



MINISTÈRE
DE L'ENSEIGNEMENT
SUPÉRIEUR,
DE LA RECHERCHE
ET DE L'INNOVATION

*Liberté
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Webinar 1: Ethics issues section in Horizon Europe calls for proposal

horizon-europe.gouv.fr

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Webinaires éthique pour la CE

Webinaire 1 : La section éthique dans les dossiers de soumission- Mercredi 19 janvier 2022, 14h00-15h00

Webinaire 2 : Exemple concret de section éthique dans une soumission de projet européen- Mardi 25 janvier 2022, 11h00 - 12h00

Webinaire 3 : Echange de bonnes pratiques - réglementation et adhésion des chercheurs- Mardi 1 février 2022, 14h00 - 15h00

- Human Embryonic stem cells and human embryos
 - Human participants to the research
 - Personal data
 - Artificial intelligence
 - Potential misuse of results
 - Other ethics issues (animals, etc.)
 - Comment motiver les chercheurs à bien répondre à la section éthique d'un projet Européen
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Ethics for projects funded in Horizon Europe

- Very simplistic example of ethics and regulation
 - Key sources and guiding principles in Horizon Europe
 - Ethics Appraisal Process (a risk-based approach):
 - Timeline
 - Practical
 - Changes to the ethics issues table
 - Complex/serious issues
-

Very simplistic example of ethics and regulation

Ethics	Policies and Regulation
The branch of philosophy that defines what is good for the individual and for society and establishes the nature of obligations, or duties, that people owe themselves and one another. In modern society, ethics define how individuals, professionals, and corporations choose to interact with one another.	The law refers to a systematic body of rules that governs the whole society and the actions of its individual members. Laws can be neutral on ethical issues, or they can be used to endorse ethics.
What should I do?	What can I do?
Set of guidelines	Set of rules (policies) and regulations
Ethical decision-making comes from within a person's moral sense or institutional moral sense	Laws are codifications of certain ethical values meant to help regulate society, and also impact decision-making.
Driving carefully, because you do not want to hurt someone is making a decision based on ethics.	Driving carefully and within the speed limit because you do not want to break the law and being punished for it

There is a confusion on law and ethics as the same thing with the excuse that if we are fulfilling our legal obligations we can consider ourselves 'ethical'

Key sources and ethics materials

- How to complete your ethics self assessment
- Horizon Europe Programme Guide
- Horizon Europe Model Grant Agreement (MGA) Article 14 and Annex 5
- HE framework Programme Regulation 2021/695: Eligible actions and ethical principles (Article 18) and Ethics (Article 19)
- HE specific programme decision 2021/ 764

• See more at:

• <http://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/reference-documents;programCode=HORIZON>

Guiding principles

Ethics is an integral part of all research activities funded by the European Union and ethical compliance is seen as pivotal to achieve real research excellence.

Article 19 of HE framework Programme Regulation 2021/695 :

“Entities participating in the action shall provide (a) an ethics self-assessment identifying and detailing all the foreseeable ethics issues related to the objective”

“Proposals shall be systematically screened to identify actions which raise complex or serious ethics issues and submit them to an ethics assessment”

Article 14 of the Model Grant Agreement (MGA):

“The action must be carried out inline with the highest ethical standards and the applicable EU, international and national law on ethical principles”

“The beneficiaries must commit to and ensure the respect of basic EU values (such as the respect for human dignity, freedom, democracy, equality, the rule of law and human rights, including the rights of minorities)”

Actions not eligible for funding

Article 18 of the regulation 2021/695:

- *Research activities aiming at human cloning for reproductive purposes;*
- *Research intended to modify the genetic heritage of human beings which could make such changes heritable;*
- *Research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.*

“Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member States involved”

- *No funding to research activities that are prohibited in all Member States*
- *No funding to research activities in a Member State forbidden in that MS*

