# Promoting an Ethics Framework for Research and Innovation

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# Outline

1. Ethics in H2020: Main principles and legislation
2. The ethics appraisal process
3. Emerging challenges

# 1. Ethics in H2020: Main principles and legislation

## Article 19 "Ethical Principles" - Regulation 1291/2013

All the research and innovation activities carried under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols

# 1. Ethics in H2020: Main principles and legislation

## Article 19 "Ethical principles"

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 high levels of human health protection.

# 1. Ethics in H2020: Main principles and legislation

## Article 19.3

The following areas will not be funded:

- 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.

# 1. Ethics in H2020: Main principles and legislation

Compliance with ethics principles is also prescribed by Article 34 of the **Grant Agreement**:

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity —as set out, for instance, in the European Code of Conduct for Research Integrity—and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

# 1. Ethics in H2020: Main principles and legislation

## Article 14 - Regulation 1290/2013

## Ethics review

1. The Commission shall systematically carry out ethics reviews for proposals raising ethical issues. That review shall verify the respect of ethical principles and legislation and, in the case of research carried out outside the Union, that the same research would have been allowed in a Member State.

# 2. Ethics appraisal steps

1. Ethics **Self-Assessment** (application phase-by the applicant)

2. The Ethics **Review** (before the finalisation of GA-by ethics experts)

   i) An Ethics Pre-screening/Screening;
   ii) An Ethics Assessment.

3. The Ethics **Checks** (for selected projects, after the signature of the GA-by ethics experts)

# Proposal Part A

Section 4 'Ethics Issues Table' :

1. Human embryo/foetuses
2. Human beings
3. Human cells/tissues
4. Personal data
5. Animals
6. Non-EU countries
7. Environment, health & safety
8. Dual-use
9. Exclusive focus on civil applications
10. Misuse
11. Other ethics issues

# 2. The ethics appraisal process:
# 2.1 Ethics self-assessment
## Part A

**1.1 Ethics issues checklist**

| Section 1: HUMAN EMBRYOS/ FOETUSES | | YES/NO | | Page | Information to be provided | Documents to be provided/kept on file |
|---|---|---|---|---|---|---|
| **Does your research involve Human Embryonic Stem Cells (hESCs)?** | | ☐ | ☐ | | | |
| If YES: | - Will they be directly derived from embryos within this project? | ☐ | ☐ | | *Research not eligible for funding* | *Research not eligible for funding* |
| | - Are they previously established cells lines? | ☐ | ☐ | | Origin and line of cells.<br>Details of licensing and control measures by the competent authorities of the Member States involved. | Copies of Ethics Approval.<br>A statement that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hescreg.eu) — both for hESCs and human-induced pluripotent stem cell (hiPSC) lines.<br>A statement confirming that the 6 specific conditions *(see* |

If 'yes' for any questions, ethics self-assessment to be completed in **Part B**

# 2. The ethics appraisal process:
# 2.1 Ethics self-assessment
## Part B

***Please refer to submission system for the definitive template for your call***

**Section 5: Ethics and Security**

⚠ *This section is not covered by the page limit.*

**5.1 Ethics**

If you have entered any ethics issues in the ethical issue table in the administrative proposal forms, you must:

- submit an ethics self-assessment, which:
  - describes how the proposal meets the national legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out;
  - explains in detail how you intend to address the issues in the ethical issues table, in particular as regards:
    - research objectives (e.g. study of vulnerable populations, dual use, etc.)
    - research methodology (e.g. clinical trials, involvement of children and related consent procedures, protection of any data collected, etc.)
    - the potential impact of the research (e.g. dual use issues, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing, malevolent use , etc.).
- provide the documents that you need under national law(if you already have them), e.g.:
  - an ethics committee opinion;
  - the document notifying activities raising ethical issues or authorising such activities

⚠ *If these documents are not in English, you must also submit an English summary of them (containing, if available, the conclusions of the committee or authority concerned).*

⚠ *If you plan to request these documents specifically for the project you are proposing, your request must contain an explicit reference to the project title.*

ble, not to complete

Explain how the ethics issues will be addressed

Demonstrate compliance with ethical and legal requirements

Provide appropriate documents as evidence if required or already obtained

# Ethics Review


Proposal passes the scientific evaluation

Pre-screening

Ethics issues

Screening

Critical ethics issues (additional information might be necessary)

Assessment

negative ethics opinion

Proposal rejected on ethical grounds

NO ethics issues

Ethics issues well addressed and documents provided

Proposal receives ethics clearance

Ethical issues partially addressed

*Requirements to be implemented*

Proposal receives conditional ethics clearance

# 2. Ethics appraisal steps:
# 2.2 Ethics Review

## A. ETHICS PRE SCREENING AND SCREENING

Concern **all proposals above threshold** and considered for funding.

