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Research Ethics (Part 2)

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SUMMARY OF TOPICS

- Research Ethics Committees
- Vulnerability of Patients
- Inclusion and Exclusion Criteria
- Data Protection
- Ethical particularities of Qualitative Research
- Ethical Challenges and Violations of Research Integrity

Research Ethics Committees

Research Ethics Committees - Definition & Nomenclature

"A committee that performs ethical review of proposed research"

- ✓ UK : Local Research Ethics Committee (LREC) 1991
  - Multi – Center Research Ethics Committee (MREC) 1997
  - Central Office for Research Ethics Committees (COREC) 2000
  - National Research Ethics Service (NRES) 2007
- ✓ Europe : Eurecnet.org (REC)
- ✓ Australia : Human Research Ethics Committee (HREC)
- ✓ USA : Institutional Review Boards (IRBs)
- ✓ Developing Countries : ?

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http://www.eurecnet.org

- 29 Countries
- National and Regional Research Ethics Committees
- Number of Committees per country variable (1-215)
  - Government, Institutions, Hospitals, Medical Associations , etc
  - Regular meetings (e.g. weekly, monthly)
- Multi-disciplinary – Multi-sectorial (e.g. biomedicine, ethics, social sciences, psychology, law +lay people)

www. Eurecnet.org
Bradin L et al, Research Ethics Review 2009

Austria | Belarus | Belgium | Bulgaria | Cyprus | Czech Republic | Denmark | Estonia | Finland | France | Germany | Greece | Hungary | Ireland | Italy | Latvia | Lithuania | Luxembourg | The Netherlands | Norway | Poland | Portugal | Romania | Slovakia | Spain | Sweden | Switzerland | Ukraine | United Kingdom

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http://www.eurecnet.org

- Limited duration of service (e.g. 2 years)
  - Independent – No conflict of interest
- Compliance to Declarations (e.g. Helsinki Declaration, Oviedo Convention etc) and National Laws

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RECs Ethical, Scientific & Methodological considerations

- The protection of trial participants
- The protection of dignity and wellbeing
- Benefits and risk ratio
- Scientific validity
- The quality of research facilities
- Qualifications and suitability of investigators
- User involvement in research design
- Data protection and safety issues

www. Eurecnet.org
Bradin L et al, Research Ethics Review 2009

National associations or national bodies of RECs

Austria | Belarus | Belgium | Bulgaria | Cyprus | Czech Republic | Denmark | Estonia | Finland | France | Germany | Greece | Hungary | Ireland | Italy | Latvia | Lithuania | Luxembourg | The Netherlands | Norway | Poland | Portugal | Romania | Slovakia | Spain | Sweden | Switzerland | Ukraine | United Kingdom

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RECs Ethical, Scientific & Methodological considerations

- Subject information and informed consent
- Recruitment issues/ fair selection of participants
- Community considerations
- Social value of research

www. Eurecnet.org
Bradin L et al, Research Ethics Review 2009

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Austria | Belarus | Belgium | Bulgaria | Cyprus | Czech Republic | Denmark | Estonia | Finland | France | Germany | Greece | Hungary | Ireland | Italy | Latvia | Lithuania | Luxembourg | The Netherlands | Norway | Poland | Portugal | Romania | Slovakia | Spain | Sweden | Switzerland | Ukraine | United Kingdom

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Ethics Advisor or Advisory Boards

- One or several experts with varied expertise related to the trial

They will :

- help you check for compliance with ethical standards throughout the project
- report to you and to the Commission/Agency, on a regular basis, on ethics concerns

- it is important that they are:
  - external to the project and to the host institution
  - totally independent
  - free from any conflict of interest

(Manual H2020) https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

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Ethics Appraisal Steps

Manual H2020) **https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm**

Activity	Who?	When?	How?
Ethics Self-assessment	Applicant	Application phase	Consideration of ethical issues of the proposal
Ethics Pre-screening/Screening	Ethics experts and/or qualified staff	Evaluation phase	Review of application material
Ethics Assessment (for proposals involving hESC or raising serious ethical issues: severe intervention on humans)	Ethics experts	Evaluation/ Grant preparation phase	Review of application material
Ethics Check/Audit	Ethics experts	Implementation phase	Review of project deliverables/interview with applicants

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IRBs and Palliative Care

- Unfamiliarity of IRB members of palliative care research holistic approach
- The study population in palliative care studies is often :
  heterogeneous
  potentially vulnerable or frail
  & may include family caregivers
- No resources to guide IRB members in their judgement on palliative care research
- They may become: “powerful gatekeepers”, “unjustly paternalistic” and deny palliative care patients the opportunity to participate in research

Abernethy AP, et al, J Pain Symptom Manage. 2014

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IRBs and Palliative Care

- Standardized methods and resources :

1) Inform IRB members about PC issues,
2) Guide PC researchers about IRB requirements
3) Establish better communication between them

- Suggestions :

1) Develop a vocabulary of key terms in PC research
2) Develop a taxonomy of key potential IRB concerns
3) Develop a “manual” especially for PC protocols

