

# **WG3.3: Ethics issues (legal elements) in H2020 Actions *post-award phase***

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## Content:

### **1. H2020 regulation on ethic issues – implementation phase**

- *Article 19 of the REGULATION No 1291/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 establishing Horizon 2020*
- *MGA - Article 34*

### **2. Ethics appraisal scheme : post-award phase**

### **3. Ethics checks and audits**

## **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**.

**\* REGULATION No 1291/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 establishing Horizon 2020**

## **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.
5. The fields of research set out in paragraph 3 may be reviewed within the context of the interim evaluation set out in Article 26(1) in the light of scientific advances.

## **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.
- (c) Funding** will be granted for activities carried out outside the EU **only if the same activities are allowed by any Member State.**

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 than in the 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 50) 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).

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**

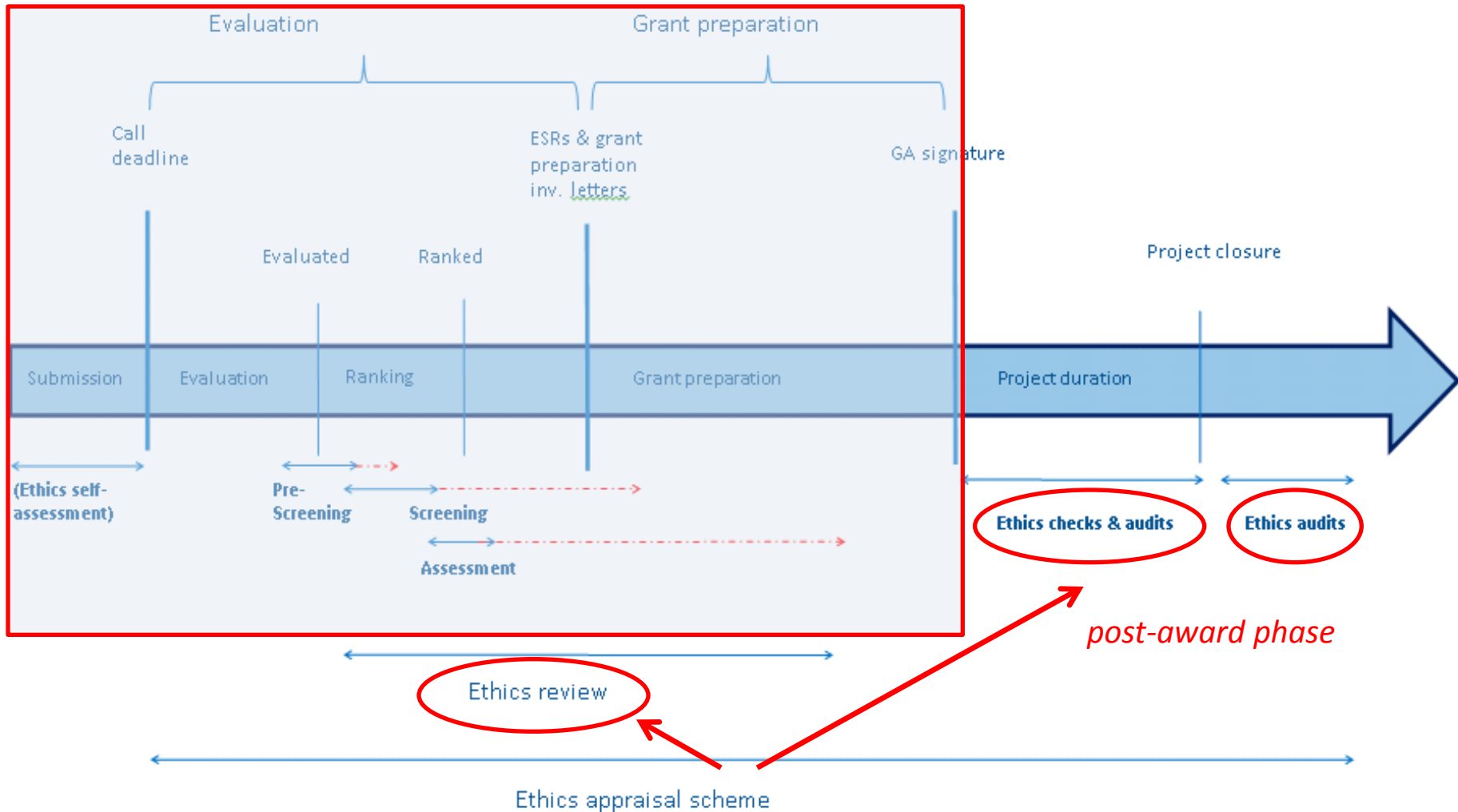
If a beneficiary breaches any of its obligations under this Article, **the grant may be reduced** (see Article 41) **or terminated** (see Article 48).

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



**Ethics appraisal scheme**

*pre-award phase*



*post-award phase*



## **ETHICS CHECKS and AUDITS**

During the project and up to 2 years afterwards if necessary.

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 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).

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.

## When to request an Ethics Check?

- In case of complex and difficult ethics issues
- Documents provided are not satisfactory
- Compliance with ER requirements needs to be checked during the implementation
- Following whistleblowing

## 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**.

### Relevant sources:

1. **REGULATION** (EU) No 1291/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 **establishing Horizon 2020** - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC
2. **REGULATION** (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the **rules for participation and dissemination in "Horizon 2020** - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006
3. **Research Participant Portal** -  
<http://ec.europa.eu/research/participants/portal/desktop/en/home.html>
4. **H2020 Annotated Model Grant Agreement**
5. **H2020 Online Manual** [http://ec.europa.eu/research/participants/docs/h2020-funding-guide/index\\_en.htm](http://ec.europa.eu/research/participants/docs/h2020-funding-guide/index_en.htm)

**Thank you for your attention!**