Ethics in Horizon Europe

Research Ethics & Integrity Sector
SCIENCE POLICY, ADVICE & ETHICS Unit
DG Research & Innovation
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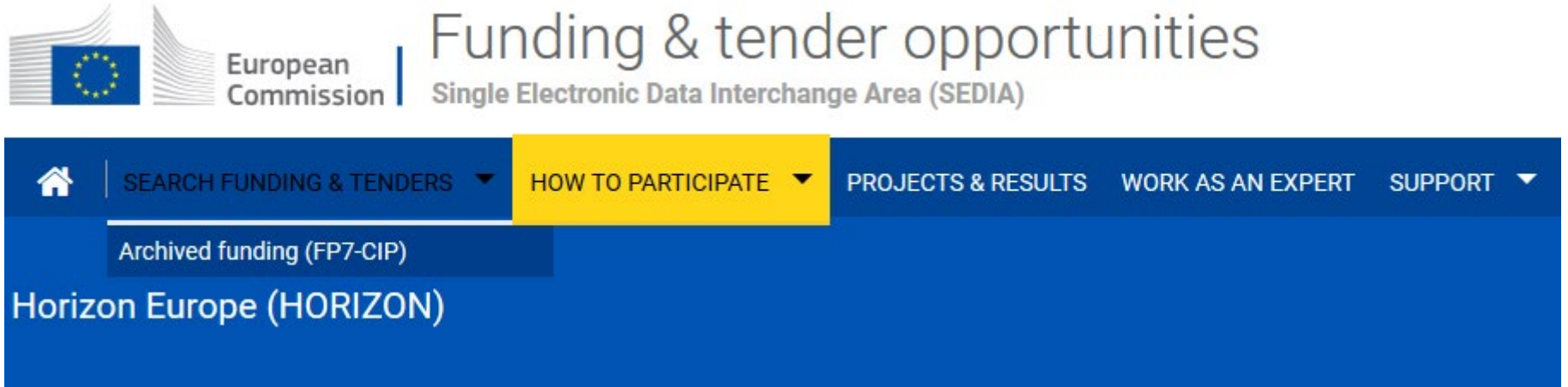
Outline

1. **Guiding principles & eligible activities**
2. **The ethics appraisal process**
   - The Ethics-Self Assessment
   - Ethics Pre-Screening and Screening
   - The independent Ethics Advisor / Board
   - Ethics Assessment for serious and complex ethics issues
   - Monitoring: Ethics Checks and Reviews
3. **A new ethics issue: Artificial Intelligence**

Key sources and materials

- How-to complete your ethics self-assessment (‘How-to’)
- Horizon Europe Programme Guide
- Horizon Europe Model Grant Agreement (MGA) (Article 14 and Annex 5)
- Horizon Europe Framework Programme Regulation 2021/695: Article 18 & 19
- Horizon Europe Specific Programme Decision 2021/764



European Commission

Reference Documents

Grants

This page includes reference documents of the programmes managed on the EU Funding & Tenders portal starting with legal documents and the Commission work programmes up to model grant agreements and guides for specific actions.

Please select the programme to see the reference documents.

Procurement

Reference Documents related to tendering opportunities are published on TED eTendering in the calls for tenders.

Filter

Expand all

- Legislation
- Work programme & call documents
- Grant agreements and contracts
- Guidance
- Templates & forms
- Funding & Tenders Portal

European Commission

Special procedures: Ethics review, security scrutiny, Ownership control check

Ethics review

In order to avoid funding of ethically problematic activities, some funding programmes require an ethics review procedure to clear the projects *(e.g. Horizon Europe, AMIF)*.

The details and the scope of the ethics review depend on each programme. Most programmes simply check whether projects raise ethics issues and, if so, whether these are adequately addressed. Some programmes, such as Horizon Europe, have a more elaborated review procedure which includes several steps depending on the complexity of the issues *(see Horizon Europe Programme Guide)*.

The participants will be informed (through the coordinating organisation) of the ethics review result and it will be posted in their Portal library (My Projects > Actions > Manage Project > Document Library).

If the ethics review leads to requirements to be implemented *before* grant signature, you will need to take immediate action to comply (and may also have to adapt the description of the action (DoA Part B) to reflect this). If the review leads to additional requirements to be fulfilled *during* the project, they are automatically added as ethics deliverables into the system and DoA Part A and will be placed in an automatically generated work package called ethics requirements. If the review shows that there are serious ethics issues that cannot be solved, funding may have to be refused.

⚠ You may be asked to provide additional information if this is needed to complete the ethics review *(e.g. in case of serious or complex ethics issues or missing information)*.

Links

- How to complete your ethics self-assessment

Disclaimer

The ethics issues raised by activities proposed in applications submitted under Horizon Europe Calls and Programs must be assessed individually. The guidance offered during this presentation cannot anticipate any outcome of the ethics appraisal for any specific application. It is quite plausible that proposed activities on very similar topics or involving similar techniques are assessed differently, in terms of the ethics issues raised, their seriousness and/or complexity, and how these ought to be addressed. The general guidance offered therefore cannot create any new obligations on the European Commission or its Executive Agencies, nor can the European Commission or any person acting on their behalf be made responsible for the use made of it.

Ethics in Horizon Europe

Guiding principles & eligible activities

European Commission

Guiding principles

Article 19 - Regulation (EU) 2021/695 establishing Horizon Europe

- 'Actions carried out under the Programme shall comply with **ethical principles** and **relevant Union, national and international legislation**, including the Charter of Fundamental Rights of the European Union and the European Convention on **Human Rights** and its Supplementary Protocols.'

Article 14 - Model Grant Agreement (MGA)

- 'The action must be carried out in line 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 respect for **human dignity**, **freedom**, democracy, **equality**, the rule of law and **human rights**, including the **rights of minorities**).'

European Commission

Guiding principles

Article 19 - Regulation (EU) 2021/695 establishing Horizon Europe

‘Particular attention shall be paid to:

- the principle of proportionality
- the right to privacy
- the right to the protection of personal data
- the right to the physical and mental integrity of a person
- the right to non-discrimination
- the need to ensure protection of the environment
- the need to ensure high levels of human health protection’

Actions NOT eligible for funding

Article 18 (1)

a) activities aimed at **human cloning** for reproductive purposes;

b) activities intended to **modify the genetic heritage** of human beings which could make such changes heritable;

c) 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.'

Model Grant Agreement (MGA) Article 14

d) activities that 'lead to the **destruction of human embryos** (for example, for **obtaining stem cells**).'

Actions NOT eligible for funding

Article 18 (2)

- 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 shall be provided within or outside the Union for research activities that are **prohibited in all Member States**.
- No funding shall be provided in a Member State for a research activity which is **forbidden in that Member State**.

and contracts (including financial transactions and audits).	
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.	☐
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 do not – aim at human cloning for reproductive purposes; – intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which 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) These activities are excluded from funding.	☐
9) We confirm that for activities carried out outside the Union, the same activities would have been allowed in at least one EU Member State.	☐
10) *[Additional option for LUMP SUM Grants:* For Lump Sum Grants with a detailed budget table: We	