Abernethy AP, et al, J Pain Symptom Manage. 2014

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Patient Vulnerability

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Patient Vulnerability Definition

"Vulnerability is defined as a state in which individuals are relatively or absolutely incapable of protecting their own interests"

They are dependent on others

Levine RJ 1988

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Patient Vulnerability in Palliative Care

- Dying Patients
- Severely ill – advanced disease - fragile patients
- Patients in low resource settings

- Psychological distress/Cognitive impairment
- Inability or unwillingness to concentrate

Masso M et al https://apo.org.au/sites/default/files/resource-files/2004-10/apo-nid75930.pdf

Research Ethics. Addington-Hall JM, in Research Methods in Palliative Care. Addington-Hall JM, Bruera E, Higginson I, Payne S eds, Oxford University 2007, p.27-41

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Patient Vulnerability in Palliative Care

- Participation out of a sense of desperation

- An obligation to participate

- The need to 'give something back'

Masso M et al https://apo.org.au/sites/default/files/resource-files/2004-10/apo-nid75930.pdf

Research Ethics. Addington-Hall JM, in Research Methods in Palliative Care. Addington-Hall JM, Bruera E, Higginson I, Payne S eds, Oxford University 2007, p.27-41

Patient Vulnerability – Contributing factors

- Advanced age
- Polypharmacy
- Institutional setting
- Dehydration
- Infection
- Hypoxia
- Direct damage to the CNS

Coping Strategies for addressing Patient Vulnerability

- ✓ Distinction between clinician and researcher
- ✓ Optimize symptom management prior to recruitment : ↓desperation
- ✓ Repeat- repeat :
  "they are free to withdraw their consent at any time" No consequences…
- ✓ Be sensitive to any signs of participants' distress

Masso M et al https://apo.org.au/sites/default/files/resource-files/2004-10/apo-nid75930.pdf

Palliative Care Research Risks & Opportunities

"Conflict of Interest"? Research in Palliative Care

Dictum:

"the interests of the patient always prevail over those of science and society"

BUT……

- The suggestion that PC patients should NOT be involved in research possibly denies these individuals an active role in "living"
- It deprives them of potential opportunities

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Opportunities for palliative care patients in research

- to reflect upon their care and illness experience
- a sense of contributing to a greater community good and offer information that may benefit others
- a sense of meaning to life

❖ *Evidence suggests that the majority of palliative care patients would not hesitate to be involved in research as long as :*

they are well informed about the purpose and potential benefits

irrespective of whether they would receive any direct benefit or not

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Ethical Issues in Patient Recruitment/Eligibility

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Ethical Implications in Recruitment Strategy

- **Indirect method** (announcements, flyers, posters, internet etc) personal privacy guaranteed – possibly poor recruitment yield
- **Direct method** (personal letters, e mails, telephone calls etc) ethical requirement : inform potential participants how they were chosen – possibly fulfilling eligibility requirements
- **Intermediate approach** (potential participants are asked to approach researchers – avoid indirect coercion)

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Inclusion and exclusion criteria

- ✓**Inclusion criteria** are those characteristics a person must have in order to be eligible to participate in a research study
- ✓**Exclusion criteria** are those characteristics that prohibit participation
- ✓They are determined by: study aims and objectives
  ethical principles : risk/benefit ratio
  autonomy
  justice
- ✓They should NOT be based "on convenience"

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Ethical Considerations in Data Management & Data Protection

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GDPR
General Data Protection Regulation


European Commission

English

Search

Home > Law > Law by topic > Data protection > Data protection in the EU

Data protection in the EU

The General Data Protection Regulation (GDPR), the Data Protection Law Enforcement Directive and other rules concerning the protection of personal data.

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European Data Protection Board

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Fundamental rights

The EU Charter of Fundamental Rights stipulates that EU citizens have the right to protection of their personal data.

Protection of personal data

Legislation

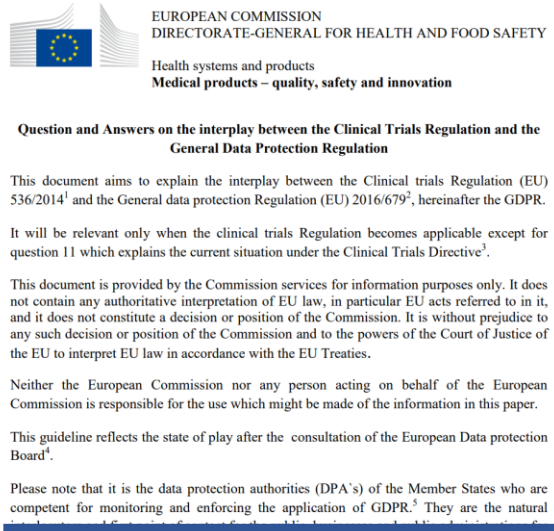
The data protection package adopted in May 2016 aims at making Europe fit for the digital age. More than 90% of Europeans say they want the same data protection rights across the EU and regardless of where their data is processed.

The General Data Protection Regulation (GDPR)

Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. This text includes the corrigendum published in the OJEU of 23 May 2018.

