The Ethics Appraisal in H2020

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Ethics Appraisal

The Ethics Appraisal procedure concerns all activities funded in Horizon 2020.

The aim is to ensure that the provisions on ethics in H2020 regulation and in the Rules for Participation are respected.

It is also complementary with the Article 34 of the Grant Agreement on "Ethics".

H2020 regulation: Article 19 "Ethical principles"

1. All the research and innovation activities carried out 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.

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 and the need to ensure high levels of human health protection.

2. Research and innovation activities carried out under Horizon 2020 shall have an exclusive focus on civil applications.

H2020 Regulation: Article 19 "Ethical principles"

3. The following fields of research shall not be financed:
(a) research activity aiming at human cloning for reproductive purposes;
(b) research activity intended to modify the genetic heritage of human beings which could make such changes heritable
(c) 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.

4. 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 granted for research activities that are prohibited in all the Member States. No activity shall be funded in a Member State where such activity is forbidden. See also Statements by the Commission in the H2020 Reg.

5. The fields of research set out in par. 3 may be reviewed within the context of the interim evaluation set out in Article 32(3) in the light of scientific advances.

Rules for Participation: Article 13 "Proposals"

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2. Any proposal for research on human embryonic stem cells shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethical approvals that will be provided. As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member States concerned.

3. A proposal which contravenes ethical principles or any applicable legislation, or which does not fulfil the conditions set out in .... the work programme, in the work plan or in the call for proposals may be **excluded from the evaluation, selection and award procedures at any time.**

…

Rules for Participation: Article 14 "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. The Commission shall make the process of the ethics review as transparent as possible and ensure that it is carried out in a timely manner avoiding, where possible, resubmission of documents.

Recital 9

…. Actions should be in conformity with …. ethical principles, which include avoiding any breach of **research integrity**.

Grant Agreement (GA): Article 34 "Ethics"

34.1 **General obligation** to comply with ethical principles

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.

Funding will be not granted for activities carried out outside the EU if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:
Same exclusions as in Article 19 of the H2020 Regulation

Grant Agreement (GA): Article 34 "Ethics"

34.2 **Activities raising ethical issues**

Activities raising ethical issues **must comply with the 'ethics requirements' set out in Annex I**.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the Commission copy of:

(a) **any ethics committee opinion** required under national law and
(b) **any notification or authorisation** for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned). *(these are brief summaries only ! See annotated article for specific details).*

If these documents are **specifically requested for the action**, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all submitted documents specifically cover the action tasks.

Grant Agreement (GA): Article 34 "Ethics"

34.3 **[OPTION]** Activities involving **human embryos or human embryonic stem cells**

34.4 Consequences of **non-compliance**

If a beneficiary breaches any of its obligations under this Article, **the grant may be reduced** (see Article 43) **or terminated** (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ETHICS APPRAISAL STEPS

1. Ethics **Self-Assessment**

2. The Ethics **Review** (before the finalisation of GA)

   i) An Ethics Screening;
   ii) An Ethics Assessment.

3. The Ethics **Check** and **Audit** (for selected projects, after the signature of the GA)

ETHICS APPRAISAL FOCUS

The main areas that are addressed during the Ethics Appraisal procedure include:

1. Human Protection (including the study participants and the researchers)
2. Animal Protection and Welfare
3. Data protection and privacy
4. Environment protection
5. Participation of third countries
6. Dual use
7. Misuse/Malevolent use of research results

Applicants' Ethics Self-assessment

For all proposal an Ethics Issues Table (EIT) must be completed and if at least one issue is signalled the applicants must:

i) Describe **how the proposal meets the national legal and ethical requirements** of the country(ies) where the tasks raising ethical issues will be performed and provide a copy of any already obtained ethics committee opinion, required notification or authorisation.

ii) **Discuss in detail how the ethics issues** identified in the Ethics Issues Table, will be addressed in particular in relation to:

- the **research objectives** per se (e.g. study of vulnerable populations, dual use, etc.)
- the **research methodology** (e.g. clinical trials, involvement of children and related consent procedures, protection of data collected etc.)
- the **potential impact** of the research (e.g. questions related to dual use, environmental damages, population stigmatisation, political or financial retaliation, benefit sharing, malevolent use, etc.).

ETHICS REVIEW

1) ETHICS SCREENING

Concerns all proposals above threshold and considered for funding.

Starts with Ethics a **pre-screening** (minimum two ethics experts) and takes into account the Self-assessment. The objective of the pre-screening is to identify (potential) ethical issues but not to assess them.

Proposals with **at least one confirmed ethical issue** will be subject to an **Ethics Screening**.

Proposals involving the use of Human Embryonic Stems Cells (hESCs) automatically undergo an Ethics Assessment.

The Ethics Screening is carried out during the scientific evaluation or soon after. Each proposal will be screened by at least two independent ethics experts (they can be the same experts who performed the pre-screening)

The possible outcomes of the Ethics Screening are:

1. The Proposal is **"ethics-ready"** the GA can be finalised

2. **Conditional clearance**
Experts formulate requirements which will become contractual obligations. These requirements constitute the condition to be fulfilled and, on this basis, the grant preparation can be finalised.

3. **Ethics Assessment**
For a limited number of proposals with complex ethical issues (e.g. severe intervention on humans, etc.) the Screening panel can recommend an Ethics Assessment prior to the signature of the GA and, if appropriate, list the additional information to be provided.

4. No Ethics clearance
Negative Ethics Opinion

ETHICS REVIEW

2) ETHICS ASSESSMENT

An in-depth analysis of the ethical issues performed on the proposals flagged by the Ethics Screening experts, by the Commission and for all HESC proposals.

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

Takes into account, when available, the analysis done by during the Ethics Screening as well as the information provided by the applicants in response to the Ethics Screening.

The possible outcomes of the Assessment are:

1 The applicants provided the necessary elements, the **GA can be finalised**.

2. **Experts formulate requirements**
Some to be fulfilled before the signature of GA the others becoming contractual obligations (Annex I). The experts may also recommend an Ethics Check and indicate the appropriate timing.

3. The experts consider that the elements submitted are not sufficient and request a **second Ethics Assessment**, indicating the weaknesses to be addressed and the information to be provided.
The **signature of the GA** agreement is **postponed** up until the results of the second Ethics Assessment.

ETHICS CHECKS and AUDITS

Following the conclusion of the Ethics Review at the initiative of the Ethics Check can be undertaken.

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 Review Reports and, when available, the reports of the ethics advisor/board.

Whenever appropriate the concerned **beneficiaries may be invited** to a meeting **in Brussels** to discuss the issues at stake. **On site visits** can also be organised.

ETHICS CHECKS and AUDITS

The Checks may also address issues related to breaches of **research integrity**, in particular scientific misconduct.

In case of substantial breach of ethical principles, research integrity, or relevant legislation an Ethics Audit can be undertaken. The procedure is foreseen in the GA (Article 22 on "Checks and Audits").

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

Ethics Advisors and Ethics Boards

On the basis of the experts opinion, or at the Commission request the beneficiaries may be asked appoint an **independent** ethics advisor or ethics board.

One of the tasks may be to **report** to the Commission **on compliance with the requirements** included in the Ethics Reports

Research carried out outside the EU

The applicants must confirm that the proposed research is compatible with the Union and International legislation and could have been legally conducted in one of the EU Member States.

This compatibility can be confirmed by an appropriate EU local or national ethics structure. If the applicants state that there are no such structures to give a positive opinion for the proposed research, the conclusions of the Ethics Review organised by the European Commission will be the binding opinion.

THANK YOU