Ethics in Horizon Europe

The Ethics Appraisal Process

European Commission

Ethics Appraisal Process

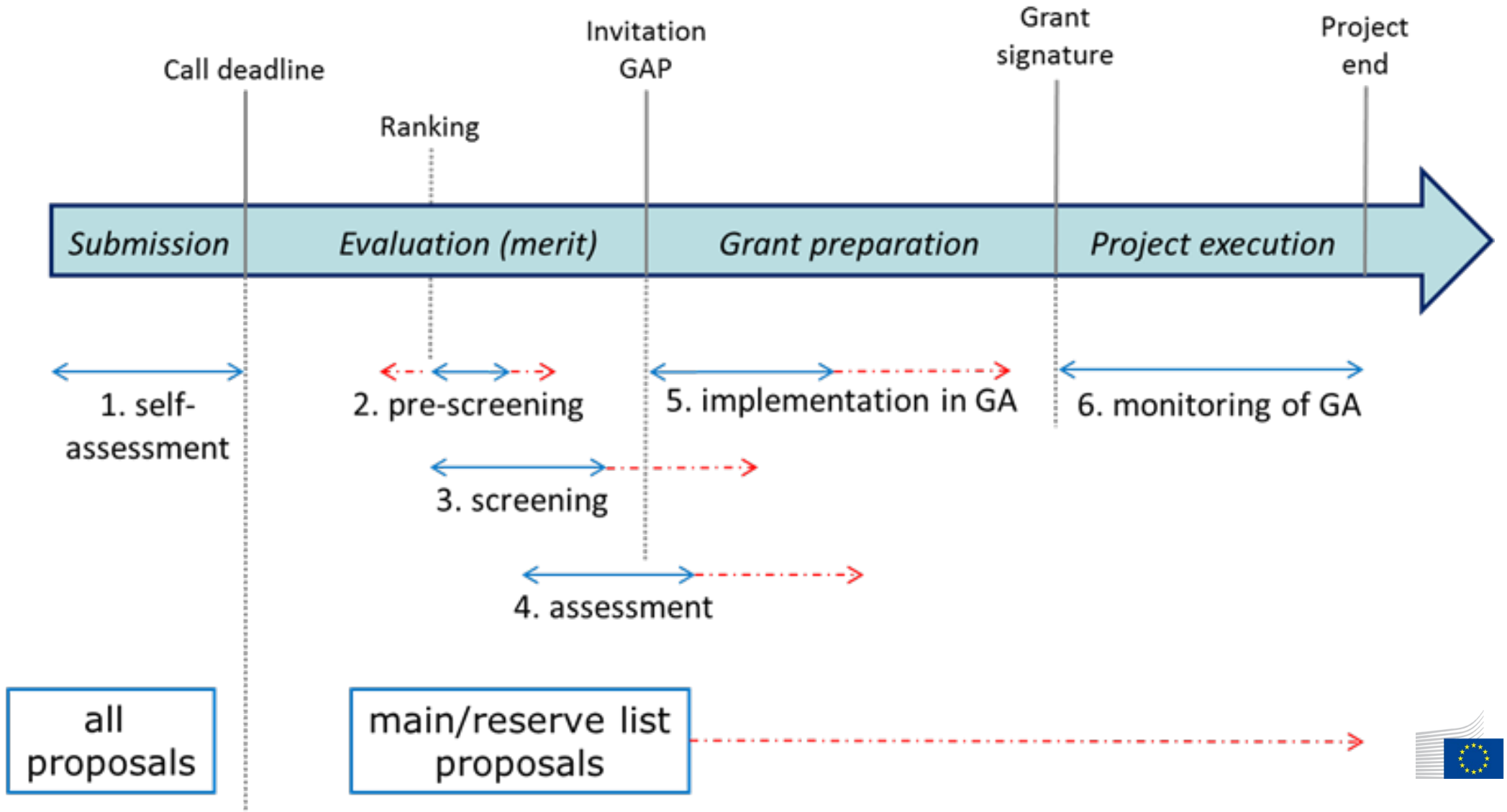
Key Goals

1. **Protect** research participants, researchers, animals, the environment, society, … from harm and undue risks
2. **Support** researchers and innovators to adopt an **ethics by design** approach
3. Contribute to **research excellence** and societal **trust** in research

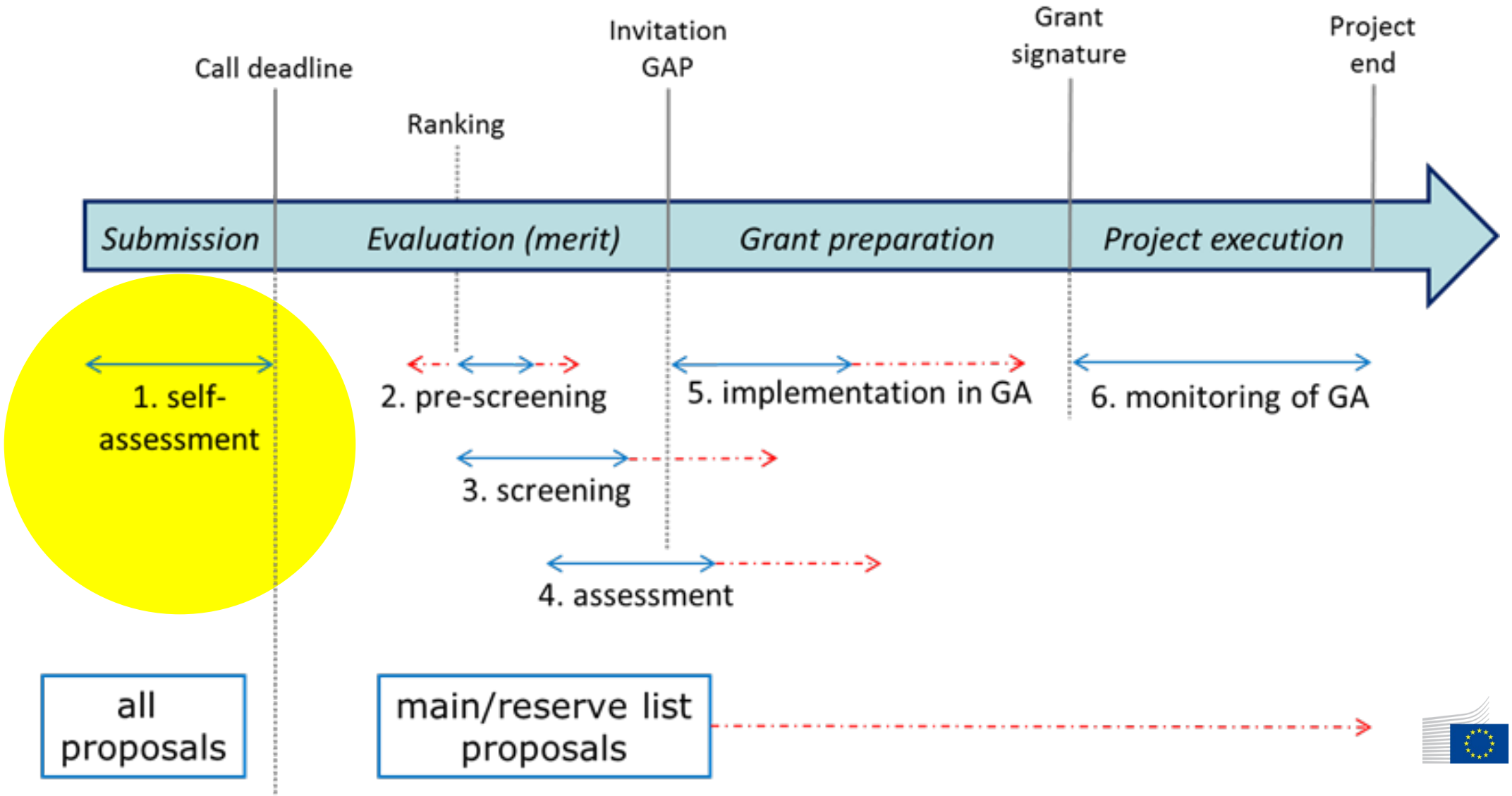
Key Principles

1. **Proportional**: Risk-based
2. **Trusting**
3. **Supportive**
4. **Subsidiarity**

Ethics Appraisal Process



Ethics Appraisal Process



1. Ethics Self-Assessment

- **Mandatory for all proposals** with one ‘yes’ in the **Ethics issues Table**. (Article 19.2(a) HE regulation)

- Applicants must **describe** the ethical dimension of their proposal and the compliance with ethics principles

Application Forms	
Proposal ID **XXXXXXXXX**	*Acronym* **XXXXXXX**

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	

4. PERSONAL DATA				Page
Does this activity involve processing of personal data?			○ Yes ○ No	
If **YES**:	Does it involve the processing of special categories of personal data (e.g.: sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)?		○ Yes ○ No	
	If **YES**:	Does it involve processing of genetic, biometric or health data?	○ Yes ○ No	
	Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?		○ Yes ○ No	
Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?			○ Yes ○ No	
Is it planned to export personal data from the EU to non-EU countries?			○ Yes ○ No	
If **YES**:	Specify the type of personal data and countries involved:			
Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country?			○ Yes ○ No	
If **YES**:	Specify the type of personal data and countries involved			

The Ethics Issues Table

1. Human Embryonic Stem Cells (hESC) and Human Embryos (hE)
2. Human participants
3. Human cells / tissues
   - ! Including foetal cells/tissues
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. ~~**Dualuse**~~

Dual use & exclusive focus on civil applications

No longer assessed by the ethics appraisal process!!