The regulation is an essential step to strengthen individuals' fundamental rights in the digital age and facilitate business by clarifying rules for companies and public bodies in the digital single market. A single law will also do away with the current fragmentation in different national systems

https://ec.europa.eu/info/law/law-topic/data-protection/data-protection-eu_en


EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Medical products – quality, safety and innovation

Question and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation

This document aims to explain the interplay between the Clinical trials Regulation (EU) 536/2014[1] and the General data protection Regulation (EU) 2016/679[2], hereinafter the GDPR.

It will be relevant only when the clinical trials Regulation becomes applicable except for question 11 which explains the current situation under the Clinical Trials Directive[3].

This document is provided by the Commission services for information purposes only. It does not contain any authoritative interpretation of EU law, in particular EU acts referred to in it, and it does not constitute a decision or position of the Commission. It is without prejudice to any such decision or position of the Commission and to the powers of the Court of Justice of the EU to interpret EU law in accordance with the EU Treaties.

Neither the European Commission nor any person acting on behalf of the European Commission is responsible for the use which might be made of the information in this paper.

This guideline reflects the state of play after the consultation of the European Data protection Board[4].

Please note that it is the data protection authorities (DPA's) of the Member States who are competent for monitoring and enforcing the application of GDPR.[5] They are the natural

https://ec.europa.eu/health/system/files/2019-04/qa_clinicaltrials_gdpr_en_0.pdf

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https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-and-data-protection_he_en.pdf

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[Table 1] Indicators of data processing operations that may entail **higher ethics risks**

Types of personal data	* racial or ethnic origin * political opinions, religious or philosophical beliefs * genetic, biometric or health data * sex life or sexual orientation * trade union membership
Data subjects	* children * vulnerable people * people who have not given their explicit consent to participate in the project
Scale or complexity of data processing	* large-scale processing of personal data * systematic monitoring of a publicly accessible area on a large scale * involvement of multiple datasets and/or service providers, or the combination and analysis of different datasets (i.e. big data)
Data-collection or processing techniques	* privacy-invasive methods or technologies (e.g. the covert observation, surveillance, tracking or deception of individuals) * using camera systems to monitor behaviour or record sensitive information * data mining (including data collected from social media networks), 'web crawling' or social network analysis * profiling individuals or groups (particularly behavioural or psychological profiling) * using artificial intelligence to analyse personal data * using automated decision-making that has a significant impact on the data subject(s)
Involvement of non-EU countries	* transfer of personal data to non-EU countries * collection of personal data outside the EU

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Data protection : Confidentiality – Anonymity – Pseudo anonymity

"They are ethical practices designed to protect the privacy of human subjects while collecting, analyzing and reporting data

The information becomes the data , not the participants"

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Data protection : Confidentiality

Confidentiality:

- refers to separating or modifying any personal, identifying information provided by participants from the data
- the researchers knows and safeguards the identity of the research subject (coding, use of passwords, encryption etc)
- usually practiced in qualitative research

https://methods.sagepub.com/reference/the-sage-encyclopedia-of-communication-research-methods/i3126.xml
https://www.evergreen.edu/humansubjectsreview/confidentiality

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Data protection : Confidentiality - Anonymity

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Data protection : Anonymity – Pseudo anonymity

- **Anonymisation**: techniques to convert personal data into anonymised data
- **Pseudonymisation**: substituting personally identifiable information (e.g.name) with a unique identifier (e.g. code)
- **Re-identification**: turning pseudonymised or anonymised data back into personal data (data matching etc)

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-and-data-protection_he_en.pdf

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-and-data-protection_he_en.pdf

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Data protection by design

- ✓ the pseudonymisation or anonymisation of data
- ✓ data minimisation
- ✓ applied cryptography (e.g. encryption & hashing)
- ✓ using data-protection service providers & storage platforms
- ✓ arrangements that enable subjects to exercise their fundamental rights (e.g. as regards direct access to their personal data and consent to its use or transfer)

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-and-data-protection_he_en.pdf

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Ethical issues in Record Keeping

- Dilemma between confidentiality and openness (*anonymization and possibility of re- identification*)
- Research reproduction and misconduct checking
- Notes, Data, Code and Logs must be securely kept
- Retention period ?Indefinite? At least 5 years?

https://www.diva-portal.org/smash/get/diva2:1355705/FULLTEXT01.pdf

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Ethical Challenges

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Ethical Issues in Qualitative Research Researcher's Role as Part of the Process

- "Sensitive" research *(threat of intrusion – sanction – political)*
- The role of reflexivity *(who am I asking questions)*
- Supervision, safety and support *(acknowledge and address researcher's values, views, emotions, defenses etc)*
- Negotiating roles and relationships *(gender, race, age, personality, sexuality, professional background etc affect perceptions & relationships)*

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Violations of Research Integrity

- Deception
- Fabrication
- Falsification
- Plagiarism
- Manipulating authorship
- Withholding research results
- Misrepresenting research achievements
- Exaggerating the importance and practical applicability of findings

EU Code
http://www.ethicsguidebook.ac.uk/Covert-or-deceptive-research-93.html
https://allea.org/code-of-conduct/

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- This publication [communication] reflects the views only of the author, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

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