA 2018 (Ireland)

Age of Consent = 18

HRRs 2018 (Ireland)

Health Research defined
High Risk Processing not defined - see DPIAs

Research Ethics Committees defined
Ethical Issues defined

Mandatory Safeguards:

1. processed as is **necessary** to achieve objectives
2. no damage or distress, or likelihood of
3. **governance measures (prescribed)**
   - i ethical approval
   - ii data controllers, processors identified
   - iii art 26 compliance, joint data controllers
   - iii funders / supporters identified
   - iv who data will be shared with identified
   - v purpose of data sharing identified
   - vi training in data protection
4. **processes and procedures (prescribed)**
   - i assess data protection implications
   - ii. conduct DPIA (high risk processing)
   - iii comply with **minimisation** principle
   - iii limitation of access to data
   - iv logging of access to data
   - iv protect **security** of data
   - v end of study data arrangements
   - vi technical and organisational measures
   - vii processes for testing tech/org measures
   - ix **transparency** arrangements
   - x. **'Explicit Consent'** or a HRCDC declaration **(broad)**

HRRs Amendments 2021 (Ireland)

Privacy Notices (prescribed text) for: i pre-screening; ii retrospective chart reviews

Low Risk not defined - see retrospective chart reviews

Exemptions to Requirement for Ethical approval:

- i Pre-screening subject to conditions

Explicit Consent' in accordance with international best practice on the ethical conduct of research which includes informed consent, transparency and independent ethical oversight, A **COPY** provided to data subject....

Exemptions to Requirement for Explicit Consent or a HRCDC Declaration:

- i Pre-screening subject to conditions
- ii 'Low Risk' retrospective chart reviews subject to conditions
- iii Deferral of explicit consent in exceptional circumstances subject to conditions
- iv Where consent for processing obtained under '95 Directive subject to conditions

Local Policy / Practice

Beaumont Hospital

- Privacy Notices (prescribed text) in place
- Mandatory DPIAs for processing of personal data for health research
- Mandatory Legal Review of Agreements / Contracts
- Safeguards listed in ethics application form provided by REC
- Transparency requirements contained in templates provided by REC
- Explicit consent requirements contained in templates
- Exemptions referenced in ethics application form provided by REC

G. Vale, 8.6.21