Ethics in Horizon Europe

The Ethics Screening

7-8 July 2022

Ethics & Research Integrity Sector (DG RTD 03.001)
# The Ethics Screening

| Which proposals? | **ALL shortlisted proposals**  
Exempt those cleared at pre-screening (no ethics issues) or directly referred to Ethics Assessment (for proposals involving hE/hESC) |
<table>
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<tbody>
<tr>
<td>By whom?</td>
<td>2 ethics experts</td>
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| What?            | - Identification of the **ethics issues** raised by the proposal  
- Identification of proposals that **raise serious/complex ethics issues** and needs to undergo **Ethics Assessment**  
For ‘cleared’ proposals:  
- Decision on **Ethics Advisor / Board** mandate, reporting needs  
- Advice on **Ethics Check / Review** during project implementation |
The Ethics Screening

<table>
<thead>
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<th>How?</th>
<th>Possible Outcomes?</th>
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<tbody>
<tr>
<td>• Full review of the content of the proposal</td>
<td>ETHICS CLEARANCE (if proposal raises NO ethics issues OR all ethics issues are properly addressed)</td>
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<tr>
<td>• Full review of the Ethics Self-Assessment</td>
<td>CONDITIONAL ETHICS CLEARANCE (no serious/complex ethics issues, but an Ethics Advisor / Board and/or Ethics Check / Review is advised)</td>
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<td>.... to determine whether the proposals is ‘Ethics Ready’ or additional monitoring (e.g., ethics check, advisor) have to be put in place</td>
<td>ETHICS ASSESSMENT (for proposals raising serious/complex ethics issues)</td>
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What are serious/complex ethics issues?

General criteria:

• The research has the potential to violate fundamental rights and freedoms or undermine fundamental EU values
• The research has the potential to result in significant harm to researchers, research participants, the public, animals or the environment
• The area of research is the subject of widespread ethical debate among scientists and ethicists
• There are grave doubts regarding the capacity of the researchers or the participating institutions to mitigate effectively the risks

Identifying serious and complex ethics issues in EU-funded research
What are serious/complex ethics issues?

General criteria:

• raise significant ethics issues ‘at scale’ – for example, due to the number of research participants, controversial methods, high-risk technologies or jurisdictions involved; or

• raise multiple or ‘intersectional’ ethics issues – meaning that the ethics issues may compound one another to exacerbate the potential impact on a particular group (e.g., research into marginalised or vulnerable groups that exposes them to the risk of stigmatisation, exclusion, reprisals or increased marginalisation).

• there is a high risk that the research results/findings could be misused, and adequate measures to mitigate or contain this risk cannot be identified or implemented;

• there is an objective and serious lack of awareness of key ethical issues in the proposal.
What are serious/complex ethics issues?

Specific criteria and indicators:

1. Human embryonic stem cells (hESCs), human embryos (hEs), human cells and tissues
2. Humans
3. Safety and security
4. Animals and the environment
5. Research in non-EU countries
6. Data protection
7. Development, deployment and use of AI and other new and emerging technologies
8. Misuse
What are serious/complex ethics issues?

3.1 Human embryonic stem cells (hESCs), human embryos (hEs), human cells and tissues

For all research activities involving human embryos or human embryonic stem cells, an ethics assessment is mandatory, the provision of Statement by the Commission on ethics/stem cell research – Art. 19 apply, and the funding of hESC or hE proposals requires and must be approved by the Horizon Europe Programme Committee.7

The ethics issues pertaining to the use in research of other categories of human tissues/cells may be considered “serious and/or complex” if these are, for example:

- collected within the project from vulnerable groups (e.g. children, unconscious patients, or patients otherwise lacking capacity to consent, prison populations) or involve foetal or embryonic tissue (other than hESC) collected within the project or

- used in organoid research concerned with neurological conditions or applications; or involving human multi-organoid complexes or related to the development of synthetic/artificial reproductive cells or organs (e.g. development of ova, in vitro gametogenesis (IVG)), or involving gastruloids or embryoids.
Humans – some examples:

- Research that employs **covert methods or deception** that may cause harm to participants (or researchers), or entails participation in **unlawful activities** (e.g., following persons making irregular border crossings or supplying illegal goods or services)
- Research that includes **children/minors/people unable to give informed consent**, with **no clear justification** for their participation or benefit to them
- Research that includes **vulnerable participants** in **first in-human or early-stage clinical studies** for new therapeutics (including new chemical entities, biologics, gene therapies), medical applications and procedures
- Research that deploys or develops medical devices, particularly implanted devices, that aim to or have the potential to bring about **involuntarily behaviour change** or **therapeutic ‘adherence’**
- Research that involves studies on **human sexuality and/or assisted reproduction** (e.g., fertility, pregnancy termination, gender reassignment and transgender issues)
What are serious/complex ethics issues?

