



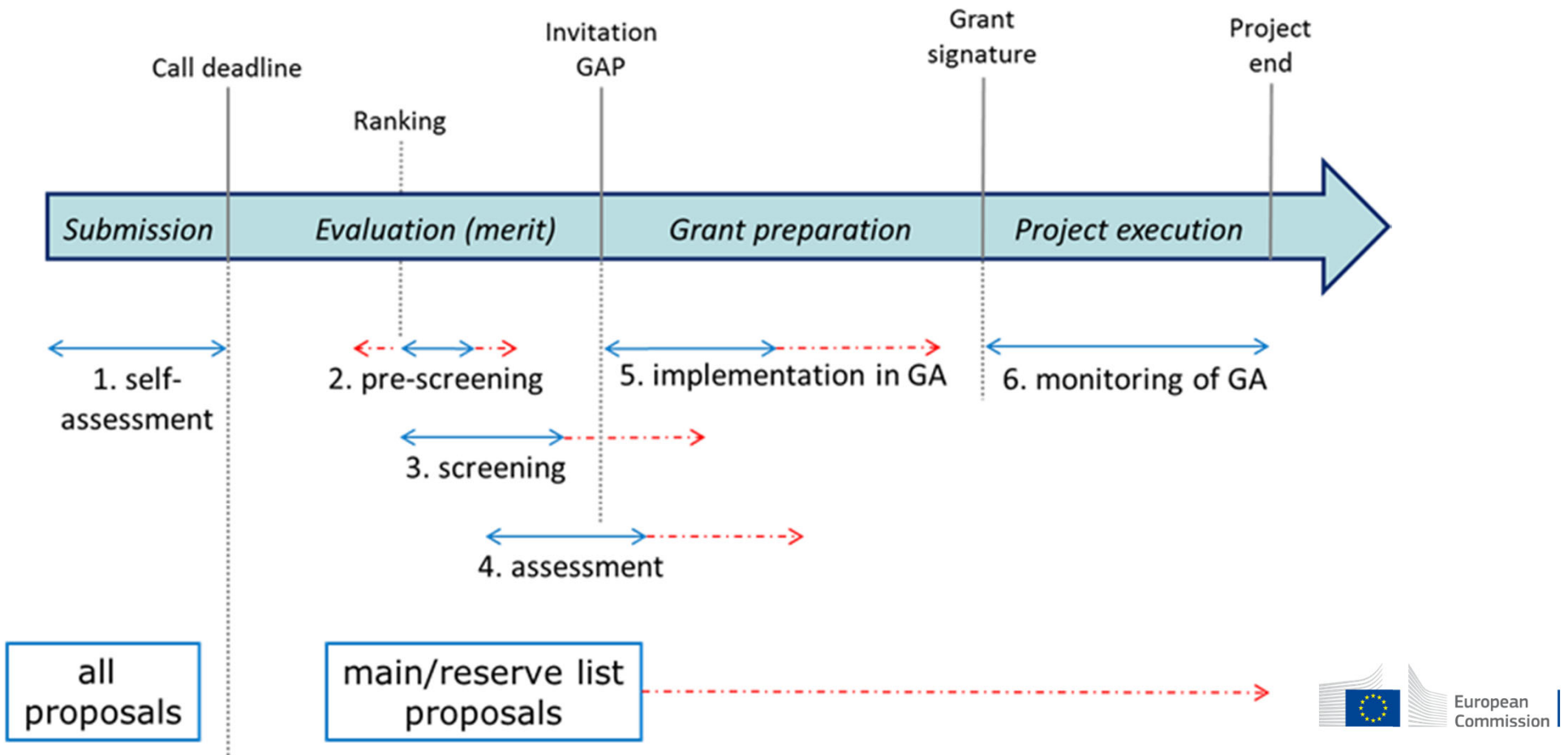
Ethics in Horizon Europe

The Ethics appraisal process and the role of Ethics Advisors, Ethics Advisory Boards, and Ethics Mentors

*Presentation of the Ethics and Research Integrity Sector for the
9th meeting of the Horizon Europe Legal & Financial NCPs*

26/10/2023

Ethics Appraisal Process



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)?		<input type="radio"/> Yes <input type="radio"/> No	
If YES:	Will they be directly derived from embryos within this project?	<input type="radio"/> Yes <input type="radio"/> No	
	Are they previously established cells lines?	<input type="radio"/> Yes <input type="radio"/> No	
	Are the cell lines registered in the European registry for human embryonic stem cell lines?	<input type="radio"/> Yes <input type="radio"/> No	
Does this activity involve the use of human embryos?		<input type="radio"/> Yes <input type="radio"/> No	
If YES:	Will the activity lead to their destruction?	<input type="radio"/> Yes <input type="radio"/> No	
2. HUMANS			Page
Does this activity involve human participants?		<input type="radio"/> Yes <input type="radio"/> No	
If YES:	Are they volunteers for nonmedical studies (e.g. social or human sciences research)?	<input type="radio"/> Yes <input type="radio"/> No	

Ethics Self-assessment

If one YES in the Ethics issues Table... → **Ethics Self-assessment**

HE Regulation (Article 19 (2))

‘Legal entities participating in an action shall provide:

(a) an ethics self-assessment identifying and detailing all the foreseeable ethics issues related to the objective, implementation and likely impact of the activities to be funded, including a confirmation of compliance with paragraph 1 and a description of how it will be ensured.’

