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** Except those cleared at pre-screening (no ethics issues) or directly referred to Ethics Assessment (for proposals involving hE/hESC)
By whom?	**2 ethics experts**
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

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

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.

What are serious/complex ethics issues?

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**.

ETHICS SELF-ASSESSMENT

If you have entered any issues in the ethics issue table, you must perform an ethics self-assessment in accordance with the guidelines "How to Complete your Ethics Self-Assessment" and complete the table below:

Ethical dimension of the objectives, methodology and likely impact
Explain in detail the identified issues in relation to: – objectives of the activities (e.g. study of vulnerable populations, etc.) – methodology (e.g. clinical trials, involvement of children, protection of personal data, etc.) – the potential impact of the activities (e.g. environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.)
Compliance with ethical principles and relevant legislations
Describe how the issue(s) identified in the ethics issues table above will be addressed in order to adhere to the ethical principles and what will be done to ensure that the activities are compliant with the EU / national legal and ethical requirements of the country or countries where the tasks are to be carried out. It is reminded that for **activities performed in a non-EU countries**, they should also be allowed in at least one EU Member State.

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

4 – Ethics and Security

Ethics issues table

This table should be completed as an essential part of your proposal. Please go through the table and indicate which elements concern your proposal by answering 'Yes' or 'No'. If you answer 'Yes' to any of the questions,

- *indicate in the adjacent box at which page in your full proposal further information relating to that ethics issue can be found, and*
- *provide additional information on that ethics issue in the Ethics Self-Assessment section.*

For more information on each of the ethics issues and how to address them, including detailed legal references, see the guidelines 'How to Complete your Ethics Self-Assessment'.

1. HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS			Page
Does this activity involve Human Embryonic Stem Cells (hESCs)?		○ Yes ○ No	
If **YES**:	Will they be directly derived from embryos within this project?	○ Yes ○ No	
	Are they previously established cells lines?	○ Yes ○ No	
	Are the cell lines registered in the European registry for human embryonic stem cell lines?	○ Yes ○ No	
Does this activity involve the use of human embryos?		○ Yes ○ No	
If **YES**:	Will the activity lead to their destruction?	○ Yes ○ No	
2. HUMANS			**Page**
Does this activity involve human participants?		○ Yes ○ No	
If **YES**:	Are they volunteers for nonmedical studies (e.g. social or human sciences research)?	○ Yes ○ No	
	Are they healthy volunteers for medical studies?	○ Yes ○ No	
	Are they patients for medical studies?	○ Yes ○ No	
	Are they potentially vulnerable individuals or groups?	○ Yes ○ No	
	Are they children/minors?	○ Yes ○ No	
	Are they other persons unable to give informed consent?	○ Yes ○ No	
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?		○ Yes ○ No	
If **YES**:	Does it involve invasive techniques?	○ Yes ○ No	
	Does it involve collection of biological samples?	○ Yes ○ No	

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.

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Ethics Screening - Ethics Individual Evaluation Report

Help

Evaluation progress: 0.00%

Expand / Collapse all criteria

+ 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:

Expand / Collapse all criteria

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'?**

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Current status:

- 1. Serious or complex ethics dimension

Current status:

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 summarise your concerns taking into account the ethics issues identified above.
*

◉CLEARED ○ASSESSMENT

COMMENTS:

0 / 10000 characters

+ 2. External Independent Ethics Advisor/Board

Current status:

+ 3. Ethics Check or Review during the project

Current status:

Expand / Collapse all criteria

! Trust-based & risk-based approach

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

- 2. External Independent Ethics Advisor/Board

Current status: NO

- In your opinion, would it be necessary to appoint an external independent ethics advisor or an ethics board (with a minimum of three experts) reporting periodically to the Commission/Agency/funding body?
- If yes, your choice between a single ethics advisor and an ethics board should reflect the size of the grant and the significance of the ethics issues. *

○NO ◉YES (Ethics Advisor) ○YES (Ethics Board)

REASONS (mandatory if YES): Please detail the reasons and the main elements of the advisor's or board's mandate, including the periodicity and timing of their reports. Note that the advisor or board will be expected to start working at the beginning of the project. The reasons and mandate you provide below will be shared with the applicants.

If YES, please explain reason, key issues to follow-up, frequency of reports, ….

0 / 2000 characters

TIMING (mandatory if YES): Number of months after project start when the ethics advisor or ethics board should submit the first report.

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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

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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 provides are unsatisfactory, problems signalled by ethics advisor / board, unexpected new activities, …)

- 3. Ethics Check or Review during the project

Current status:

- In your opinion, would an Ethics Check or Ethics Review be necessary during the project? An Ethics Check is an internal check by the project officer or ethics officer who may be supported by ethics experts. An Ethics Review is a more elaborate and in-depth procedure carried out by up to 5 external ethics experts.
- If yes, your choice between an Ethics Check and an Ethics Review should reflect the size of the grant and the significance of the ethics issues.
- An Ethics Check or Review may be needed when it is important to reassess the global situation or specific ethics issues during the implementation of the project, or when the self-assessment in the proposal does not contain the necessary elements. *

◉NO ○YES (Ethics Check) ○YES (Ethics Review)

REASONS (mandatory if YES): Please detail the reasons and the main elements of the Ethics Check/Review mandate:

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.'

TIMING (mandatory if YES): Please enter the number of months after project start when the check or review should be carried out (e.g., entering the number 12 means the check/review will be carried out in month 12 of the project).

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- General requirement applicable to all grants

The beneficiaries must ensure that all ethics issues related to activities in the grant are addressed in compliance with ethical principles, the applicable international and national law, and the provisions set out in the Grant Agreement. This includes the ethics issues identified in this report and any additional ethics issues that may emerge in the course of the grant. In case any substantial new ethics issues arise, beneficiaries should inform the granting authority. For each ethics issue applicable, beneficiaries must follow the guidance provided in the How to complete your ethics self-assessment

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):
  - ClAirE
  - 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?*