- Applicant declarations

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 2021/821, 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).	☐

- Exclusive focus on civil applications verified by scientific evaluators.

  → Guidance note on research focusing exclusively on civil applications

  → Commission Recommendation on internal compliance programmes for controls of research involving dual-use items under Regulation (EU) 2021/821

Cross-cutting issue: misuse

- The **Security Issues Table** covers **misuse from the security perspective**.

2. MISUSE			Page
Does this activity have the potential for misuse of results?		○ Yes ○ No	
If **YES**:	Does the activity provide knowledge, materials and technologies that could be channelled into crime and/or terrorism?	○ Yes ○ No	
	Could the activity result in the development of chemical, biological, radiological or nuclear (CBRN) weapons and the means for their delivery?	○ Yes ○ No	

- **Misuse not related to the security dimension** will be considered as part of the relevant **ethics sections** (humans, **personal data**, **artificial intelligence, …** or as 'other ethics issue')
  - E.g., the development of surveillance technologies that could curtail human rights and civil liberties.
  - E.g., research that involves minority or vulnerable groups or develops social, behavioural or genetic profiling technologies that could be misused to stigmatise, discriminate against, harass or intimidate people.

→ Guidance note on potential misuse of research results

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.’

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.

Ethics Self-Assessment

- In the 'how-to' you can find:
  - Brief explanation of the ethics issues (humans, human cells and tissues, animals, artificial intelligence, …), how to address them, **the information and documents** to provide.
  - Reference to background documents & further guidance, e.g.:
    - Note on ethics and data protection
    - TRUST Global code of conduct for research in resource-poor settings
    - Guidance note — Research on refugees, asylum seekers and migrants

EU Grants

How to complete your ethics self-assessment

European Commission

Section 2: HUMANS		YES/ NO		Information to be provided in the proposal	Documents to be kept on file and provided on request
Does your activity involve human participants?		☐	☐	Please provide information in one of the subcategories below	
If **YES:**	Are they volunteers for nonmedical studies (e.g. social or human sciences research)?	☐	☐	1) Details on recruitment, inclusion and exclusion criteria and informed consent procedures. 2) Details on unexpected findings policy.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.
	Are they healthy volunteers for medical studies?	☐	☐	1) Details of the recruitment, inclusion and exclusion criteria and informed	1) Copies of ethics approvals. 2) Informed consent forms and information sheets.

If **YES**:	Does it involve the processing of special categories of personal data *(e.g. sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)*?		☐	☐	1) Justification for the processing of special categories of personal data (if relevant). 2) Justification to why the project objectives cannot be reached by processing anonymised/pseudonymised data (if applicable).	
	If **YES:**	Does it involve processing of genetic, biometric or health data?	☐	☐		1) Declaration confirming compliance with the laws of the country where the data were collected.

Ethics Self-assessment

- Explain how ethics issues will be addressed

  →Describe the ethical and legal requirements applicable to your activities and how they will be met

- List appropriate documents that will be provided/kept on file as evidence

  →!! Depending on the call: possibility to submit additional information and/or supporting documents in separate annex to **Part B**

- Applications should be 'Ethics Ready'

Clinical trials / studies / investigations

New in Horizon Europe

[Additional modular extension for Calls with clinical trials: Essential information to be provided for proposals including clinical trials / studies / investigations

Clinical study means, for the purpose of this document, any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but it is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices.

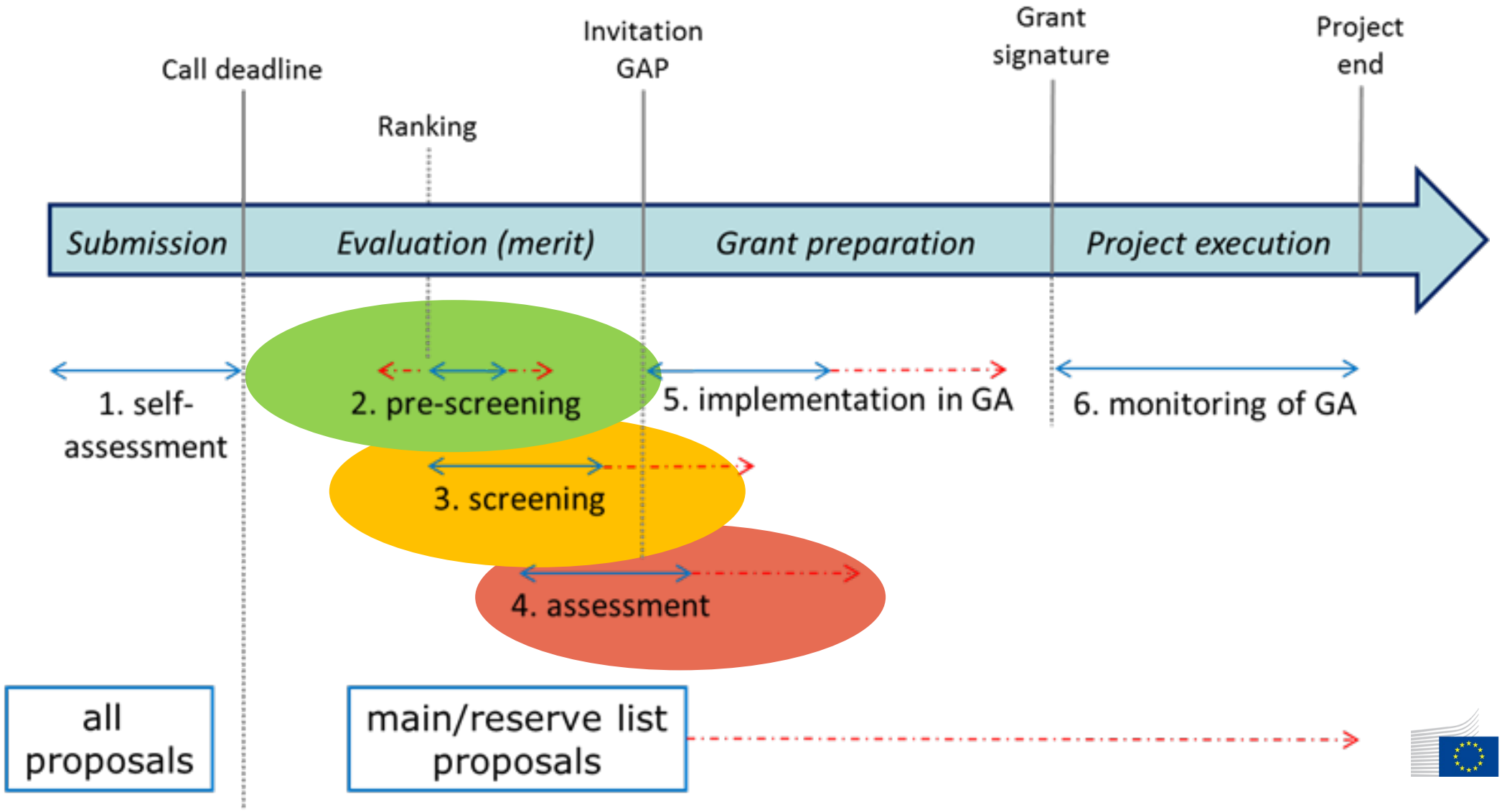
Are clinical studies / trials / investigations included in the work plan of this project?	○ Yes ○ No

Please upload the dedicated annex 'Essential information for clinical studies / trials / investigations' (a Word template is provided under 'download templates' in the up-load section for Part B and Annexes).

This document should include the relevant information of each clinical study / trial / investigation included in the work plan of this project.

Please give a short title, an acronym or a unique identifier to each clinical study / trial / investigation, to be used as a reference / identifier in the other parts of the proposal	Add / Remove

Ethics Appraisal Process



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(2. Ethics Pre-screening)

- **Optional** filtering step of **all** proposals (with and 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**

3. Ethics Screening

- All proposals (with and without ethics issues flagged) **OR** flagged proposals after pre-screening
- By at least two ethics evaluators (external experts)

➔ **Key goal: Identifying proposals that raise serious or complex ethics issues** and must undergo a **full ethics assessment, where ethics requirements can be defined.**

All other, non-critical proposals are cleared without ethics requirements.