- **Pre-screening** (for proposals with **no declared ethics issues**):
  1. Confirmation of no ethics issues = "ethics clearance"
  2. Ethics issues identified= Ethics Screening required
- **Ethics Screening** ( for proposals with **at least one confirmed ethics issue**)

The Ethics Screening is carried out **during the scientific evaluation or soon after**, by **at least two independent ethics experts.**

# 2. Ethics appraisal steps:
# 2.2 Ethics Review

A. ETHICS SCREENING OUTCOMES

1. The Proposal is **"ethics-ready"** the GA can be finalised.
2. **Conditional clearance**
Experts formulate requirements which become contractual obligations. These requirements constitute the condition to be fulfilled and, on this basis, the GA can be finalised.
3. **Ethics Assessment**
For proposals with complex ethics issues (e.g. severe intervention on humans) an Ethics Assessment prior to the signature of the GA may be recommended.

# Ethics Review


Proposal passes the scientific evaluation

Pre-screening

Ethics issues

Screening

Critical ethics issues (additional information might be necessary)

Assessment

negative ethics opinion

Proposal rejected on ethical grounds

NO ethics issues

Ethics issues well addressed and documents provided

Proposal receives ethics clearance

Ethical issues partially addressed

*Requirements to be implemented*

Proposal receives conditional ethics clearance

# 2. Ethics appraisal steps:
# 2.2 Ethics Review

B. ETHICS ASSESSMENT

An **in-depth analysis** of the ethics issues for:
Proposals flagged by the screening experts
All hESC proposals

Carried out by a panel consisting of **at least 5 independent ethics experts**

# 2. Ethics appraisal steps:
# 2.2 Ethics Review

B. ETHICS ASSESSMENT OUTCOMES:

1. **Ethics Clearance:** The applicants provided the necessary information, the **GA can be finalised.**

2. **Conditional Clearance: experts formulate requirements**
Some need to be fulfilled before the signature of GA, whilst others become contractual obligations.
*Conditions may include:*

*Regular reporting to the Commission/Executive Agency;*

*Appointing an Independent Ethics Advisor or Ethics Board;*

*Further Ethics Check at a later stage;*

*Submission of further information/documents; or*

*Adapting project methodology to comply with ethics principles and relevant legislation*

# 2. Ethics appraisal steps:
# 2.2 Ethics Review

B. ETHICS ASSESSMENT OUTCOMES:

3. **Second Ethics Assessment:** The experts consider that the elements submitted by the applicant are insufficient.
The **signature of the GA** agreement is **postponed** until the conclusion of the second Ethics Assessment.

4. **No ethics clearance**

# 2. Ethics appraisal steps:
# 2.3 Ethics Checks

Following the conclusion of the Ethics Review at the initiative of the Ethics Experts, an Ethics Check can be undertaken, during the lifetime of the project.

**When are Ethics Checks requested?**

- For projects raising complex or difficult ethics issues;
- Documents provided are unsatisfactory;
- Compliance with ethics requirements needs to be checked during the implementation;
- For issues related to breaches of research integrity, in particular scientific misconduct.

# 2. Ethics appraisal steps:
# 2.3 Ethics Checks

The objective of the procedure is to:

- **assist the beneficiaries** to deal with the ethics issues raised by their research and if necessary
- **to take preventive or/and corrective measures** primarily on the basis of the requirements of the Ethics Reports and, when available, the reports of the ethics advisor/board.

The Checks **can result in an amendment** to the GA and, in severe cases, potentially lead to a **reduction of the grant**, its **termination** or any other appropriate measures, in accordance with the provisions of the GA.

# 3. Challenges

1. Low awareness of researchers regarding ethics

(especially in social sciences)

2. New challenges stemming from IT and other emerging technologies (e.g. big data)

3. Ethics appraisal vs implementation of law

4. Finding a balance between promoting research and innovation and maintaining the highest level of research ethics


# THANK YOU
# FOR YOUR ATTENTION!