



The Ethics Appraisal Scheme in Horizon Europe

An updated process

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

(draft) Regulation ** establishing Horizon Europe Article 19

'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.'

Ethics and Values

Model Grant Agreement Article 14 (HE and *corporate*, draft)

'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).'



!! Actions NOT eligible for funding

HE Regulation ** 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.'

and HE Model Grant Agreement – Art 14

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

→ Assessed by Scientific Evaluators if any of those is present and 'qualifying'

Horizon Europe Novelties

- 1. New ethics issue: Artificial intelligence*
- 2. New process: focus on serious and complex cases.*

Ethics Issues (1/2)

1. Human Embryonic Stem Cells and Human Embryos
2. Human participants
3. Human cells / tissues
4. Personal data
5. Animals
6. Non-EU countries
7. Environment & Health and Safety
8. Artificial Intelligence – NEW!
9. Other ethics issues

Misuse: across all categories and also part of the Security Appraisal procedure (ChBN weapons)

Ethics Issues (2/2)

9. Artificial Intelligence (new)

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

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.)?

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)?

Scientific questions (1/2) hESC, civil focus, dual-use ...

- **Human Embryonic Stem Cells** (hESC) and **Human Embryos** (hE)?

Are they present? Are they necessary to achieve scientific objectives?

→ Mandatory **Ethics Assessment**

- Exclusive focus on **civil applications**? *Yes / No*

→ Decision to fund/reject the action

- **Dual Use** (Regulation 428/2009)

→ Applicants declaration

→ Grant Agreement Preparation

Scientific questions (2/2)

Artificial Intelligence, DNSH

- **Artificial intelligence?**

Is it technically robust?

- Assessed in the excellence criterion
- Taken into account by **ethics evaluators**

- **Do no significant harm** (DNSH) principle ('Taxonomy Regulation' 2020/852)

- assessed in the excellence criterion
- taken into account by **ethics evaluators**

The Ethics Appraisal process

Regulation ** Article 19 (2)

`Entities participating in the action shall provide:

(a) an ethics self-assessment (...)'

Regulation ** Article 19 (3)

`Proposals shall be systematically screened to identify those actions raising complex or serious ethics issues and submit them to an ethics assessment. (...)'

Application

- Ethics Issues Table (1a)
- Ethics **Self-Assessment** (1b)

Shortlisted PROPOSALS

- Before Grant agreement!
- **Ethics Screening** of all proposals (2)
- **Ethics Assessment** of proposals raising complex and/or serious ethics issues (3)

Ongoing RESEARCH PROJECTS

- **Ethics Review*** for selected projects (4)

(1a) Ethics Issues Table – proposal application form

To be completed as an essential part of the proposal

Section 1: HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS	YES/no
Does this activity involve Human Embryonic Stem Cells (hESCs).	
Does this activity involve the use of living (viable or non-viable) human embryos.	
Section 2: HUMANS	YES/no
Does this activity involve human participants.	

If any YES... → Ethics Self-assessment

(1b) Ethics Self-assessment

HE Regulation (art. 19.2): to detail all ethics issues of the proposal, confirm compliance with HE ethical principles/relevant legal framework and describe how it will be ensured



➤ **'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 not eligible for funding</i>	<i>Research not eligible for funding</i>
	Are they previously established cells lines?			1) Origin and line of cells.	1) Copies of ethics approval.
	...			2)...	2)...

(2) Ethics Screening

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

→ *No ethics issues* → **CLEARED**

→ *Ethics issues* → **FLAGGED**

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

→ **!** Experts can require ethics review* or external independent ethics advisor or board

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



Ethics screening - Key changes...

Horizon 2020

Pre-screening /
Screening

→ Formulation of Ethics Requirements
= contractual obligations in Grant
Agreement

Horizon Europe

Full Screening
for all proposals

Ethics Issues → Flagged, but no
requirements are formulated

...and similarities

Ethics Assessment for proposals **raising complex/serious ethics issues**
(including **hE and hESC**)

Independent ethics advisor or board can be required

Ethics Reviews* can be required and technical reviews can check ethics issues

(3) Ethics Assessment *(similar to H2020)*

An **in-depth analysis** of the ethics issues for:

- All **hE or hESC** proposals
- Proposals raising **serious and/or complex ethics issues**
- 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
 - may not have exclusive focus on civil applications
 - raises multiple or 'intersectional' ethics issues (e.g. research into marginalised or vulnerable individual groups that exposes them to the risk of stigmatization, exclusion, reprisals or increased marginalisation)
 - 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
 - ...



<https://twitter.com/GoldingCartoons/status/1101341612121026560/photo/1>

(3) Ethics Assessment

Possible Outcomes

1. **ETHICS CLEARANCE** → GA is finalized
2. **CONDITIONAL CLEARANCE** → Requirements need to be fulfilled, contractual obligations are included in GA
3. **Second ethics assessment** → GA is postponed
4. **NO ETHICS CLEARANCE** → Proposal cannot be funded

(4) Ethics Review*

- During the lifetime of the project

When are Ethics Reviews* requested?