Safety & security – some examples:

- Research that takes place in a situation of international or internal armed conflict, other situations of violence (including domestic violence) or humanitarian crises or emergencies
- Research that takes place in a political climate that is hostile to the research topic or its objectives and endangers researchers, research collaborators (e.g., local staff) and/or research participants

Animals & the environment – some examples:

- Research that involves special categories of animals (e.g., non-human primates, animals living in the wild, endangered species) without clear benefit to their species or habitat
- Research that involves untested forms of animal bio-engineering, animal-machine integration or animal interspecies chimerism
- Research that has the potential to result in significant and irreversible harm to the environment, flora or fauna;
What are serious/complex ethics issues?

Non-EU countries – some examples:

- Research that seeks to exploit **scarce or protected local resources**, without benefit-sharing community consent (where practised and relevant) and/or appropriate permission from relevant local authorities

- Research that takes place in a setting where the subject matter or research methods are likely to be perceived as **highly controversial by a local community**

Data protection – some examples:

- envisages the **large-scale collection of** data related to **criminal convictions and offences**, if the intended processing poses a significant risk to the rights and freedoms of the research participants; or

- involves **profiling and/or systematic monitoring** of individuals or group of individuals, and/or **intrusive methods of data processing** (e.g., data-mining, web-crawling, social network analysis, geolocation tracking); or
What are serious/complex ethics issues?

Artificial Intelligence – some examples:

• surveillance technology that is **not necessary or proportionate** in a democratic society – for example due to the degree of intrusion, its **blanket or indiscriminate effect**, or **lack of safeguards** for affected individuals

• **societal scoring, automated behavioural or psychological profiling**, to make probabilistic determinations about individuals and their behaviour, groups or entire populations that could violate human dignity or lead to stigmatisation, or discrimination against them

• systems/techniques that have the potential to lead to **significant negative social impacts** (e.g., on democracy, media, labour market, freedoms, educational choices) and/or **significant negative environmental impacts** – either through intended applications or plausible alternative uses
What are serious/complex ethics issues?

1. Established fields of scientific research, such as medicine and clinical practice, are subject to legal regulation and well-established norms and principles through which serious and complex ethics issues can be identified and addressed.

   ➔ If the activities are standard practices, with a clear legal/ethics framework, the related ethics issues should be addressed by at local, regional and national level.

   ➔ No need to send for Ethics Assessment

2. The seriousness and complexity of the ethics issues are assessed on a proposal-by-proposal basis.
1. Examine:

- **Part A** of the proposal (the Ethics Issues Table, the Ethics Self-Assessment, list of participants)

- **Part B** of the proposal (containing the proposed (research) activities, workplan, ethics annexes, …)

!! Additional information on clinical studies as Annex in Part B
2. Identify the ethics issues

!! Identifying issues =/= assessing their seriousness and/or complexity

The Ethics Summary Report must give the applicants/beneficiaries overview of all the applicable ethics issues, not only those that are serious and/or complex.
Ethics Screening - Ethics Individual Evaluation Report

+ Section 1: HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS
Current status:

+ Section 2: HUMANS
Current status:

+ Section 3: HUMAN CELLS/TISSUES (not covered by section 1)
Current status:

+ Section 4: PERSONAL DATA
Current status:

+ Section 5: ANIMALS
Current status:

+ Section 6: NON-EU COUNTRIES
Current status:

+ Section 7: ENVIRONMENT, HEALTH AND SAFETY
Current status:

+ Section 8: ARTIFICIAL INTELLIGENCE
Current status:

+ Section 9: OTHER ETHICS ISSUES
Current status:

+ 1. Serious or complex ethics dimension
Current status:

+ 2. External Independent Ethics Advisor/Board
Current status:

+ 3. Ethics Check or Review during the project
Current status:
3. **Determine seriousness/complexity** of the ethics issues

When proposals are **CLEARED**, no comments or recommendations can be added to the report.

!! **Exceptions**: Comment box when ‘9. Other ethics issue’ is selected

Ethics advisor/board mandate and duties AND/OR Reasons for recommending ethics check/review

But please make sure that this text does not include other **specific ethics requirements**.