Application Forms

Proposal ID XXXXXXXXX

Acronym XXXXXXXX

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.

The Ethics Issues Table

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

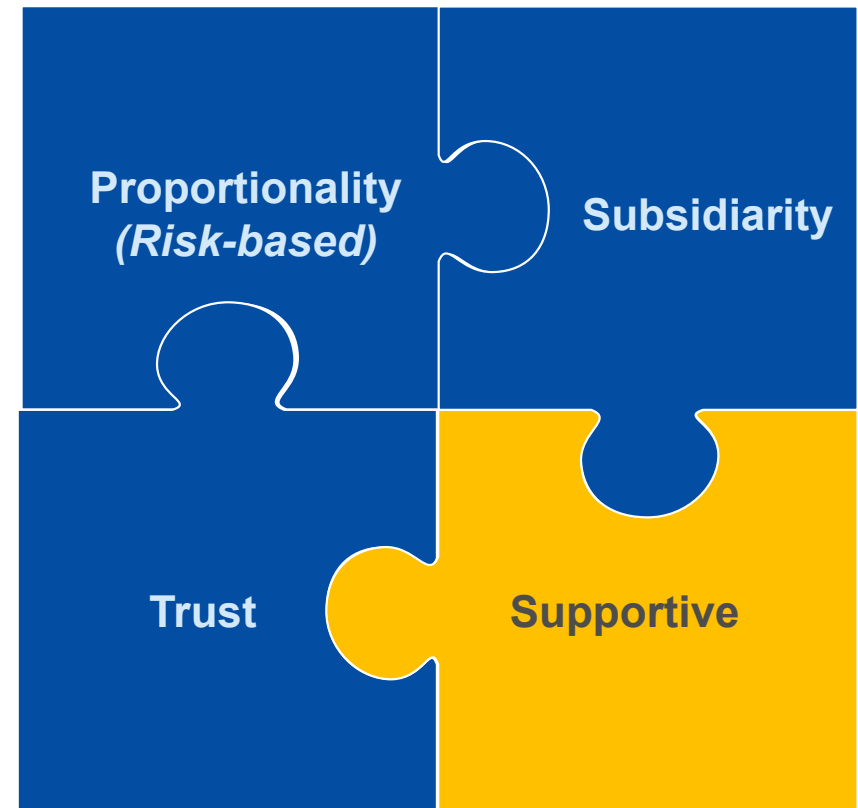
Ethics Appraisal Process

Goals

Protect research participants, researchers, animals, the environment, society, ... from harm and undue risks

Support researchers and innovators to adopt an **ethics by design** approach

Contribute to **research excellence** and societal **trust** in research



Key change

Horizon 2020

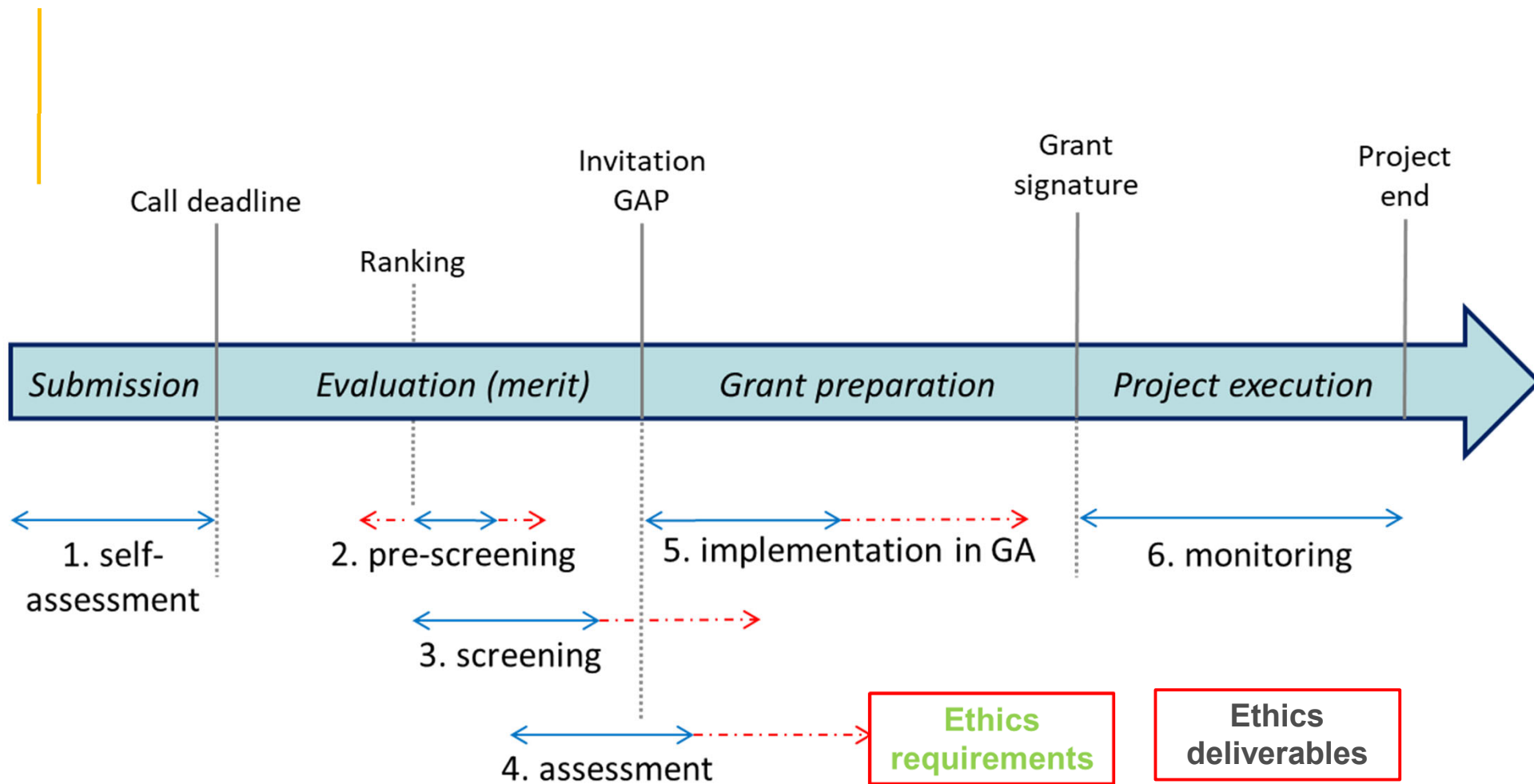
Ethics issues → Formulation of ethics requirements

