Being Ethics Ready and Compliant

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Ethics in the EU - Framework

Three aims:

• To respect legal obligations
• To respect ethical principles in research
• To help researchers think about and elaborate on the ethics aspects of their projects
What is new in Ethics H2020

• Legal base
  ➔ Art. 19 in H2020 – Regulation (EU) n° 1291/2013
  ➔ Art. 13 & 14 Rules for Participation - Regulation (EU) n° 1290/2013

• List of ethics issues

• Ethics procedure
  ➔ Ethics Appraisal (Ethics Review in ERCEA)

• Ethics in submission system
  ➔ Integral part of the proposal (part A)

• New templates
  ➔ EIT ethics issues table
Established by the European Commission

Three inter-acting sources in Ethics H2020

- Ethical teams in EU Commission or Agencies
  - Implement the legal framework voted by the parliament
  - establish the rules applied within the agencies
  - Deal with the proposals and follow emerging trends in ethics

- The European Parliament
  - Votes Directives and Regulations
  - Its texts must be applied in all EU Member States
  - Review the proposals

- Experts in ethics
  - Participate in working groups to draft ethics guidelines to be applied within the EU and its bodies
  - Review the proposals
Ethics Review procedure in ERCEA

**Proposal**
- parts B1 and B2
- Ethics issue table
- Ethics self assessment

**Pre-screening comments**

**Screening report**
- Additional info from PI

**Ethics Pre-Screening**
(40%-45% proposals cleared)

**Ethics Screening**
(90% proposals cleared)

**Ethics Assessment**
ERCEA or RTD
(99% proposals cleared)

**hESC**
Programme Committee
Commission decision

End of evaluation

- 1 week
- 3 weeks + answer from PI
- 3 months + answer from PI
- 6 months + voting and EC decision

Signature of Grant Agreement
Three actors involved

The researcher:
- flags the ethics issues which concern the project
- elaborates on the issues in the Ethics Self Assessment
- provides the adequate authorizations

Ethics experts:
- can flag issues not identified by the researcher
- define the ethics requirements:
  - documents needed
  - elements on which the researcher has to provide more details

The Agency:
- controls whether all ethics issues involved are flagged
- controls and assesses all the answers and documents submitted
- clears the projects
What is expected from the applicant? (Ethics Self-Assessment – PDF)

Ethics Issues Table

Ethics self-assessment

- **Description** of the potential ethics issues of the proposed action regarding its objectives; the methodology and the possible implications of the results;

- **Explanation** of how the ethical requirements set out in the work programme will be fulfilled;

- **Statement** about how the proposal meets the national legal and ethical requirements of EU and/or third country where the action is to be performed;

- **Indication** of which particular authorisations may be needed during the lifetime of the project.

**Annexes** can be included (approvals, authorizations, …)
Main ethics issues

• Human Embryonic Stem Cells or Foetal Tissue
  - *No destruction of the embryos!*
  - *Scientific Evaluators to confirm NECESSITY to use hESC*
  - *Programme Committee and EC decision*

• Human cells/tissues
  - *Human genetic material and biological samples: Directive 2004/23/EC*
    - *Keep track on the origin of the cells*
    - *Authorizations/licenses*
    - *Fully informed consent of the donors*
  - *Cells/tissue from clinical practice (Secondary use): informed consent from patients*
  - *Biobanks: International Charter of principles for sharing bio-specimens and data*

• Research on animals
  - *3Rs, animal welfare*
  - *Non-human primates: strict limits to their use*
  - *Directive 2010/63/EU of the European Parliament*
Main ethics issues

• Involvement of Human participants

Medical studies
- Declaration of Helsinki/ Oviedo Bioethics Convention
- CT Regulation No 536/2014

Children involved in research
- Information sheet /assent/ reconsenting when turning adults

Social or Human Sciences Studies
- Oral and written consent
  - Illiterate individuals
  - Oral tradition countries
  - Risks of written consent

Vulnerable populations
- Free will of university students as research subjects
- Financially vulnerable populations and use of incentives
Main ethics issues

- Privacy and personal data
  - **Personal data** is any information which relates to an identified/identifiable person
  - **Processing** of personal data include any operation: collection, recording, storage, alteration, disclosure,…
  - **Informed consent** is mandatory
  - Only use/process **data necessary** for your research
  - Sensitive data (health, sexual lifestyle, political opinions,…) specific authorization
    - Data transfer to third countries (non-EU/EEA): **Data transfer agreements** (except Commission list of countries offering adequate protection)
Main ethics issues

- Research in low and middle-income countries

Declaration/Charter (EU Fundamental Rights; UN Rights of Child, UNESCO Universal Declaration)

Involving the communities where research takes place
- Benefit sharing
- Absence of local ethics structures

War, epidemics and political pressure
- Safety of participants
- Safety of researchers

Use of local resources
- Use of local materials or human resources
- Compensation policy
Main ethics issues

• Environment & Health Safety
  - Toxic chemicals and/or explosives
  - Radioactive material
  - Research on the field
  - GMOs

• Dual Use
  - Potential military/terrorist application

• Misuse
  - Aim of the research: Possible distortion of the facts by the methodology used
  - Discrimination and stigmatisation: During research and/or dissemination of results
  - Misinterpretation of results: Preventing wrong political use of results
**Do's and don'ts**

**Do**
- Include reflexion on ethics right from the start
- Take it as a way to broaden the perspective on your subject
- When in doubt, always tick the issue and elaborate on your doubts

**Don't**
- Don't think that issues depend on the general domain your research belong to
- Don't do it in the last 5 minutes before submission of your proposal
- Do not abstain from ticking thinking that it will go unnoticed (and/or that it will be less work to do!)
What is expected from the applicant?

After Screening and/or Assessment:

Explanatory Note (signed and dated by PI):

- It should address all requirements present at SER or EAR one by one

Any extra documents needed to meet the Requirements: approvals, authorisations, training certificates,...

- When authorisation/approval is pending, an indicative timeframe should be provided
Ethics Monitoring

Monitoring (if need be):
During the implementation of the project ERC proceeds to the ethics monitoring:

• Before interim/final payment stage (to a maximum of 4 times, as per GA)
• In case of amendments (Change of Description of Work/Annex I (DoA/DoW), extension, change of Host Institution, subcontractors, others)

Outcome
• Ethics Monitoring Clearance Note
Ethics issues to be monitored

- The **open ethics issues** at the signature of Grant Agreement:
  - Renewals of approvals/authorisations
  - Training certificates of newly recruited staff
  - Pending authorisations/approvals of subprojects starting at later stages of the project
  - ...
- In case of amendments (changes of HI, changes of DoA,..)
  - **New ethics issues** that may arise, new documentation can be asked.
  - In case of substantial changes with **complex ethics issues** an **Ethics Review** may be needed.
Checks and Audits

- Ethics Checks and Audits are organised by the Commission
- Performed by Ethics Experts
- Audits may involve on-site visits
- The experts produce an Audit Report which is sent to the PI

ERCEA is in charge of:
- Communication with the PI
- Issue the ethics clearance
You're not alone!

- Ethics committees
- Data protection officers
- Persons specialized in your domain and/or in ethics
- Ethics Adviser or Board
- ERC internet site – www.erc.europa.eu
- Guidance – How to complete your ethics self-assessment?
The end

Thank you for your attention