• Article 14 of the MGA

- *Activities that lead to the destruction of human embryos*

Assessed by the scientific evaluators if any of those is present and qualifying

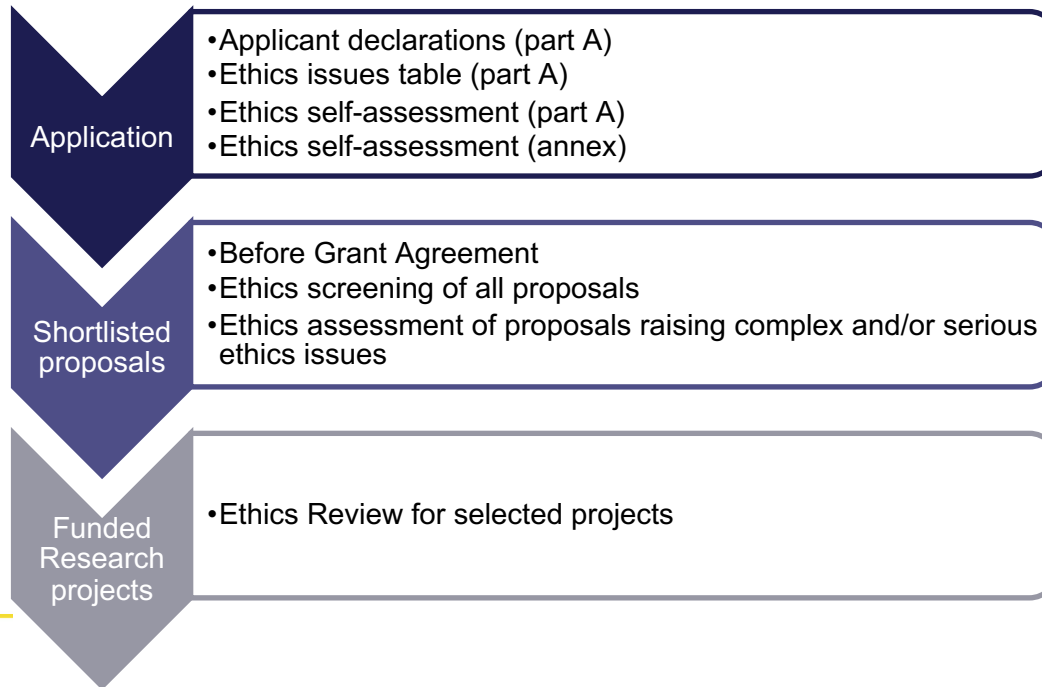
Changes in Horizon Europe

- Applicant declarations
 - Changes to the Ethics Issues table questions
 - ~~Dual use and exclusive focus on civil application~~
 - Misuse as cross-cutting issue
 - New issue: Artificial Intelligence
 - Risk-based process focus on serious and complex cases
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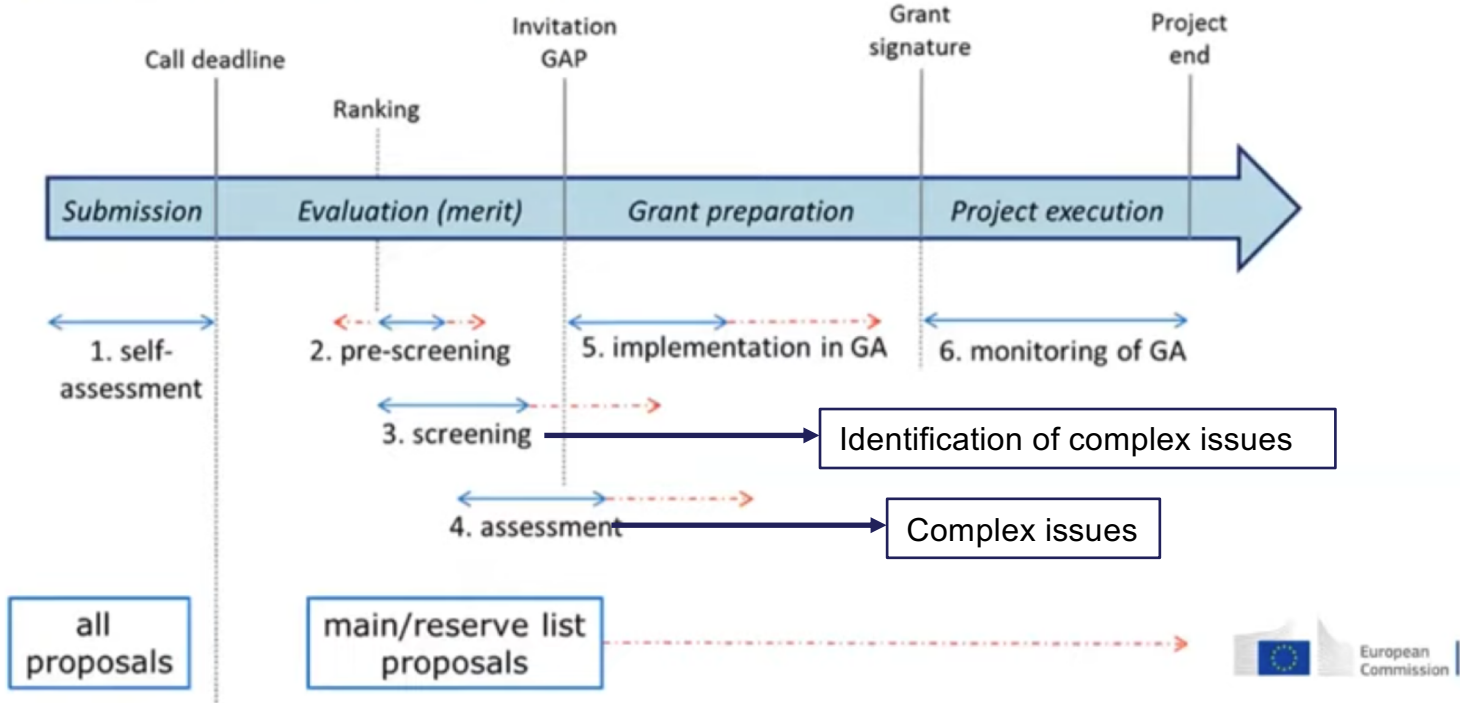
Ethics Appraisal Process

The process to assess and address the ethical dimension of activities funded under Horizon Europe is called the:

Ethics Appraisal Process (EAP)



Ethics Appraisal procedure timeline





- Applicant declarations (part A)
- Ethics issues table (part A)
- Ethics self-assessment (part A)
- Ethics self-assessment (annex)



- Before Grant Agreement
- Ethics screening of all proposals
- Ethics assessment of proposals raising complex and/or serious ethics issues



- Ethics Review for selected projects

Applicant declarations related to ethics

Research Integrity



- 6) We declare that the proposal complies with ethical principles (including the highest standards of research integrity as set out in the ALLEA European Code of Conduct for Research Integrity, as well as applicable international and national law, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Appropriate procedures, policies and structures are in place to foster responsible research practices, to prevent questionable research practices and research misconduct, and to handle allegations of breaches of the principles and standards in the Code of Conduct.

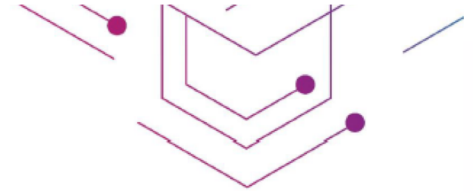


Applicant declarations related to ethics

Research Integrity



6) We declare that the proposal complies with ethical principles of research integrity as set out in the ALLEA European Code of Conduct as applicable international and national law, including the European Union and the European Convention on Human Rights. Appropriate procedures, policies and structures are in place to prevent questionable research practices and research breaches of the principles and standards in the Code of Ethics.



Guideline for Promoting Research Integrity in Research Performing Organisations



The 'Standard Operating Procedures for Research Integrity' (SOPs4RI) project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 824481



Applicant declarations related to ethics

Civil applications

Verified by
scientific
evaluators

7) We declare that the proposal has an **exclusive focus on civil applications** (activities intended to be used in military application or aiming to serve military purposes cannot be funded). If the project involves **dual-use items** in the sense of [Regulation 428/2009](#), or other items for which authorisation is required, we confirm that we will comply with the applicable regulatory framework (e.g. obtain export/import licences before these items are used).



