



Putting the Health Research Regulations in the wider Data Protection context

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Data Protection Commission

Trinity Round Table: 'Amendments to the Health Research Regulations - What researchers need to know'

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Fundamental Rights

Charter of Fundamental Rights of the European Union

Article 8: Protection of personal data

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
3. Compliance with these rules shall be subject to control by an independent authority.

Legal Framework

- Treaty of Lisbon 2009 (Charter of Fundamental Rights)
- General Data Protection Regulation, 2018
- Directive (EU)2016/680 “Law Enforcement Directive”
- The Data Protection Act 2018
- European Communities (Electronic Communications Networks and Services) (Privacy and Electronic Communications) Regulations 2011
- Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018

Controller, Processor, Joint Control

Controller: the natural or legal person, public authority, agency or other body which, **alone or jointly with others**, determines the purposes and means of the processing of personal data.

Processor: a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller.

- Consider the correct application of these roles in terms of end-to-end data processing
- The same organisation may have different roles at different points in the process

Responsibilities of the Controller

- Article 24 GDPR: “implement appropriate technical and organisational measures to ensure and to be able to demonstrate that processing is performed in accordance with this Regulation”
- Article 24(2): Data Protection Policies as appropriate
- Article 30: Records of Processing – should reflect research activities accurately
- Article 35: Data Protection Impact Assessments
- Article 28: Data Processing Agreements

Health Research Regulations in context

- Article 89 GDPR: Safeguards and derogations relating to processing for scientific research purposes
- Section 42, Data Protection Act: Processing for scientific research purposes
- Section 36, Data Protection Act 2018: Suitable and specific measures to safeguard fundamental rights for processing
- Section 36(2), Data Protection Act 2018: Ministerial Regulations to specify particular measures to safeguard fundamental rights as mandatory in a particular processing context i.e. health research

Data Protection Officers

- Inform and advise the controller or the processor of their obligations
- Provide advice where requested as regards the DPIA and monitor its performance pursuant to Article 35
- Must be involved properly and in a timely manner in all matters relating to the protection of personal data
- Point of contact for both the Supervisory Authority and Data Subjects who wish to exercise their rights or obtain information

Key Points

- Understand the roles of all parties, at all points in the chain of data processing.
- The HRRs comprise a part of the overall data protection obligations for your organisation.
- Is data protection compliance in terms of health research recognised as an organisational obligation where you work?
- Does the organisation have knowledge, oversight, and understanding of all data processing? Proper data governance is key!
- Know your DPO and involve them as necessary



Coimisiún
Cosanta Sonraí
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Thank you



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