3. Ethics Screening: Possible outcomes

→**Ethics issues?**

→ **NO? ➔ ETHICS CLEARANCE**

→ **YES? ➔ Serious and/or complex ethics issues?**

1. **NO**: Beneficiaries further deal with ethics issues in accordance with national and European legislation – **no further analysis or requirements** in the Ethics Summary Report ➔ **ETHICS CLEARANCE**

2. **NO**: Beneficiaries further deal with ethics issues in accordance with national and European legislation BUT **need to appoint external independent ethics advisor or board** ➔ **CONDITIONAL ETHICS CLEARANCE**

3. **YES**: ➔ **ETHICS ASSESSMENT**

Ethics Summary Report

Call Reference	HORIZON-CL6-2021-CLIMATE-01
Proposal Number	
Acronym	

Ethics Issues

Humans	Yes
Personal data	Yes
Non-EU countries	Yes

Ethics Opinion

Ethics clearance (the proposal is 'ethics ready')

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 Summary Report

Call Reference	HORIZON-CL6-2021-FARM2FORK-01
Proposal Number	
Acronym	

Ethics Issues

Humans	Yes
Personal data	Yes
Non-EU countries	Yes
Artificial intelligence	Yes

Ethics Opinion

Conditional ethics clearance (clearance is subject to conditions, i.e. ethics requirements. The requirements must either be fulfilled before grant signature or become part of the grant agreement)

External Independent Ethics Advisor/Board

In your opinion, would it be exceptionally 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?	**Yes (Ethics Advisor)**

European Commission

The mandate of the Ethics Advisor / Board

- 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
- The choice between a single external independent ethics advisor and an ethics board (with a minimum of three experts) reflects **the size of the grant and the seriousness/complexity of the ethics issues**.
- They are **paid** for this service (via e.g., a service contract).

Independent?

= The 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
- 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

Report by the Independent Ethics Advisor or Ethics Advisory Board

Funding Programme	
Call	
Grant Agreement Number	
Acronym	
Project Title	
Project start date-end date	
Period covered	

Where to find them?

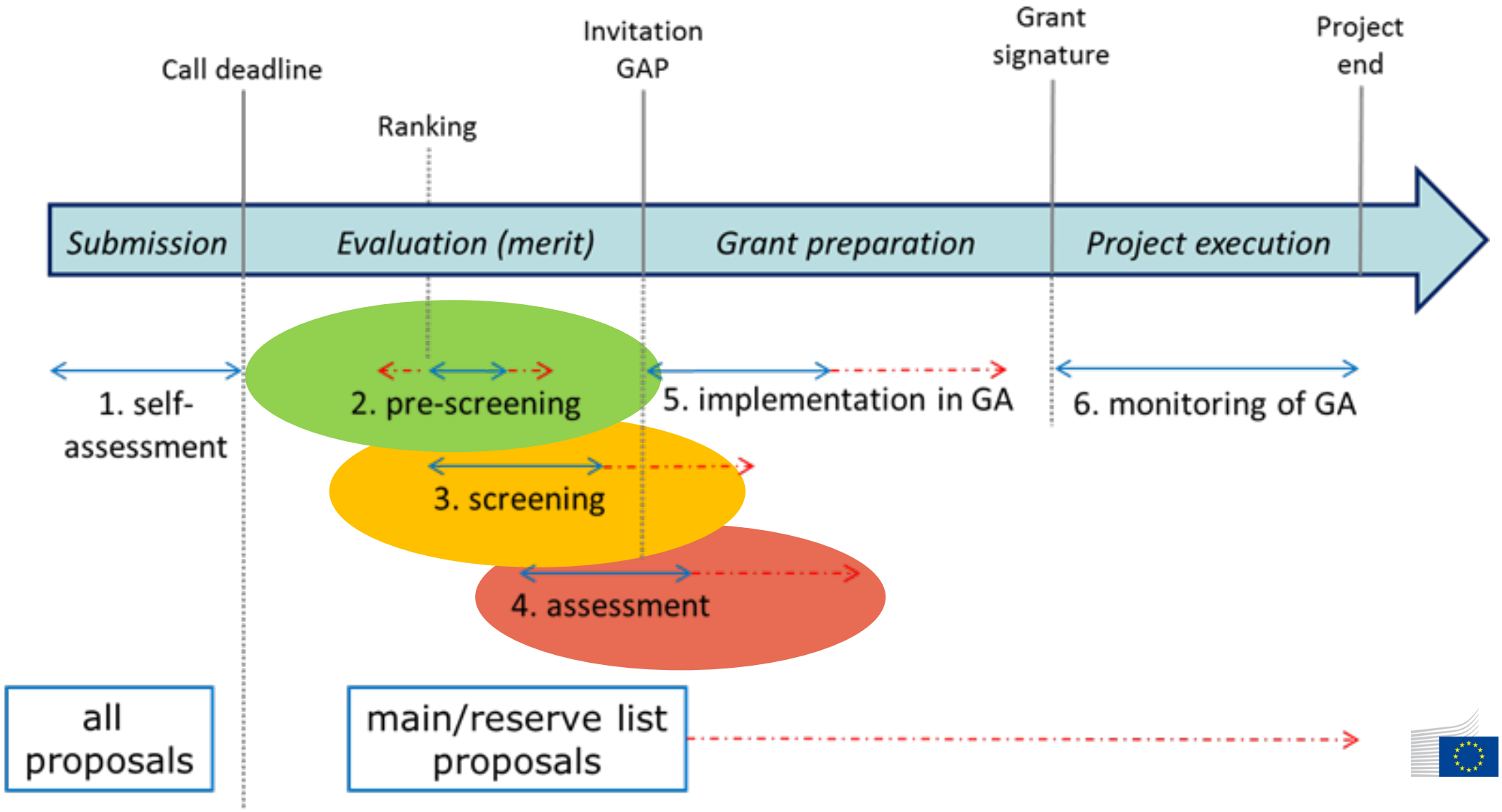
- Ask for referrals / advice from institutional ethics committees, ethics departments, law departments, etc.

- **!!** Possible that the appointment of an **Ethics Mentor** **is recommended.**

  - Not 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 Agency, although it is recommended to keep a report of the activities performed.

Ethics Appraisal Process



European Commission

4. Ethics Assessment?

An **in-depth analysis,** by panel of **5 ethics experts,** of the ethics issues raised by:

1. All proposals involving **human embryos (hE)** or **human embryonic stem cells (hESC)**

2. Proposals raising **serious and/or complex ethics issues**

Decided during Ethics Screening

Key goal: to identify additional measures that must be implemented during grant preparation or during grant implementation, for ethics issues not satisfactorily addressed in the proposal.

European Commission

hESC and hE

- **Mandatory Ethics Assessment** (Article 19(3)) + **Programme committee (MS) approval procedure** (Joint Declaration of the EP, Council and EC 2021/C 185/01 & Council Decision (EU) 2021/764)
- High sensitivity:
  - Divergence in member state legal and ethical frameworks
  - **!** Non-eligible activities, e.g., destruction of human embryos

Serious and/or complex ethics issues

What are serious and/or 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

Serious and/or complex ethics issues

What are serious and/or 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

→ **Guidelines on serious and complex ethics issues**

European Commission

What are serious and/or 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 and/or complex ethics issues?

- **Examples**:
  - Research involving untested forms of **human bio-engineering, human-machine integration or human-animal chimeras**
  - 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

What are serious and/or complex ethics issues?

- **Examples**:
  - 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)
  - Research that appears to **take advantage of differences in standards or the absence of legislative protection** for research participants, local researchers and other local staff, data protection and privacy, animals, the environment or the public, particularly **in lower-income settings**.
  - Research resulting in the **transfer of special category data to countries with inadequate data protection regimes**, without the knowledge or explicit consent of the data subjects.

What are serious and/or complex ethics issues?

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.**

!! The seriousness and complexity of the ethics issues are assessed on a **proposal-by-proposal basis**.

