The EC Ethics Appraisal Process and Common Ethics Issues in Research with Humans

Louiza KALOKAIRINOU, PhD
Policy Officer
Ethics and Research Integrity Sector
DG Research Innovation
European Commission
Outline

1. Research in human beings
   - Medical Research
   - Research in Social Sciences and Humanities
   - Informed consent procedures

2. Data Protection

3. The Ethics Appraisal Process: What changes in Horizon Europe?
1. Research in human beings
1. Research in human beings

Does the research involve human participants?

Information to be provided:

- Confirm that informed consent will be obtained.
- Confirm that an ethics approval will be obtained.

- No related requirements
1. Research in human beings

- Medical Research
- Research in Social Sciences and Humanities
- Informed consent procedures
1. Research in human beings

Medical research must comply, among others, with:

- the Declaration of Helsinki.
- the Oviedo Convention on Human Rights and Biomedicine
- EU Regulation No 536/2014 on clinical trials on medicinal products for human use.
1. Research in human beings

Medical research

Issues addressed in the Declaration of Helsinki include:

- Medical research involving human subjects must conform to generally accepted scientific principles
- Research should be conducted by medically / scientifically qualified individuals
- Risks should not exceed benefits
- Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.
- Informed consent from research participants is necessary
- Research protocols should be reviewed by an independent committee prior to initiation
1. Research in human beings
Medical research

Are they patients/healthy volunteers?

Information to be provided:

- Details on recruitment, inclusion and exclusion criteria and informed consent procedures
- What disease/condition/disability do they have? (if applicable)
- Incidental findings policy

Documents to be obtained:

- Informed consent forms + information sheets
- Copies of Ethics Approvals

Requirements:

- No related requirements
1. Research in human beings

- Medical Research
- Research in Social Sciences and Humanities
- Informed consent procedures
1. Research in human beings

SSH Research

Examples of ethics issues:

- Potential harm to human participants (psychological, social, economic etc.)
- Data protection and privacy
- Misuse (e.g. discrimination or stigmatization)
- Safety of research participants and researchers
1. Research in human beings

**SSH Research**

<table>
<thead>
<tr>
<th>Participants</th>
<th>Children, vulnerable groups (e.g. persons unable to consent, minorities, marginalised people, migrants, refugees, victims of abuse and violence)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sites of research</td>
<td>Conflict regions, sites of historical value to indigenous people, troubled neighbourhoods, non-EU countries or regions within them where the economic, political, environmental and health conditions may pose risks.</td>
</tr>
<tr>
<td>Sensitive areas of research</td>
<td>Risk of exposure to harm to participants, researchers; potentially sensitive topics, such as participants’ sexual behaviour; illegal or political activities; experience of violence, abuse or exploitation; mental health; participants’ personal or family lives; or their gender or ethnic status. Research into criminal activity.</td>
</tr>
<tr>
<td>Methodology</td>
<td>Deception, covert research, invasive methods (fMRI for children) as part of interdisciplinary research, profiling and web-crawling</td>
</tr>
<tr>
<td>Data processing, sensitive data</td>
<td>Data collection and processing to be implemented – risk of traceability and re-identification through small groups of participants, linking of large amounts of data from different sources; uncertainty whether children are participating; sensitive data</td>
</tr>
<tr>
<td>Consequences of research</td>
<td>Potential for misuse of findings (see section 10)</td>
</tr>
</tbody>
</table>
1. Research in human beings

Are they volunteers for social sciences or humanities research?

Information to be provided:
- Details of recruitment inclusion and exclusion criteria
- Informed consent procedures
- Ethical implications of chosen methodology
- Risk assessment (for research entailing more than minimal risk) and the steps taken to minimise it
- Details on incidental findings policy (if applicable)

Requirements

- Yes
- No

- No related requirements
1. Research in human beings

SSH Research

Challenges:

• Lack of awareness of ethics issues
• Research ethics guidelines and review processes usually focus on biomedical issues.
• No clear guidance and ethics structures available for SSH research.
1. Research in human beings
SSH Research

What happens when there is no proper structure to provide authorizations/approvals in the institution performing SSH research?

Based on the principle of **proportionality and according to practice**, an ethics opinion may be given, for example, by:

- The University committee of the co-ordinator
- The University committee of another research partner
- Approval from a relevant authority in the country (if applicable)

Researchers are bound to act ethically independently of obtaining an ethics approval.
1. Research in human beings

- Medical Research
- Research in Social Sciences and Humanities
- Informed consent procedures
1. Research in human beings

Informed consent

**Informed Consent:** a subject's free and voluntary expression of his or her willingness to participate in a particular research, after having been informed of all aspects of the research that are relevant to the participant's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the research.
1. Research in human beings
Informed consent: General information

The information sheet must:

- describe the **aims, methods, duration and implications** of the research, the nature of the participation **and any benefits, risks or discomfort that might ensue**

- explicitly state that participation is **voluntary** and that anyone has the **right to refuse to participate and to withdraw** their participation, samples or data at any time — without any consequences
1. Research in human beings
Informed consent: General information

- Information about the organisation and **funding** of the research.
- For research involving **more than minimal risk** for the participants, an explanation of the measures that will be taken to minimise those risks.
- A description of how **incidental findings** will be handled.
- A reference of a **contact person**
- Information about what will happen to the **results** of the research.
1. Research in human beings