8) We confirm that the activities proposed

- aim at human cloning for reproductive purposes
- intend to modify the genetic code of human beings (with the exception of heritable (with the exception of heritable (with the exception of heritable) may be financed), or
- intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.
- lead to the destruction of human embryos (for example, for obtaining stem cells)

The declaration is sufficient, no further checks, no longer reviewed by ethics evaluators

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These activities are excluded from funding.

Applicant declarations related to ethics

Civil applications

Verified by
scientific

EU Grants: Research with exclusive focus on civil applications: V2.0 – 14.09.2021

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EUROPEAN COMMISSION
 Directorate-General for Migration and Home Affairs
 Directorate-General for Research and Innovation
 Directorate-General for Trade

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Guidance note — Research with an exclusive focus on civil applications

These activities are excluded from funding.

Cross-cutting issue: Misuse

The security issues table (application from Part A covers misuse from the security perspective)

- *E.g.* research activities that could generate knowledge, materials and technologies that could be adapted for criminal/terrorist activities; or result in the development of chemical, biological, radiological or nuclear weapons and the means for their delivery

Misuse not related to the security dimension will be considered under the Ethics Issues Table and analysed as part of the relevant ethics sections (humans, personal data, animals, environment, health and safety, artificial intelligence) or as “other ethics issue

- *E.g.* a research lab successfully reconstitutes an extinct virus. Although this is a scientific breakthrough, releasing the virus – whether accidentally or on purpose – would jeopardise public health and safety and might result in millions of deaths.
-

Ethics self-assessment

- Ethics self assessment is mandatory for all proposals (as in H2020)
 - Now included in part A of the proposal
 - Applicants describe the ethics dimension of their proposal and the compliance with ethics principles in part A
 - Depending on the call: possibility to submit additional information and/or supporting documents in separate annex to part B (e.g. Health, ERC, some MSCA actions)
 - Risk-based approach: submission of evidence of ethics compliance only if and as needed (e.g. hESC proposals)
-

Ethics Issues Table: Proposal application form

4 - Ethics & security

Ethics Issues Table

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1. Human Embryonic Stem Cells and Human Embryos		Page
Does this activity involve Human Embryonic Stem Cells (hESCs)?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does this activity involve the use of human embryos?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
2. Humans		Page
Does this activity involve human participants?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they volunteers for non medical studies (e.g. social or human sciences research)?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Are they healthy volunteers for medical studies?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Are they patients for medical studies?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Are they potentially vulnerable individuals or groups?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Are they children/minors?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Are they other persons unable to give informed consent?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014) ? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)	<input type="radio"/> Yes <input checked="" type="radio"/> No	

- ***Needs to be completed as an essential part of the proposal***
- ***If you say YES to one or more of the questions, you need to explain further (in part A and as an ethics annex if needed)***

What is included in the questions?

1. ~~Human embryos & fetuses~~ Human Embryonic Stem Cells (hESC) and Human Embryos (hE)
 2. Human participants
 3. Human cells/tissues
 - Does your research involve the use of human foetal tissues/cells?
 4. Personal data
 5. Animals
 6. Non-EU Countries
 7. Environment & Health and Safety
 8. Artificial Intelligence (New)
 9. Other ethics issues
 10. Cross-cutting issue: potential misuse of results
 11. ~~Exclusive focus on civil applications~~
 12. ~~Dual use~~
-

Artificial Intelligence

Does the proposed activity involve the development, deployment and/or use of Artificial Intelligence?

- Could AI system/technique **stigmatise or discriminate** against people (based on sex, race, ethnic social origin, age, disability, sexual orientation, religion, political affiliation, etc.)?
 - Does the AI system/**technique interact, replace or influence human decision-making processes** (e.g. issues affecting human life, health, well-being or human rights, or economic, social or political decisions)?
-

Self-assessment proposal application form

Ethics Self-Assessment

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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.)