4. Ethics Assessment: Possible outcomes

1. **ETHICS CLEARANCE** → GA is finalized

2. **CONDITIONAL ETHICS CLEARANCE**

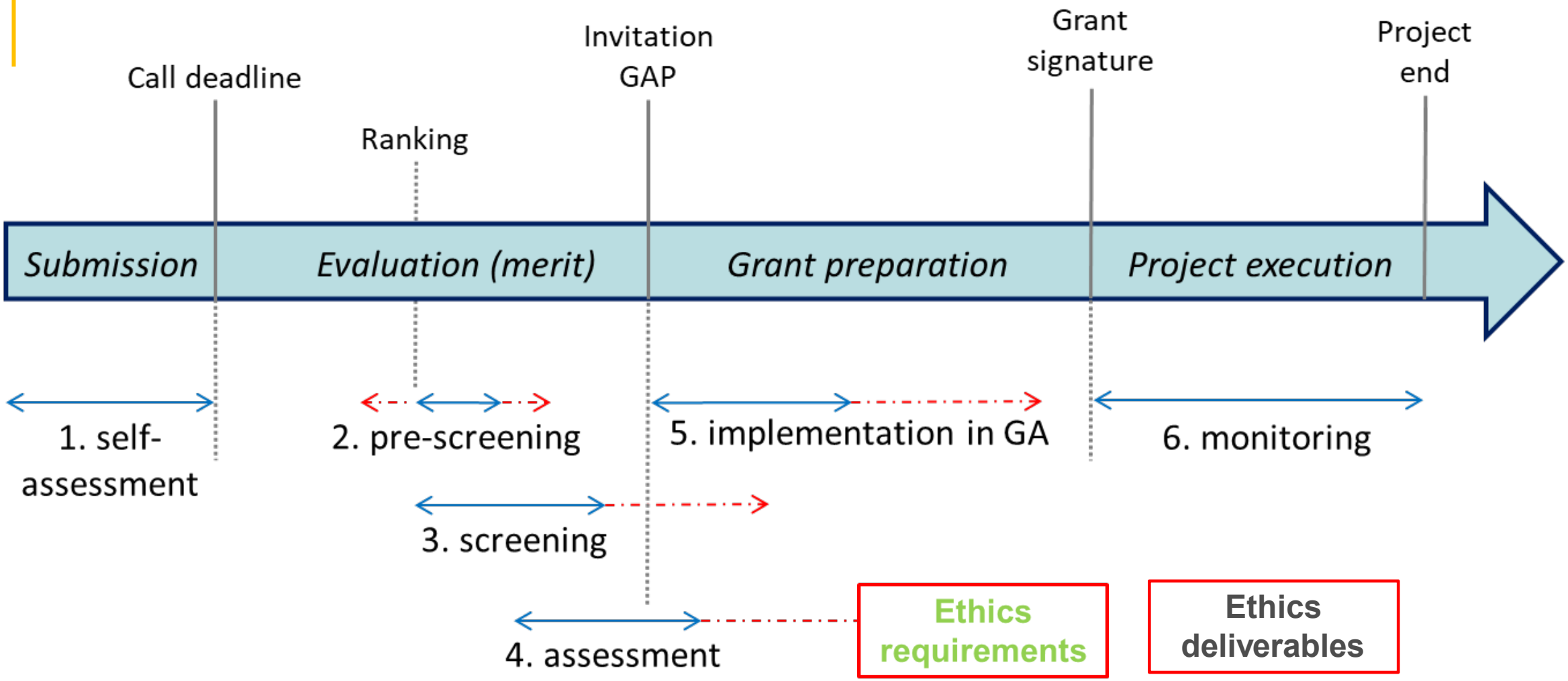
   →The Ethics Summary Report contains **ethics requirements that need to be fulfilled**

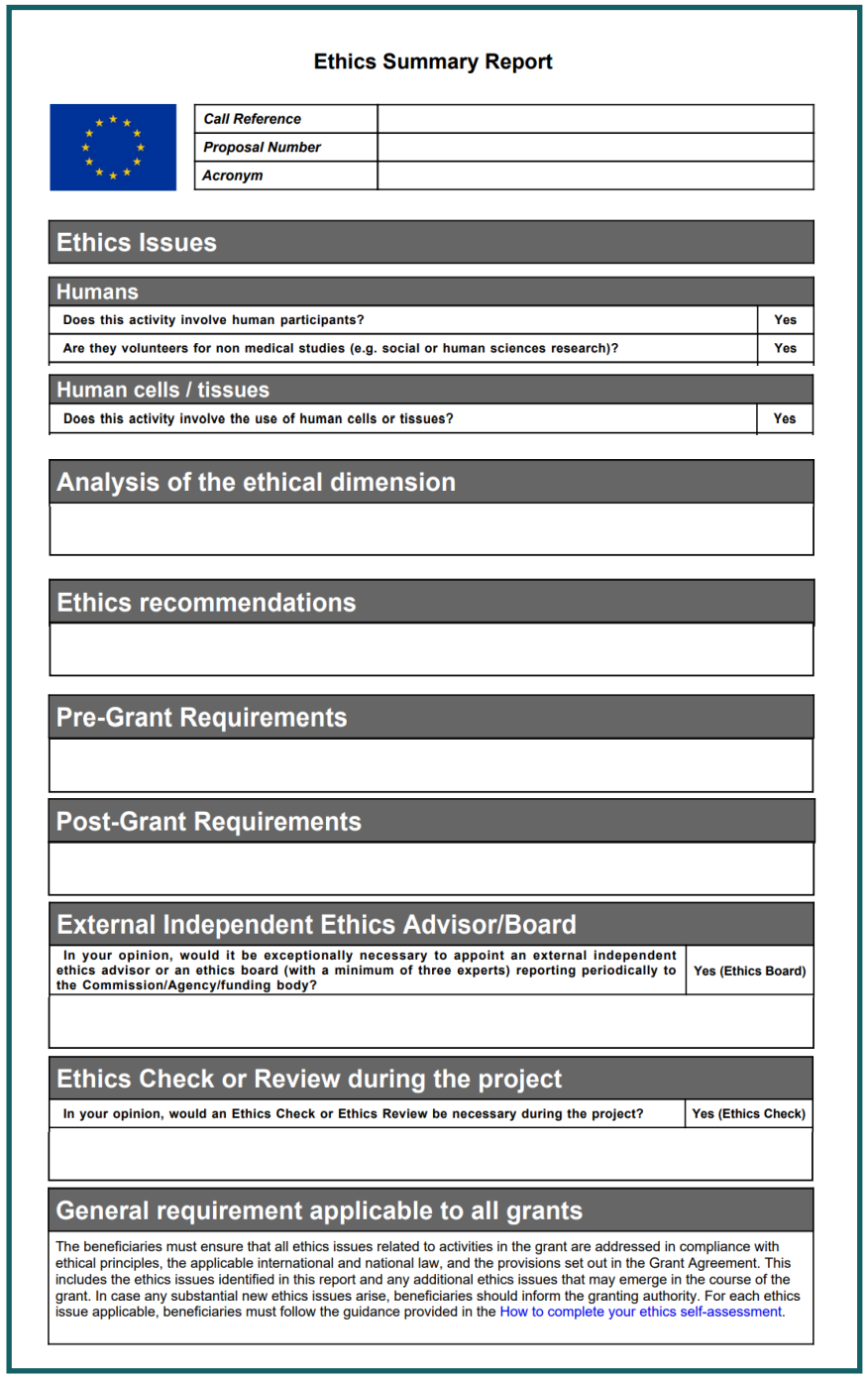
   →Before GA and/or contractual obligations included in GA

   →**Ethics work package & Ethics deliverables** *(e.g., information on consent procedures, copies of ethics approvals, …)* as part of project reporting and monitoring

3. ***Second ethics assessment or more information needed*** → GA is postponed

4. **NO ETHICS CLEARANCE** **(after second assessment)** → Proposal cannot be funded


Call deadline
Ranking
Invitation
GAP
Grant
signature
Project
end
Submission
Evaluation (merit)
Grant preparation
Project execution
1. self-
assessment
2. pre-screening
3. screening
4. assessment
5. implementation in GA
6. monitoring
Ethics
requirements
Ethics
deliverables



Ethics Summary Report

Call Reference	
Proposal Number	
Acronym	

Ethics Issues

Humans

Does this activity involve human participants?	Yes
Are they volunteers for non medical studies (e.g. social or human sciences research)?	Yes

Human cells / tissues

Does this activity involve the use of human cells or tissues?	Yes

Analysis of the ethical dimension

Ethics recommendations

Pre-Grant Requirements

Post-Grant Requirements

External Independent Ethics Advisor/Board

In your opinion, would it be exceptionally 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?	Yes (Ethics Board)

Ethics Check or Review during the project

In your opinion, would an Ethics Check or Ethics Review be necessary during the project?	Yes (Ethics Check)

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.