4. Is the proposal ‘Ethics Ready’?
1. Serious or complex ethics dimension

Based on the proposal, including the ethics self-assessment, do you consider that this activity can be qualified as serious or complex from an ethics perspective and should therefore undergo a complete ethics assessment?

Your judgment should be consistent with the guidelines on Serious and complex ethics issues.

If you find that the proposal involves the use of human embryos (hE) or human embryonic stem cells (hESC) please answer ‘Assessment’. In this case, the proposal must undergo an ethics assessment.

If ‘Assessment’, please summarize your concerns taking into account the ethics issues identified above.

@CLEARED  ☐ ASSESSMENT

COMMENTS:

0 / 10000 characters

2. External Independent Ethics Advisor/Board

3. Ethics Check or Review during the project

Current status:
3. If there is **not enough information** in the Ethics Self-Assessment…(frequently due to a lack of time…) key question remains whether the *activities raise serious and/or complex ethics issues*:

   - **NO?** Requiring **Ethics Advisor / Board** and/or requesting **Ethics Check**
   - **YES?** Transfer to Ethics Assessment (and ask additional information)

4. For the ‘borderline’ cases, raising ethics issues of ‘**medium**’ seriousness/complexity, consider whether *the ethics issues are well addressed by the applicant*:

   - **YES?** Requiring **Ethics Advisor / Board** and/or requesting **Ethics Check / Review** to monitor implementation
   - **NO?** Transfer to Ethics Assessment
The Ethics Advisor / Board

• **Appointed** by the beneficiary

• Responsibility to **advise** the beneficiary on identifying and addressing ethics issues

• Responsibility to **report** to the Commission/Agency/Funding Body

• **In accordance with the mandate specified in the EthSR:**
  
  • E.g., ‘The advisor must assist the beneficiary in addressing ethical risks related to the involvement of children in the research, to ensure their interests are adequately protected and the consent procedures appropriate, and submit yearly report.’

• ! Not responsible for ethics management and compliance

• Remain **independent** from the beneficiary
If YES, please explain reason, key issues to follow-up, frequency of reports, ....

TIMING refers to due date of first report

If NO, the appointment of an Ethics Mentor can be recommended:
• E.g., experienced colleague assisting/advising in dealing with ethics issues
• Not independent
• Not paid
• No reporting duties
# Ethics Checks / Review

**An Ethics Check:**

- An internal check by the PO
- Assisted by *one or more ethics experts*

**An Ethics Review:**

- Elaborate and in-depth procedure
- By *panel of 5 external ethics experts*

Depending on the **size** of the grant and the **seriousness/complexity** of the ethics issues.

**During** the lifetime of the project, to:

- *assist the beneficiaries* to deal with the ethics issues raised by their research and if necessary
- to take *preventive or/and corrective measures*

**Initiated when:**

- Recommended by the ethics evaluation panel
- Decision by the Project officer in the EC/Agency (e.g., documents provided are unsatisfactory, problems signalled by ethics advisor / board, unexpected new activities, …)
If YES, please explain reason(s)
E.g., ‘The justification of the use of non-human primates needs to be reviewed before the start of the relevant activities.’
No ethics requirements, no obligations? Ethics obligations are contained in:

- The ethics-self assessment
- The description of Action (becomes part of the GA)
- Ethics Summary Report
- How-to complete your ethics self-assessment ('How-to')
- GA (Article 14 and Annex 5)

Activities raising ethical issues must comply with the additional requirements formulated by the ethics panels (including after checks, reviews or audits; see Article 25).

Before starting an action task raising ethical issues, the beneficiaries must have obtained all approvals or other mandatory documents needed for implementing the task, notably from any (national or local) ethics committee or other bodies such as data protection authorities.

The documents must be kept on file and be submitted upon request by the coordinator to the granting authority. If they are not in English, they must be submitted together with an English summary, which shows that the documents cover the action tasks in question and includes the conclusions of the committee or authority concerned (if any).
Exercise – 16:00 – 17:00

- 6 groups

- 3 cases (2 groups per case):
  - CIAirE
  - PALYDIAS
  - StORIIA

- Appoint a rapporteur!

- Read proposals & prepare IER: max. 30 minutes, to allow time for consensus phase

- 17:00 – 17:30: Plenary discussion of the cases:
  - What did you find difficult?
  - Which ethics issues did you identify?
  - What did you decide on? Ethics clearance? Assessment? Ethics Advisor/Board?
  - Did the group discussion change your opinion?