- For projects raising complex or difficult 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)

Full ethics review (5 experts) v **technical review** (lighter procedure – ‘ethics check’*)

** New terminology, ethics reviews are equivalent to the H2020 ethics check. ‘Ethics check’ now refers to lighter procedure.*



Ethics Appraisal Process (overview comparison)

Horizon 2020

Horizon Europe

Screening

Assessment

Review

- Expert-driven
- Pre-screening / Screening
- Requirements (GA obligations)
- May request ethics review
- May request ethics advisor/board
- Requested by screening for complex / serious ethics issues and hE/hESC
- Requested by screening/assessment for monitoring of ethics issues

- = Expert-driven
- ≠ Full Screening of all proposals
- ≠ Flagging of issues (no requirements)
- = May request ethics review
- = May request ethics advisor/board
- = Requested by screening for complex / serious ethics issues and hE/hESC
- = Requested by screening/assessment for monitoring of ethics issues
- ≠ Increased possibility of technical reviews of ethics issues ('ethics check')

Ethics and Grant Agreement Preparation (GAP) - Time to grant

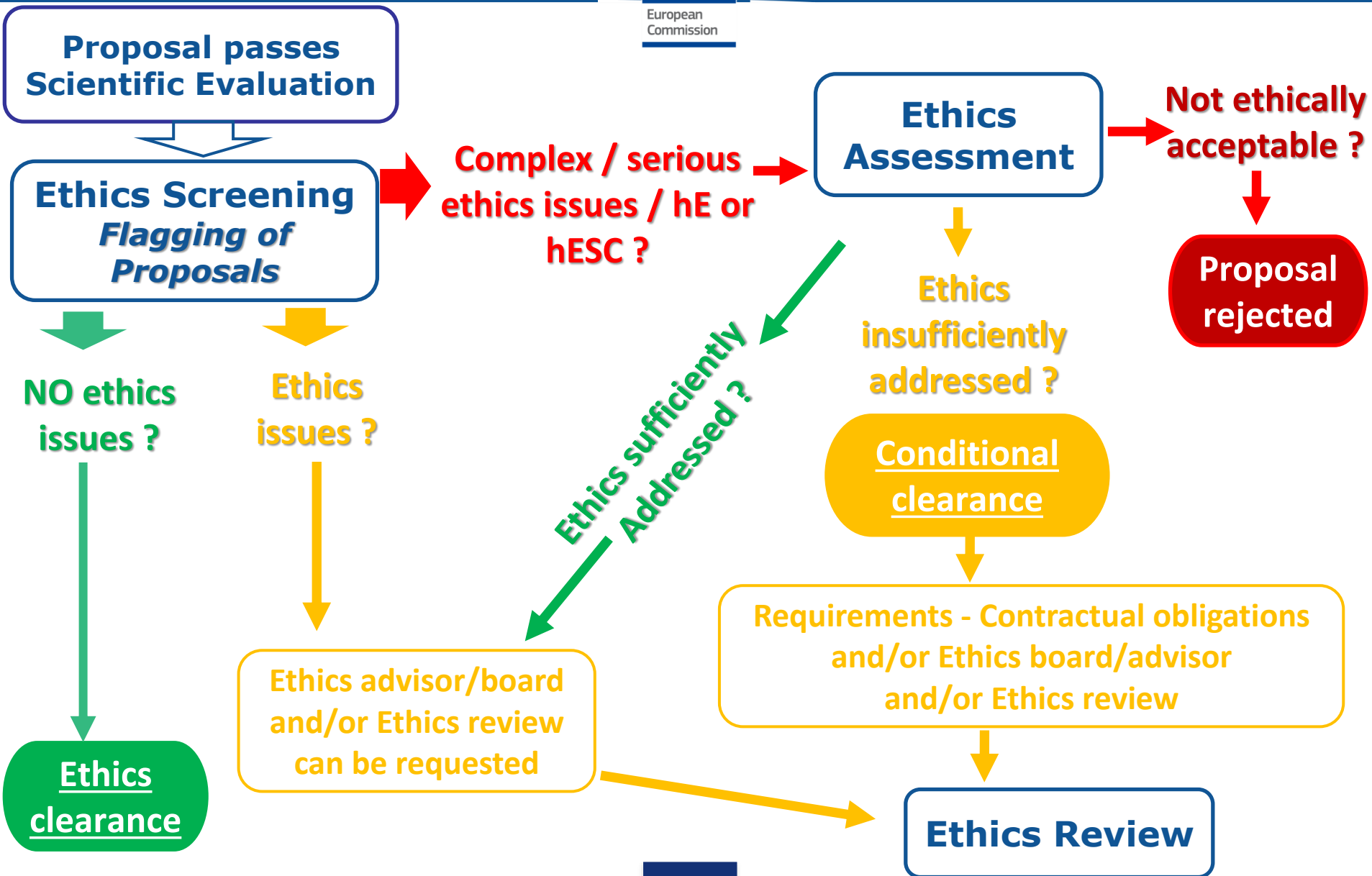
From the submission of proposals, the Regulation (Article 28) establishes:

- a maximum period of five months to inform all applicants of the outcome of the evaluation
- a maximum period of eight months to sign all grant agreements with successful applicants

However...

The periods set forth by the regulation may be exceeded when actions are submitted to an **ethics assessment**

Ethics Review





HELP is on its way!

- 1. Ethics help desk:** RTD-ETHICS-REVIEW-
HELPDESK@ec.europa.eu
- 2. How to complete your Ethics Self-Assessment**
- 3. Serious and Complex cases guide**
- 4. Data protection guidance**
- 5. Social sciences guidance**
- 6. Informed consent guidance**
- 7. Horizon Europe Regulation**
- 8. General Model Grant Agreement**
- 9. European Code of Conduct for Research Integrity**
- 10. Charter of Fundamental Rights of the European Union**