4. Ethics Assessment

When ethics requirement are defined (following Ethics Assessment):

- Either as ethics deliverables (e.g., to request supporting documents or additional reports)
- Or in the grant agreement before signature e.g., by changing the Description of the Action (Annex 1) in order to introduce a justification, change a methodology, …

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Ethics requirements – some examples…

- 1.3. Information on the origin of embryos must be provided **before grant signature**.
- 2.6. The applicant must clarify whether vulnerable individuals/groups will be involved, and the measures to protect them and minimise the risk of their stigmatisation must be included **in the grant agreement** before signature.
- 4.1 The beneficiary must check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and **submit as a deliverable** a declaration of compliance with respective national legal framework(s).
- 5.4. The applicant must clarify whether non-human primates will be involved in this study and justify their inclusion in the research. This information must be included **in the grant agreement** before signature.

Key change

Horizon 2020

Screening

Ethics issues → Formulation of ethics requirements

= contractual obligations in Grant Agreement

Horizon Europe

Screening

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

5. Implementation

!!! No ethics requirements =/= 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.

➔ Risk-based & trust-based approach

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Ethics summary report after screening

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 obligations

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 of the relevant activities. Those documents **shall be kept on file** and provided to the Commission or the relevant funding body upon request.

3.3 Ethics issues checklist

3 HUMAN CELLS / TISSUES		YES/ NO		Information to be provided in the proposal	Documents to be provided on request
Does your activity involve the use of human cells or tissues (other than those covered by *section 1*)**?**		☐	☐	Please provide information in one of the subcategories below.	
If **YES:**	Are they human embryonic or foetal cells or tissues?	☐	☐	1) Origin of human foetal tissues/cells. 2) Details on informed consent procedures. 3) Confirmation that the informed consent has been obtained. 4) If applicable, details on the induced human pluripotent cell lines.	1) Copies of ethics approvals. 2) Informed consent forms and information Sheets. 3) If applicable, registration certificates of the cell lines and project from the hPSCreg.
	Are they available commercially?	☐	☐	1) Details on cell types and provider (company or other).	1) Copies of import licences (if relevant).

	Are they obtained from a biobank?	☐	☐	1) Details on cell types 2) Details on the biobank (name and country where it is located) 3) Details of the legislation under which material is stored. 4) Confirmation that material is fully anonymised or that consent for secondary use has been obtained.	1) Copies of import licences (if relevant). 2) Statement of biobank that informed consent has been obtained.

5. Implementation

!!! **No ethics requirements =/= no ethics obligations**

- Proposals ‘cleared’ after screening without ethics requirements :
  - may have to **appoint an independent ethics advisor or ethics board**
  - Can still be subject to an **ethics check or ethics review**

6. Monitoring: Ethics Checks & Reviews

- 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**
  - ! All documents 'to be kept on file' may be requested!

- **When are Ethics Checks or Reviews requested?**
  - For projects raising serious / complex ethics issues
  - Compliance with ethics requirements needs to be checked during the implementation
  - Decision by the Project officer in the EC/Agency (i.e., documents provides are unsatisfactory)

6. Monitoring

- An **Ethics Check:**
  - internal check by the project officer or ethics officer who may be supported by ethics experts.
- An **Ethics Review:**
  - more elaborate and in-depth procedure carried out by up to 5 external ethics experts (formerly know as 'Ethics Check' in H2020)
- Depending on the **size** of the grant and the **seriousness/complexity** of the ethics issues.

Legal basis

Article 19 (5)

‘If appropriate, ethics checks shall be carried out by the Commission or the relevant funding body. (…)’

Article 19 (6)

‘Actions which do not fulfil the ethics requirements referred to in paragraphs 1 to 4 and are therefore not ethically acceptable, shall be **rejected or terminated once the ethical unacceptability has been established**.’

Key conclusions for applicants/beneficiaries

1. Proper Ethics self-assessment is pivotal
2. Only for serious and/or complex proposals specific ethics requirements will be set
3. Full responsibility for proper ethics compliance management
4. Make sure to be able to submit proof of compliance at all times

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Artificial Intelligence

A new ethics issue

European Commission

Artificial intelligence

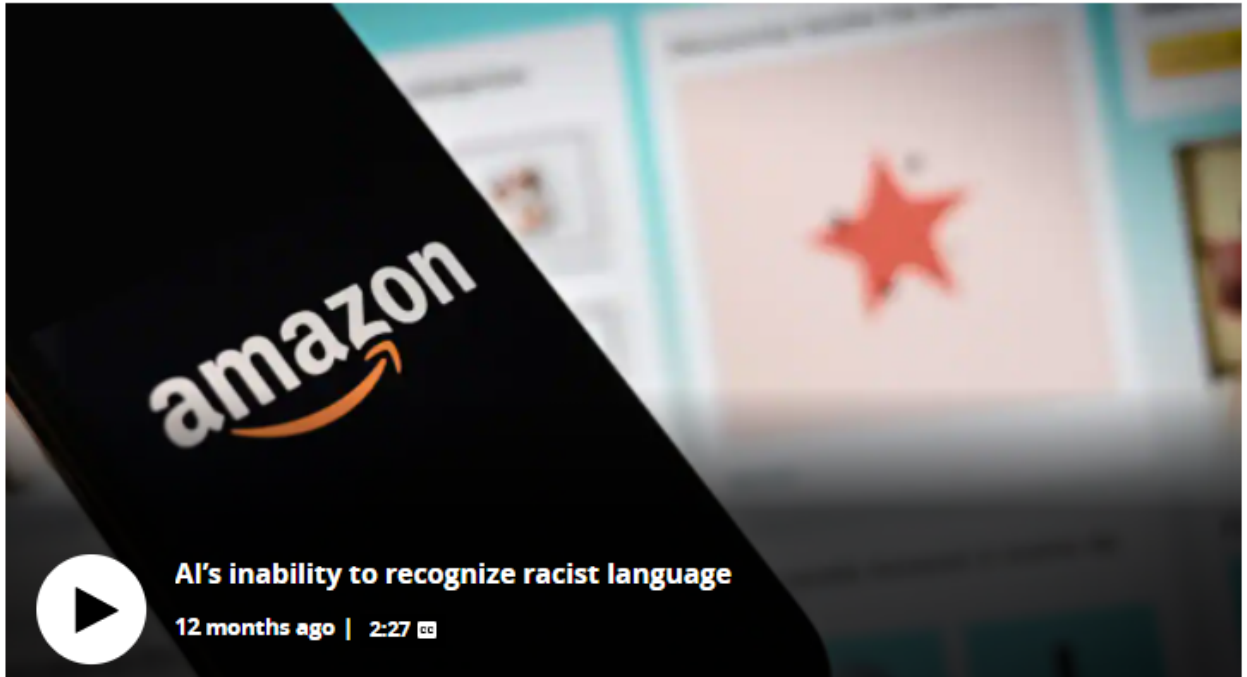
- **Why?** Various ethical concerns raised by the development and use of AI-based applications:
  - Discrimination & bias. *E.g. selection and recruitment tools, clinical decision support tools, etc.*
  - Safety & Liability. *E.g. Self-driving cars, etc.*
  - Transparency and the algorithmic 'black box'
  - Privacy & data protection. *E.g. surveillance, facial recognition, etc.*
- **Goal? Protect research participants + "Ethics by Design"** = addressing ethical issues during research and development

Ethics of Artificial Intelligence

AI has a racism problem, but fixing it is complicated, say experts

Use of N-word in product description of a toy listed on Amazon just 1 recent example