Informed consent: clinical/medical trials

- A disclosure of **appropriate alternative procedures for treatment/diagnosis** if any
- A description of any planned genetic tests.
- For research involving **more than minimal risk**, information on whether there are any treatments or compensation if injury occurs.
- Description of **insurance policy**.
1. Research in human beings

Informed consent: research involving children

- Informed consent from the legally authorised representative
- If possible, the **assent** of the participants should also be obtained.
- **Dissent** should be respected.
- Participants must be asked for consent if they reach the age of majority in the course of the research project.
- Informed Consent and Information sheets are comprehensive and **separate for parents/legal representative and for children**.
1. Research in human beings
Informed consent: administrative requirements

- The information must be given in **lay terms**
- **Without pressure** of any kind
- The information means used for obtaining consent should be **adjusted to the particularities of situation/research participant**
- Informed consent must **be written, dated and signed** by the person performing the research and by the research participant
- **Adequate time** needs to be given to the research participant/legally designated representative to consider the decision to participate
2. Data Protection: new requirements for Horizon 2020 Projects
# 2. Data Protection

## Higher Ethics Risk Indicators

| Types of personal data used in the research | * 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 involved in the research      | * children;  
* vulnerable persons;  
* persons who have not given their explicit consent to participate in the research project. |
| Scale or complexity of data processing     | * large-scale processing of personal data;  
* systematic monitoring of publicly assessable 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”). |

*Guidance Note on Ethics and Data Protection (2018)*
### 2. Data Protection

**Higher Ethics Risk Indicators**

| Data collection or processing techniques involved in the research | * privacy-invasive methods or technologies (e.g. the covert observation, surveillance, tracking or deception of individuals);  
* the use of camera systems to monitor behaviour or record sensitive information;  
* “data-mining” (including data collected from social media networks), “web-crawling” or “social network analysis”;  
* the profiling of individuals or groups (particularly behavioural or psychological profiling);  
* the use of “artificial intelligence” to analyse personal data;  
* the use of automated decision-making which 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. |
2. Data Protection
Higher Ethics Risk Indicators

In case of higher-risk data processing, researchers must provide a detail analysis of the ethics issues raised by the project methodology including:

• An overview of all planned data collection and processing operations
• Identification and analysis of the ethics issues raised
• An explanation of how these ethics issues will be mitigated in practice
2. Data Protection Requirements in Horizon 2020 Ethics Review

- Consent is the main pillar ensuring fairness of data processing;
- DPO plays a key role in ensuring compliance and safeguarding the rights of the research participants;
- Specific derogation reminder (for health, genetic and biometric data);
- Data minimisation principle to be adhered at all times;
2. Data Protection Requirements in Horizon 2020

Ethics Review:

- Anonymisation/pseudonymisation as a default safeguard;
- Stringent data security measures;
- Evaluation of the ethics risks related to the data processing activities of the project. This includes also an opinion if data protection impact assessment should be conducted under art. 35 GDPR.
2. Data Protection

Ethics risks may include:

- Discrimination
- Stigmatisation
- Exposing identity and sensitive data (privacy breach)
- Security/safety risks
- Reputational risk and loss of position within occupational and other settings
- Harms to the interests and wellbeing on the research participants, third parties and the community
3. The Ethics Appraisal Process
3. The Ethics Appraisal Process

Regulation 1291/2013 establishing Horizon 2020

Article 19 "Ethical Principles"

"All the research and innovation activities carried under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols."
3. The Ethics Appraisal Process

- Research and innovation activities with exclusive focus on civil applications.
- Research aimed at human reproductive cloning;
- Research intended to modify the genetic heritage of human beings which could make such changes heritable;
- Research intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement.
- Destruction of human embryos
3. The Ethics Appraisal Process

1. Ethics **Self-Assessment** (preparation phase: by the applicant)

2. The Ethics **Review** (before the finalisation of GA: by ethics experts)
   i) An Ethics Pre-screening/Screening;
   ii) An Ethics Assessment.

3. The Ethics **Checks** (for selected projects, after the signature of the GA: by ethics experts)
The Ethics Appraisal Process: Horizon Europe

What stays the same?

- Ethics maintain a central role in EU funded research
- Same areas of research remain ineligible for EU funding (reproductive cloning, heritable genetic modifications, creation of embryos for research purposes, destruction of human embryos)
- The main structures and steps of the ethics appraisal process remain the same
The Ethics Appraisal Process: Horizon Europe

What changes?

- Defence budget (no longer exclusive focus on civil applications)
- Emphasis on serious and complex cases
- Responsibility of beneficiaries to identify and detail all the foreseeable ethics issues in their ethics self-assessment explicitly mentioned in the Regulation
The Ethics Appraisal Process: Horizon Europe

What changes?

• Entities need to provide:
  ➢ Confirmation of compliance with ethics principles and relevant legislation
  ➢ Confirmation that the activities will comply with the ALLEA Code and that no activities excluded from funding will be conducted.
  ➢ For activities carried out outside the EU, a confirmation that the same activities would have been allowed in a Member State.
THANK YOU FOR YOUR ATTENTION!