



#HorizonEU

THE EU RESEARCH & INNOVATION PROGRAMME

2021 – 2027

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DEVELOPMENT AND CLIMATE ACTION

Cluster 6 Coordinators' Day -22/09/2022

Research and
Innovation

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HORIZON EUROPE CLUSTER 6 COORDINATORS DAY

Ethics aspects





Ethics in Horizon Europe

Integral part of research
from beginning to end

Essential to achieve
excellence

Participation in Horizon Europe requires compliance with the highest standards of research ethics and integrity, and with EU, national and international law.

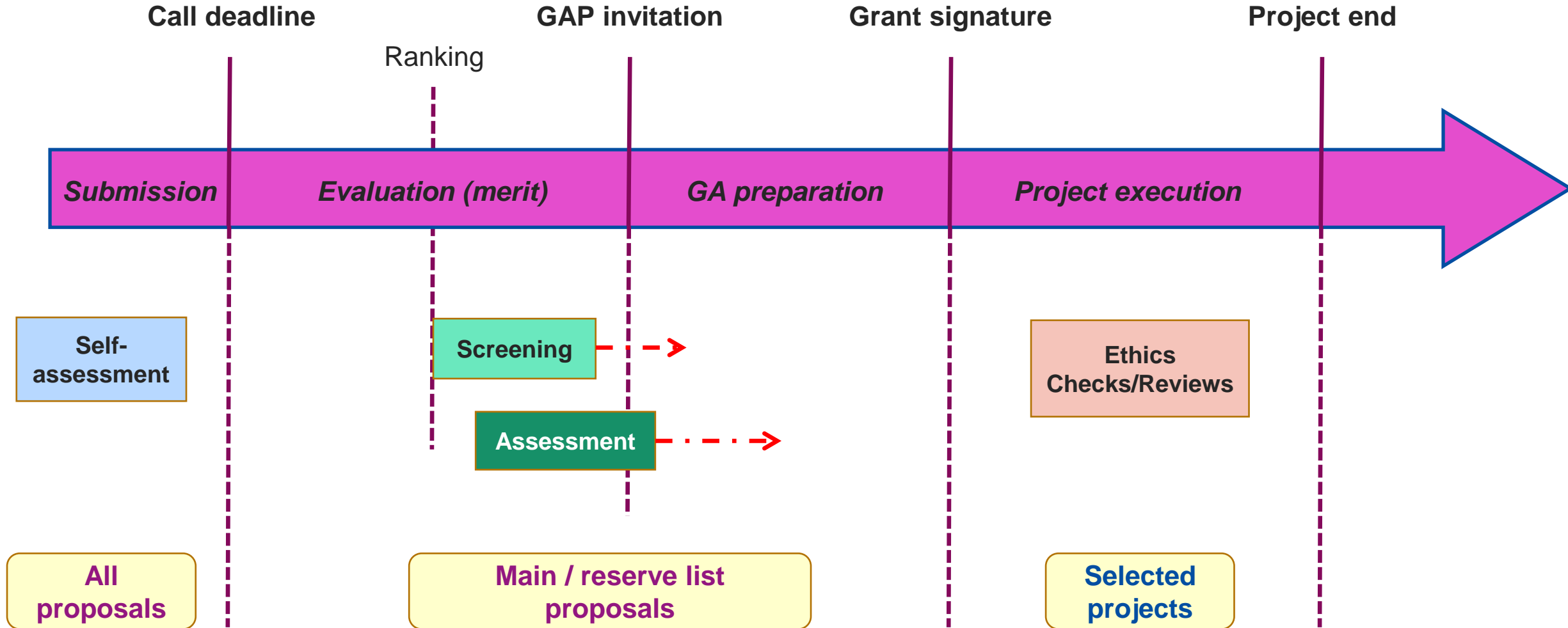
Horizon Europe regulation 2021/695 (Articles 18 and 19) & **Grant Agreement** (Art 14, Annex 5): guiding principles and general obligations (including ineligible activities and specific rules e.g. in case of hESC/hE).

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.

The documents must be kept on file and submitted by the coordinator to the granting authority upon request.