= contractual obligations in Grant Agreement

Horizon Europe

Ethics issues → Flagged, but no specific ethics requirements are formulated

Unless the ethics issues are considered as **serious and/or complex** and the proposal is transferred to **ethics assessment**



Some interesting facts & figures

percentage of eligible HE proposals	Any Issue?
42.69%	No
57.31%	Yes

number of signed HE projects	Ethics Incidence: Ethics Opinion
89.71%	CLEARED
10.19%	CONDITIONALLY_CLEARED
0.09%	

Risk-based & trust-based approach

- **!!! Ethics clearance \neq no ethics obligations**
- The **applicant declarations** and **ethics self-assessment** become part of the description of the action (Annex 1 of the grant agreement) and create obligations for the beneficiaries.
- The **Ethics Summary Report (EthSR)** reminds applicants/beneficiaries of the ethics issues raised by their proposal.
- Applicants/beneficiaries are **responsible** for complying with ethics standards and rules as applicable to their project. They must keep all relevant documents on file and submit individual documents on request.

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](#).



Ethics Advisors and Ethics Advisory Boards Roles and Function in EU-funded Projects

Version 2.0
15 February 2023

- **Voluntarily** proposed by the applicant / beneficiary in their application
- **Mandatory** as a result of the Ethics Review.
 - Appointed by the beneficiary/consortium
 - **External** and **independent** from the beneficiary/consortium
 - Responsibility to **advise** the beneficiary/consortium on identifying and addressing ethics issues
 - Responsibility to **report** to the Commission/Agency/Funding Body
 - **!** Not responsible for ethics management and compliance

External and independent?

- **External** to the project and to the department(s) or group(s) conducting the research
- Absence of professional, financial, family or other relationships or common interests **that would result in a conflict of interest.**

Disqualifying factors:

- involved in the preparation of the proposal/project
- stands to benefit should the project be positively evaluated
- has a close relationship with any person representing the beneficiary (but not anyone from the institution, in case of large organizations)
- Is a director, trustee or partner of beneficiary (hierarchical position or position of authority)
- is in a situation that compromises his impartiality vis-à-vis the project
- is involved in any substantial collaboration with the (sub-)group/department involved
- is in any other situation that could appear to cast doubt on their independence



Ethics Advisors and Ethics Advisory Boards

Roles and Function in EU-funded Projects

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- The appointment of external independent Ethics Advisor or an Ethics Advisory Board should be **clearly justified** in light of the *number, severity and complexity of the ethics issues* raised by the proposal and the *capacity* of the Applicant/Beneficiary to address the ethics issues appropriately.
- The choice between an Ethics Advisor and Board should reflect **the size of the grant** and the **number, severity, and complexity of the ethics issues** raised by the proposal.

Ethics Mentor

!! Possible that the appointment of an **Ethics Mentor is recommended (for cleared proposals) or required (for conditionally cleared proposals).**

- Not external / independent of the beneficiary. Can be a member of the same department or institution that advises, shares experience and knowledge on how to properly identify and address ethics issues.
- Not obliged to independently report to the Commission / Agency, although it is recommended to keep a report of the activities performed.

Questions?

Thank you for your attention

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