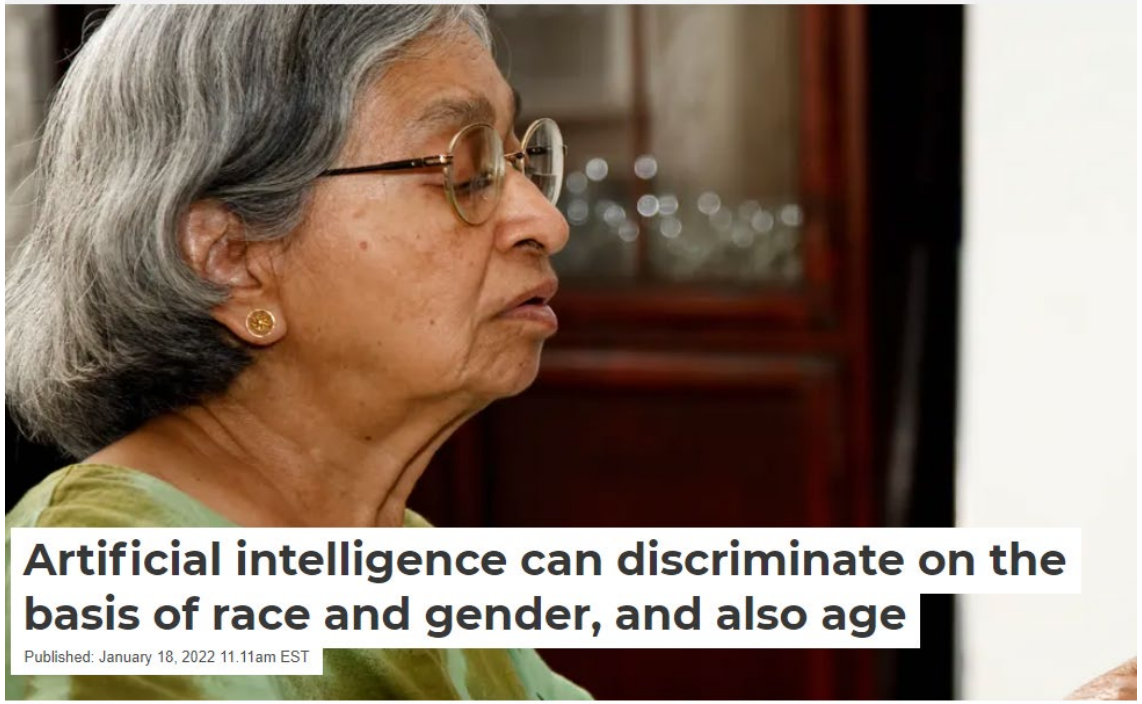
Jorge Barrera, Albert Leung · CBC News · Posted: May 17, 2021 4:00 AM ET | Last Updated: May 17, 2021



THE CONVERSATION

Academic rigor, journalistic flair

COVID-19 Arts + Culture Economy + Business Education Environment + Energy Ethics + Religion Health Politics + Society Scienc



Artificial intelligence can discriminate on the basis of race and gender, and also age

Published: January 18, 2022 11.11am EST

Older adults are increasingly using technologies in their everyday lives, but the needs of this population are often ignored in AI design. (Shutterstock)

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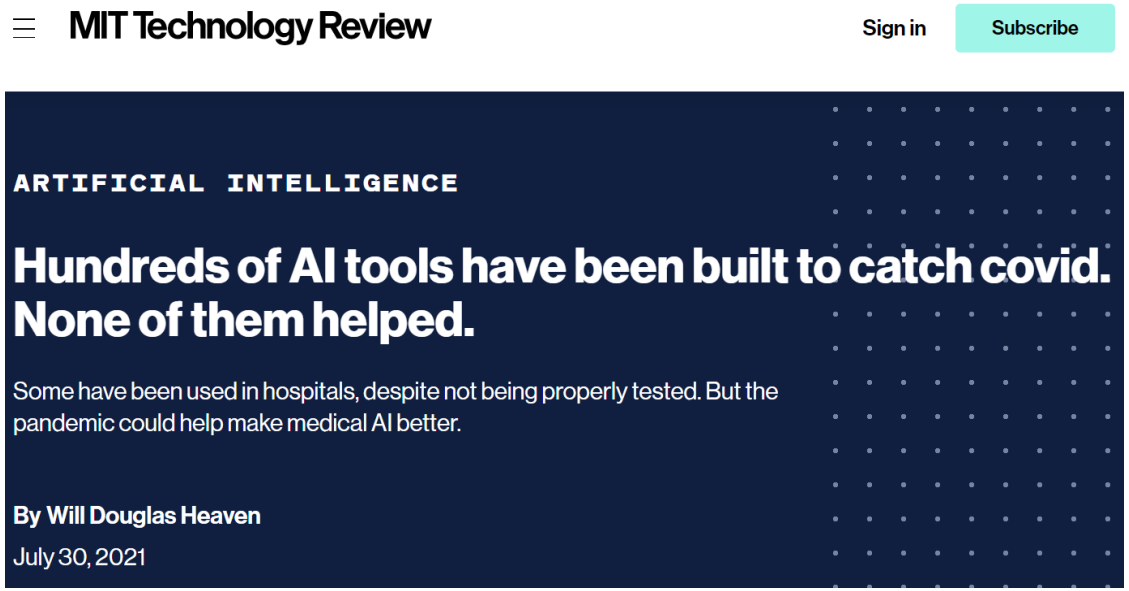
We have accepted the use of artificial intelligence (AI) in complex processes — from health care to our daily use of social media — often without critical investigation, until it is too late. The use of AI is inescapable in our modern society, and it may perpetuate discrimination without its users being aware of any

Ethics of Artificial Intelligence



"In yet other cases, some AIs were found to be picking up on the text font that certain hospitals used to label the scans. As a result, fonts from hospitals with more serious caseloads became predictors of covid risk."

European Commission

"**Trustworthy AI** has three components, which should be met throughout the system's entire life cycle:

1. it should be **lawful**, complying with all applicable laws and regulations;

2. it should be **ethical**, ensuring adherence to ethical principles and values; and

3. it should be **robust**, both from a technical and social perspective, since, even with good intentions, AI systems can cause unintentional harm."

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Trustworthy AI ensures:

1. Human agency and oversight
2. *Technical robustness and safety*
3. Privacy and data protection
4. Transparency
5. Fairness, diversity and non-discrimination
6. Societal and environmental well-being
7. Accountability

Scientific + Ethical Evaluation

European Commission

Artificial intelligence
Scientific & ethics evaluation

Trustworthy Artificial Intelligence

- **Scientific experts** to answer a specific question:
  - Do the activities proposed **involve the use and/or development** of AI-based systems and/or techniques?
  - If so, scientific experts' must assess the **technical robustness** of the proposed AI-system as part of the excellence criterion.
- **The ethics experts** take into account the assessment on the technical robustness when performing their ethics evaluation.

Artificial intelligence
Scientific evaluation

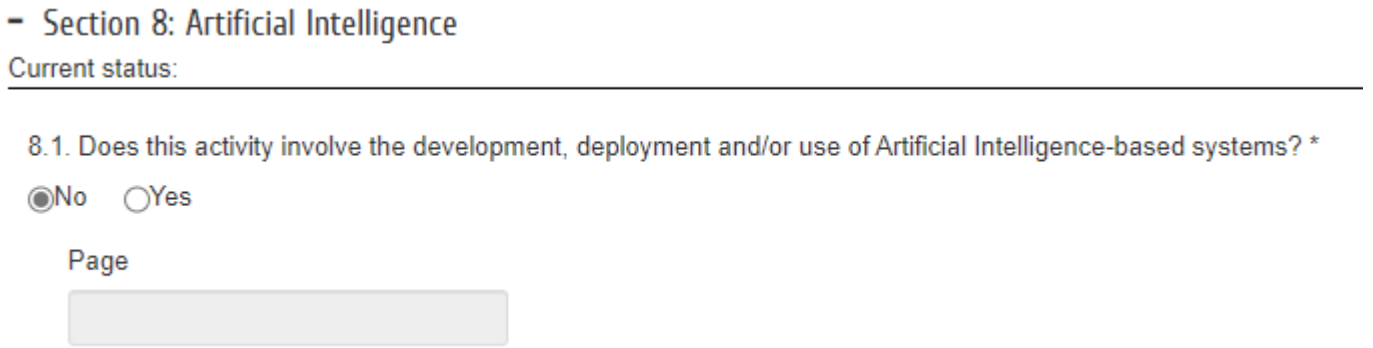
Technical robustness

- Evaluated as part of the excellence criterion
- technical aspects of AI systems and development: AI-based systems or techniques should be (or be developed to become):
  - **Technically robust**, **accurate and reproducible**, and able to deal with and inform about possible failures, inaccuracies and errors, proportionate to the assessed risk posed by the AI-based system or technique.
  - **Socially robust**, in that they duly consider the context and environment in which they operate.
  - **Reliable and function as intended**, minimizing unintentional and unexpected harm, preventing unacceptable harm and safeguarding the physical and mental integrity of humans.
  - Able to provide a suitable explanation of its **decision-making process**, whenever an AI-based system can have a significant impact on people's lives.