Ethics

Remaining characters

5000

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.

Regulation

- **5000 characters, but possibility of further explanation IN AN ANNEX (we are expecting you to explain in fact!)**

How to complete your ethics self-assessment

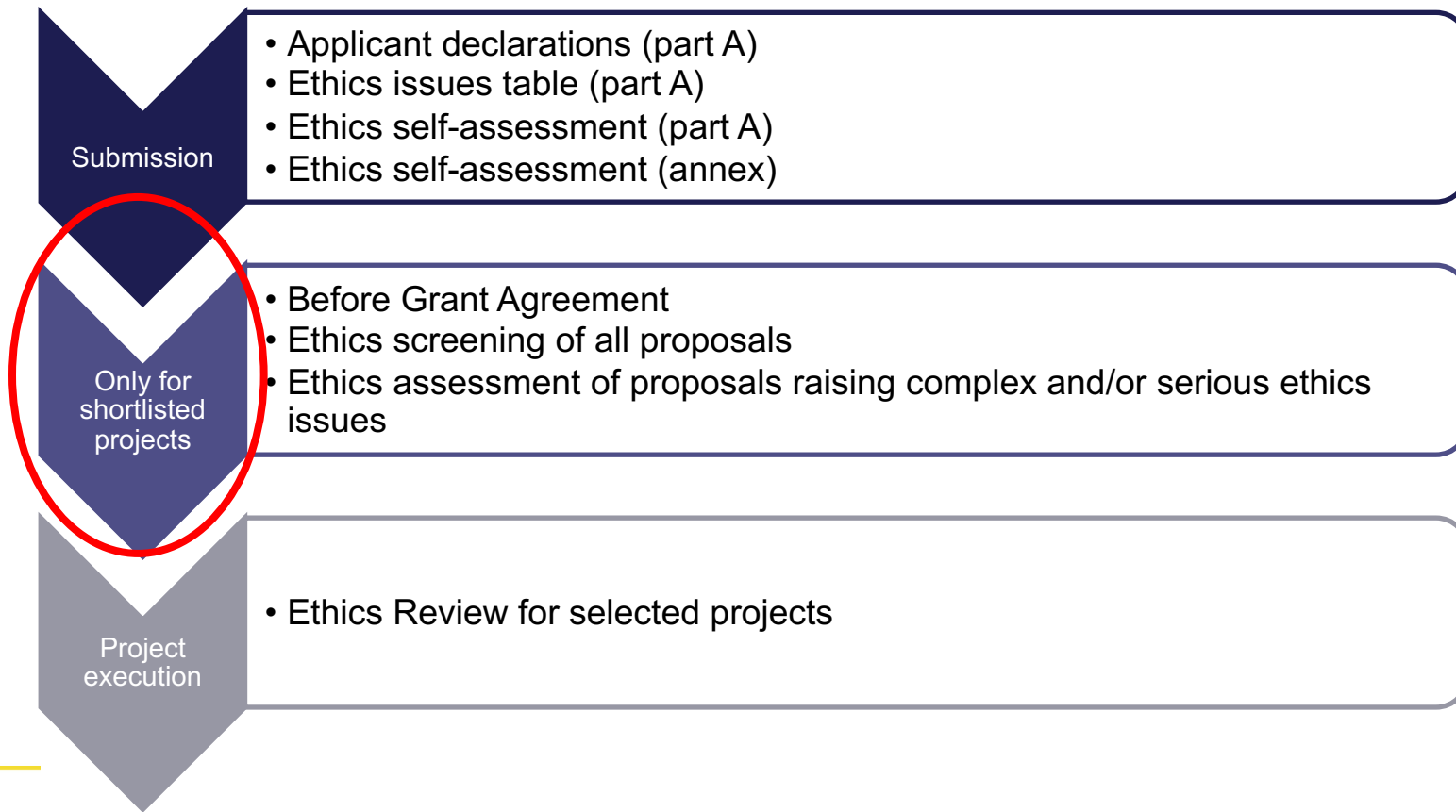


➤ 'How to complete your...' guidelines

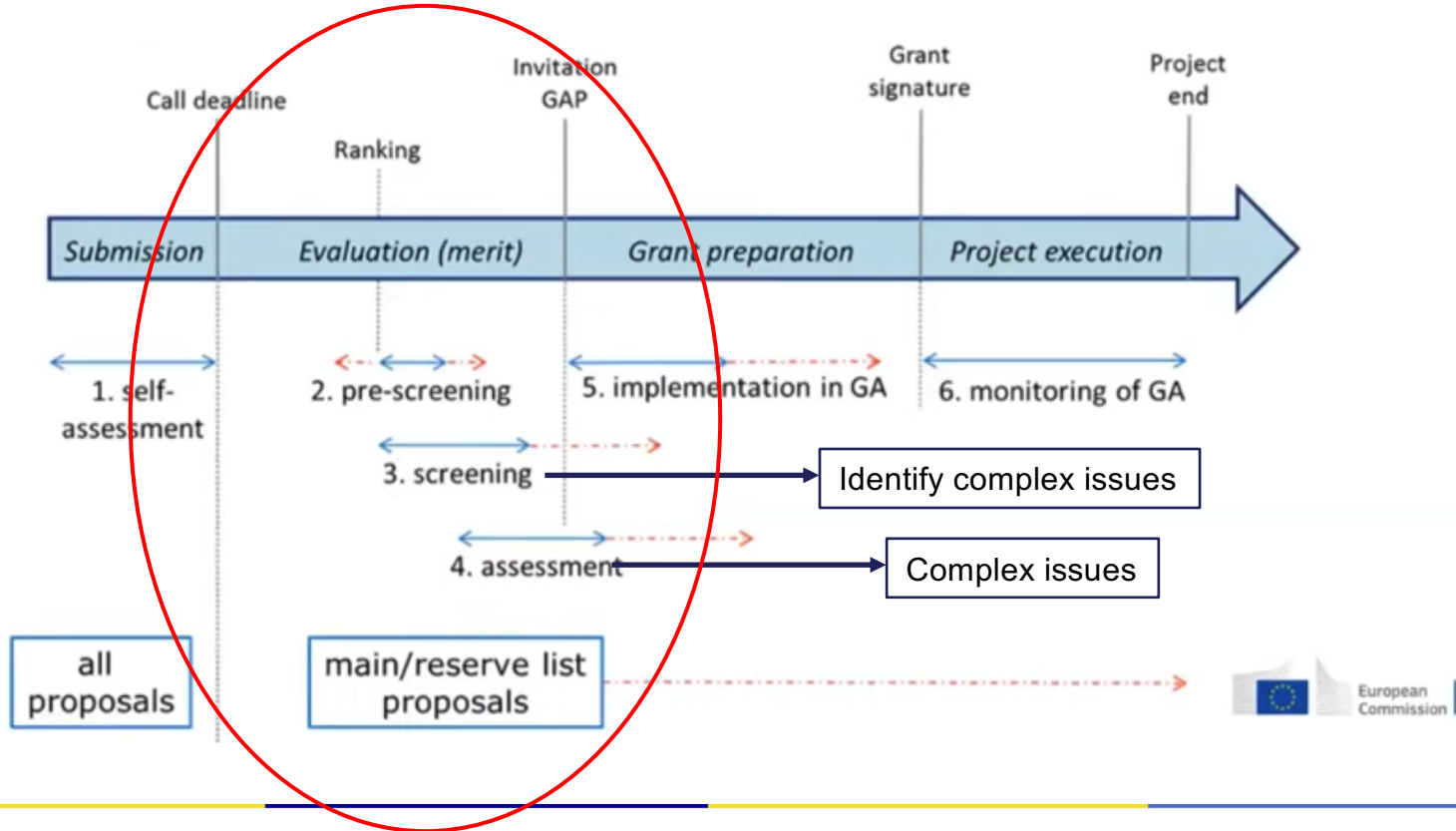
Section 1: HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS		YES/NO	Information to be provided in the proposal	Documents to be provided/kept on file
Does your activity involve Human Embryonic Stem Cells (hESCs)?				
If YES:	Will they be directly derived from embryos within this project?		<i>Research eligible for funding</i>	<i>Research not eligible for funding</i>
	Are they previously established cells lines?		1) Origin and line of cells. 2)...	1) Copies of ethics approval. 2)...
	...			