Ethics Appraisal in the Project Life Cycle





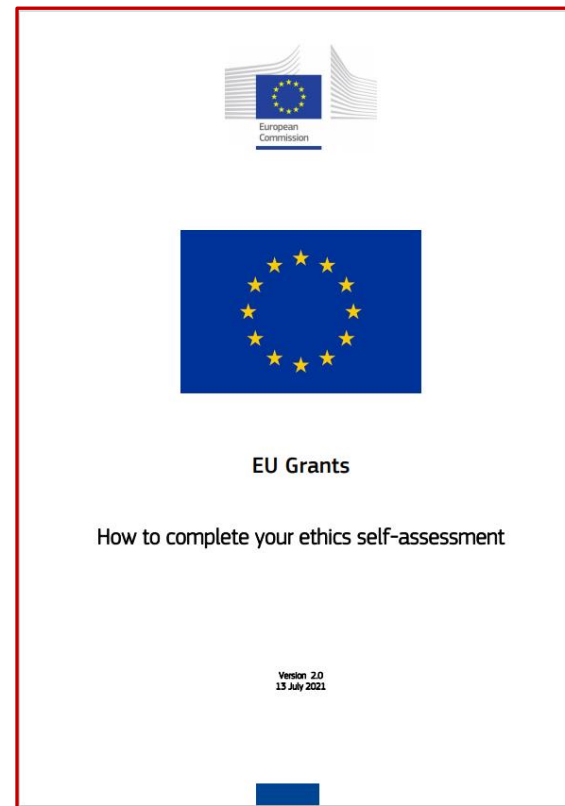
Applicants' Ethics Self-Assessment

Part A – Section 4

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
	Are they healthy volunteers for medical studies?	<input type="radio"/> Yes <input type="radio"/> No
	Are they patients for medical studies?	<input type="radio"/> Yes <input type="radio"/> No
	Are they potentially vulnerable individuals or groups?	<input type="radio"/> Yes <input type="radio"/> No
	Are they children/minors?	<input type="radio"/> Yes <input type="radio"/> No
	Are they other persons unable to give informed consent?	<input type="radio"/> Yes <input 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 type="radio"/> No
If YES:	Does it involve invasive techniques?	<input type="radio"/> Yes <input type="radio"/> No
	Does it involve collection of biological samples?	<input type="radio"/> Yes <input type="radio"/> No



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Ethics Review: deliverables

Ethics requirement =
legal obligation

- REA carries out systematic ethics review on all Horizon Europe proposals in main/reserve list, to identify actions raising ethics issues.
- Outcomes of the Ethics Review -> **Ethics Summary report** – shared with beneficiaries during GAP. It includes list of ethics issues raised by the project and reminder of ethics obligations.
- Even if no specific deliverables are set (no work-package), **the PO may request any supporting documents for any of the activities at any time.**
- 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 Review: possible outcomes

- **Appointment of an external, independent ethics Advisor / Board**
 - ❖ **When:** it is necessary for the project to be advised by one or more independent experts. The ethics advisor/board will periodically report to the REA on ethics compliance.
 - ❖ **Ethics WP/Deliverables:** **yes**, for appointment and regular reporting by the ethics advisor/board (**conditional ethics clearance**).
- **An Ethics Check / Review is requested**
 - ❖ **When:** it is important to reassess the global situation or specific ethics issues during the implementation of the project, or when the ethics self-assessment does not contain all necessary elements.
 - ❖ **Ethics WP/Deliverables:** no specific deliverables, although the PO may establish one or more deliverables during GAP to allow submission of supporting ethics documents and/or information to check/review (**clearance**).
- **Specific Ethics Requirements are formulated:**
 - ❖ **When:** if serious/complex ethics issues are identified, then ethics requirements may be included in the ethics summary report.
 - ❖ **Ethics WP/Deliverables:** **yes**, specific deliverables are set; they may include ethics supporting documents, additional information or clarifications (**conditional ethics clearance**).



Thank you!

#HorizonEU @EUgreenresearch @REA_research

<http://ec.europa.eu/horizon-europe>



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