→ Key ethical requirements:

- ⇨ People must be made **aware** that they are interaction with an AI system, its abilities and limitations, risks and benefits
- ⇨ Mechanisms for **human oversight**, **transparency** and **auditability** must be 'built in' the AI system
- ⇨ AI-system must be designed to **avoid bias** in input data and algorithmic design
- ⇨ Compliance with **data protection and privacy principles** (e.g., data minimisation) must be demonstrated
- ⇨ The **impact** of the developed and/or used AI system/technique on the individual, society and environment must be **carefully evaluated and any possible risk of harm must be avoided**.

Artificial intelligence
Ethics evaluation



When is AI an Ethics Issue?

For **ALL** activities involving the development, deployment and/or use of AI-based systems

- Includes the **use** of existing AI-based techniques (e.g., use of AI-based data analytics)
- **!** AI-based system are usually components of larger systems.
- **!** Even when it does not pose the ethics risks associated with AI (e.g., bias, discrimination, …), applicants and ethics evaluators must **always** identify the issue and explain why it is not a valid risk or concern in the particular context.

!!! Ethics issues
=/=
Serious/complex ethics issue

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What counts as ‘AI-based technique or application’?

No ‘right’ answer, but for the ethics appraisal process, the same definition is used as the one proposed by the High-level Expert Group (AI HLEG) in its Ethics guidelines for trustworthy AI:

“Artificial intelligence (AI) systems are software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by **perceiving their environment** through **data acquisition, interpreting the collected structured or unstructured data**, **reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s)** to take to achieve the given goal. AI systems can either **use symbolic rules or learn a numeric model**, **and** they can also **adapt** their behaviour by analysing how the environment is affected by their previous actions.

As a scientific discipline, AI includes several approaches and techniques, such as **machine learning** (of which **deep learning** and **reinforcement learning** are specific examples), **machine reasoning** (which includes planning, scheduling, knowledge representation and reasoning, search, and optimization), and **robotics** (which includes control, perception, sensors, and actuators, as well as the integration of all other techniques into cyber-physical systems).”

A separate document prepared by the AI HLEG and elaborating on the definition of AI has also been published.

! Not all automation is AI

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8 ARTIFICIAL INTELLIGENCE	YES/NO		Information to be provided	Documents to be provided/kept on file
Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?	☐	☐	1) Explanation as to how the participants and/or end-users will be informed about: - their interaction with an AI system/technology (if relevant); - the abilities, limitations, risks and benefits of the proposed AI system/technique; - the manner in which decisions are taken and the logic	1) Detailed risk assessment accompanied by a risk mitigation plan (if relevant). These must cover the development, deployment and post-deployment phases. 2) Copies of ethics approvals (if relevant).

Artificial intelligence

E.g.: *Could the AI system/technique stigmatise or discriminate against people (based on sex, race, ethnic/social origin, age, disability, sexual orientation, religion, political affiliation, etc.)?*

→Applicants must explain how potential bias, discrimination and stigmatization **could arise**.

→Applicants must indicate **how it will be addressed**.

- E.g., testing for algorithmic bias during the detailed development phase by using counterfactual evaluation methods
- E.g., testing whether the system becomes unequally functional for different end-users, and adapt design to ensure that interface design is universally accessible

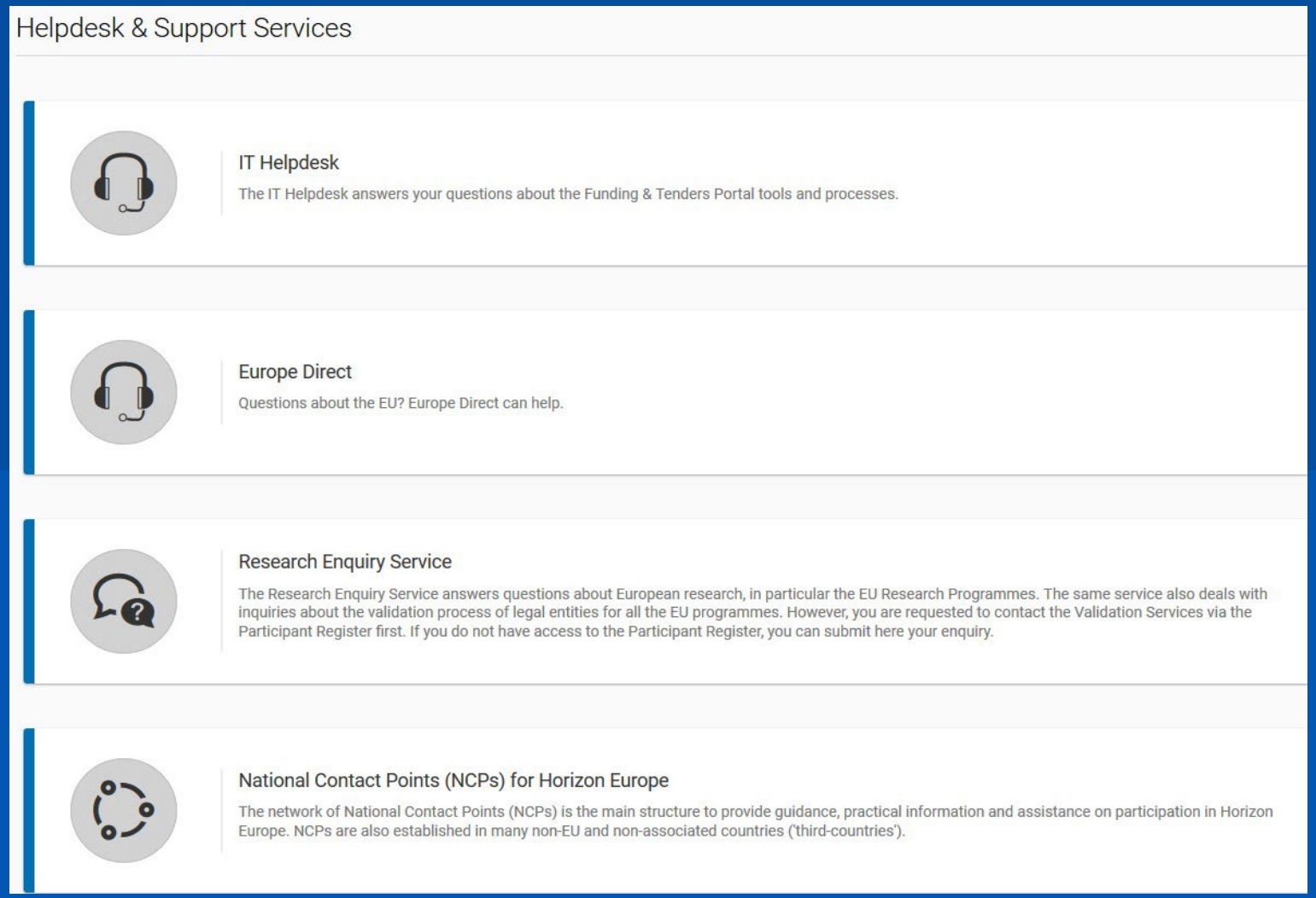
Ethics requirements

- 8.2. A detailed explanation on the **measures taken to prevent, avoid and mitigate potential bias, discrimination and stigmatisation** in input data, algorithm design and outcomes must be [submitted as a deliverable before the start of the relevant activities] [included in the grant agreement before signature].
- 8.3. A detailed explanation on how **the research participants and/or end-users will be informed about**: (1) their interaction with an AI system/technology (if relevant); (2) the abilities, limitations, risks and benefits of the AI system/technique; (3) the manner in which decisions are taken and the logic behind them (if relevant) must be [submitted as a deliverable before the start of the relevant activities] [included in the grant agreement before signature].
- 8.5. A detailed explanation on **how humans will maintain meaningful control** over the most important aspects of decision-making process (*please specify*) must be [submitted as a deliverable before the start of the relevant activities] [included in the grant agreement before signature].

Further guidance

- **Guidelines on ethics by design for AI**.
  - ! Checklist for ethics of use
- **Assessment List for Trustworthy Artificial Intelligence** (ALTAI) (Independent High-Level Expert Group on AI)
- **Ethics guidelines for trustworthy AI** (Independent High-Level Expert Group on AI)

Help is on its way!



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Questions?

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Thank you!

HorizonEU

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

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