This is how it looks

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf



Ethics Appraisal procedure in Horizon Europe



Ethics pre-screening and screening

Pre-screening:

Optional filtering step for all proposals (with or without ethics issues flagged)

By at least two ethics evaluators (external experts or qualified members of staff)

Possible outcomes: → Ethics issues?

→ NO? → ETHICS CLEARANCE

→ YES? → FLAGGED for SCREENING

Screening:

All proposals

By at least two ethics evaluators (external experts)

Key goal: identify proposal that raises serious or complex ethics issues and must go a full ethics assessment where ethics requirements can be defined

All other, non-critical proposals are cleared with out ethics requirements

(2) Ethics Screening

Experts screen all proposals to identify main ethics issues, and flag them for the next steps

→ *No ethics issues* → **CLEARED**

Ethics questions well addressed and no complex issues identified

→ *Ethics issues* → **FLAGGED**

Ethics questions not well addressed (screening report to be answered and ethics deliverables in the GA)

→ Beneficiaries further deal with national and European legislation – **no further requirements** in the Ethics Screening Report

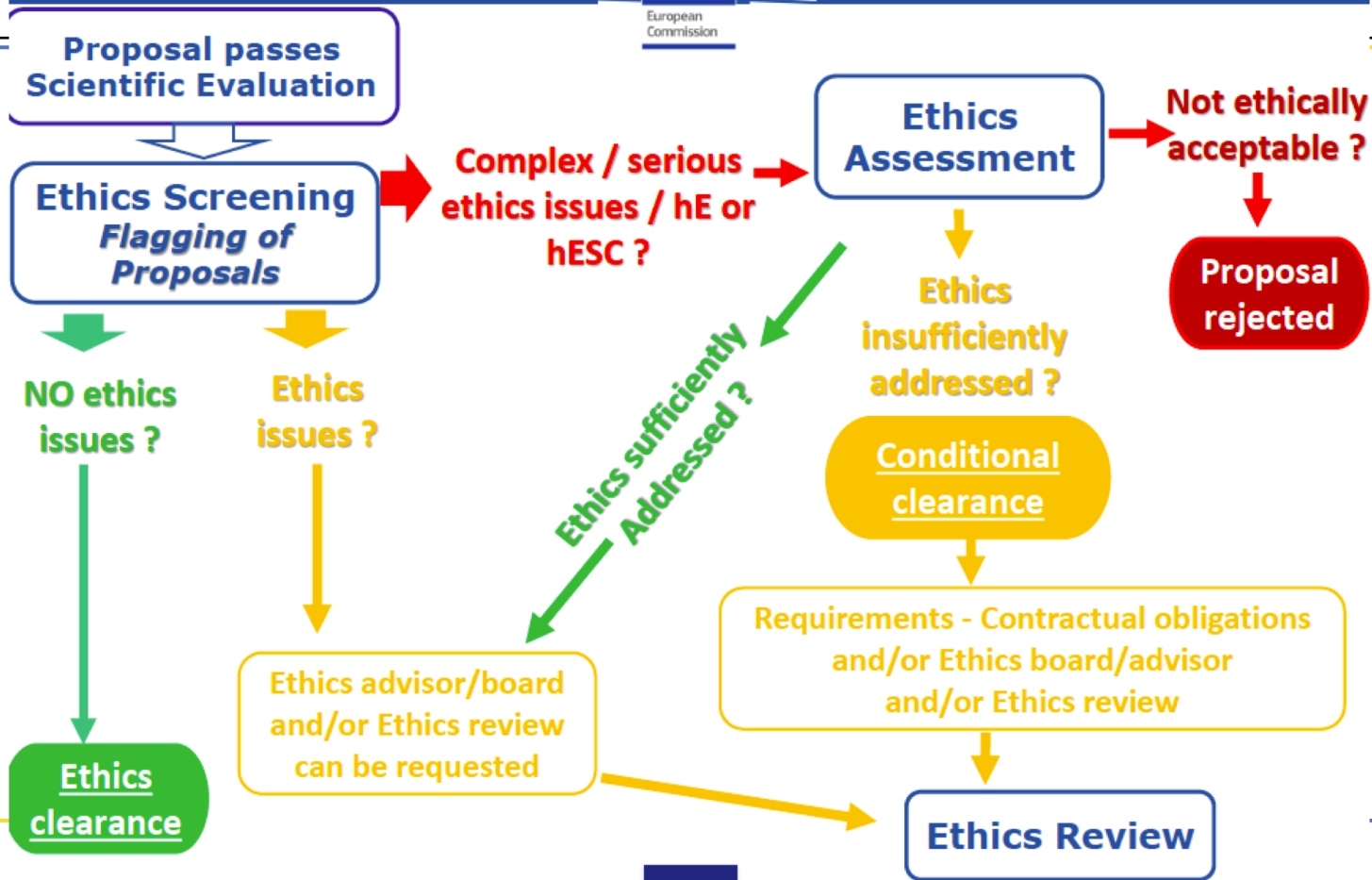
→ ! Experts can require ethics independent ethics advisor or board

Complex issues identified, screening report to be answered and ethics deliverables in the GA, risk management

→ *Serious and/or complex ethics issues* → **ETHICS ASSESSMENT**

Ethics assessment

- An in-depth analysis of the ethics issues for:
 - 1) All proposal involving hE and/or hESC (directly to assessment)
 - 2) Proposals raising serious and/or complex ethics issues
 - Panel of at least 5 external experts
 - Key goal: to identify additional measures that must be implemented during grant preparation or later during grant implementation, for ethics issues not satisfactorily addressed in the proposal
 - Ethics requirements should be in proportion to the severity of the ethics issues, according to the a risk-based approach
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Serious/complex ethics issues

1) All proposal involving hE and/or hESC (directly to assessment)

2) For example when research proposals:

- Have the potential to violate fundamental rights and freedoms or undermine fundamental EU values
 - Have the potential to result in significant harm to researchers, research participants, the public, animals or the environment (DNSH principle)
 - May not have exclusive focus on civil applications
 - Raises multiple or intersectional ethics issues (for example research with marginalised or vulnerable individual groups exposing them to the risk of stigmatisation, exclusion, etc.)
 - The area of research is the subject of widespread ethical debate among scientists and ethicists
 - Doubts regarding the the capacity of the researchers or the institutions to mitigate effectively the risks
 - Etc
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Serious/complex ethics issues

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- Etc



Identifying serious and complex ethics issues in EU-funded research

<https://youtu.be/QJtGzWmBQBw>

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Ethics obligations and risk-based approach

- No ethics requirements DO NOT mean no ethics obligations
 - Cleared proposal can still be subject to an ethics check or review and/or may have to appoint and independent ethics advisor or ethics board
 - Article 19(4)- Legal entities participating in an action shall obtain all approvals or other mandatory documents from the relevant national, local ethics committees or other bodies, such as data protection authorities, before the start
 - Ethics Summary Report will remind beneficiaries of the declarations they made and the ethics raised by their proposals
 - Applicants/beneficiaries are responsible to comply with ethics standards. They must keep relevant documents and submit them on request
 - Avoid unnecessary requirements and administrative efforts should be in pace with the projects
 - Focus on high-risk projects
 - Ethics requirements should not be imposed or documentation should not be requested as routine activities for low risk projects
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Ethics advisor or board

- The choice between a single external independent ethics advisor and an ethics board (with a min of 3 experts) should reflect the size of the grant and the seriousness/complexity of the ethics issues
 - Ethics requirements also offer the possibility to request the appointment of an “ethics mentor” when there is lower ethics risk, and no need for an independent advisor/board.
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