



***COFUND Beneficiaries Meeting
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ETHICAL ISSUES in MSCA COFUND

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Overview of the presentation:

- **Introduction to Ethics in H2020 projects**
- **EC Ethics appraisal procedure-adaptation for COFUND**
- **EC ethical clearance for projects with hESC**





Horizon 2020 Model Grant Agreement

Article 34 – Ethics

- **34.1** – Obligation to comply with ethical principles
- **34.2** – Activities raising ethical issues
- **34.3** – Activities involving human embryos or hESC

Article 39 – Processing of Personal Data



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 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.

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



Grant Agreement (GA): Article 34 "Ethics"

34.2 Activities raising ethical issues (changes as of 20th July 2016)

ARTICLE 34 – ETHICS AND RESEARCH INTEGRITY

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the 'ethics requirements' set out as deliverable in Annex 1.

Before the beginning of an activity raising an ethical issue, ~~the coordinator must submit (see Article 52) to the [Commission][Agency] copy of~~ each beneficiary must have obtained:

- (a) any ethics committee opinion required under national law and
- (b) any notification or authorisation for activities raising ethical issues required under national and/or European law, needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the [Commission][Agency] (see Article 52). ~~If these documents they are not in English, the coordinator they must be also submitted together with an English summary, which shows that the action tasks in question are covered, and includes of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned (if available)).~~

~~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 the submitted documents cover the action tasks.~~



Rules for Participation of Horizon 2020

Article 13 – Proposals

Article 14 – Ethics Review

Article 18 – Grant Agreement

Article 23 – Implementation of Actions



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.
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.



ETHICS APPRAISAL FOCUS

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

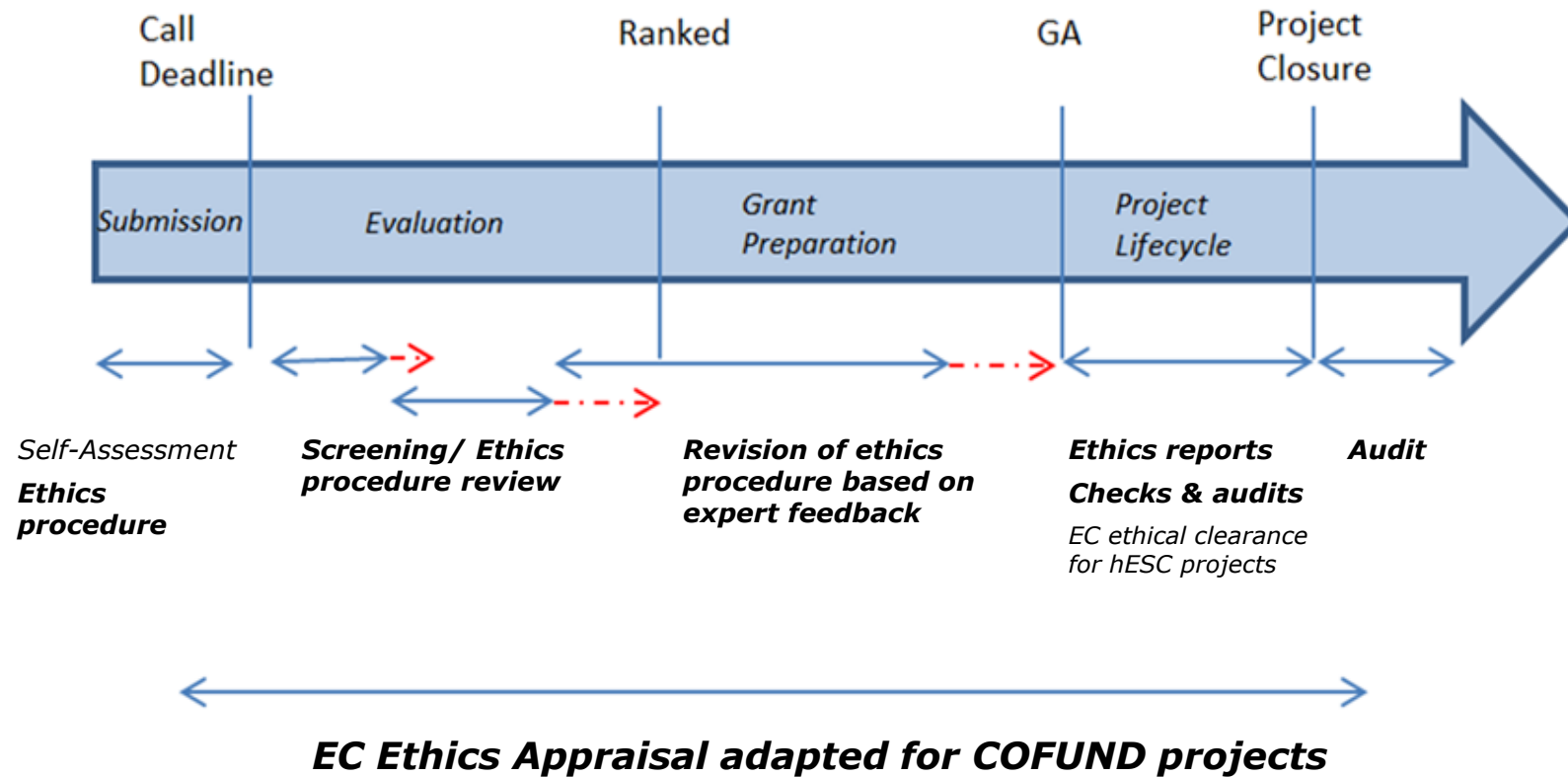
1. Human embryos and fetuses
2. Humans
3. Human cells/tissues
4. Personal data
5. Animals
6. Third countries/ Non-EU Countries
7. Environment & Health and Safety
8. Dual use
9. Misuse
10. Other issues (Ethics & Research Integrity)



EC 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)

EC Ethics appraisal procedure-adaptation for COFUND





Ethics procedure in COFUND projects:

- should have an overall approach and be **integrated in the different phases of the project lifecycle** from the application and selection/ evaluation to implementation and monitoring of individual research projects
- **should be able to address any ethics issues identified under H2020- 9 ethics issues** (see the Ethics self-assessment table)
- procedure to be adapted based on the evolving needs and lessons learned



Deliverables on Ethics- Ethics Reports:

Frequency: 1 Ethics Report after each call and a Final Ethics Report (included in the Final Report)

Content:

- A short description on how the ethics procedure in place was followed and the adaptations made if relevant
- A list containing: name of the researcher; the title of research project with ethical issues; the ethics area(s) concerned; conditions to be fulfilled for funding and ethics requirements to be monitored during implementation; follow-up during the implementation.



Prior EC ethical clearance needed for projects with hESC:

- An individual research project under a **COFUND grant can only be funded** following an **EC ethical clearance (EC ethics review and positive opinion from Member States Programme Committee)**
- EC ethical clearance is given on project basis and only for the cell lines mentioned in the project application
- **Ethics requirements** mentioned in the EC Ethics Review Report are **becoming contractual obligations** and will be closely monitored by REA
- Legal basis: [Statement by the Commission \(OJ C 373, 20.12.2013, p.12\)](#)



What is expected from the beneficiaries:

Important!: *It is the beneficiaries' obligation to contact the REA project officer if they intend to fund an individual research project using hESC in order to obtain the EC ethics clearance.*

Documents to be submitted to REA for the EC ethics clearance (non-exhaustive list):

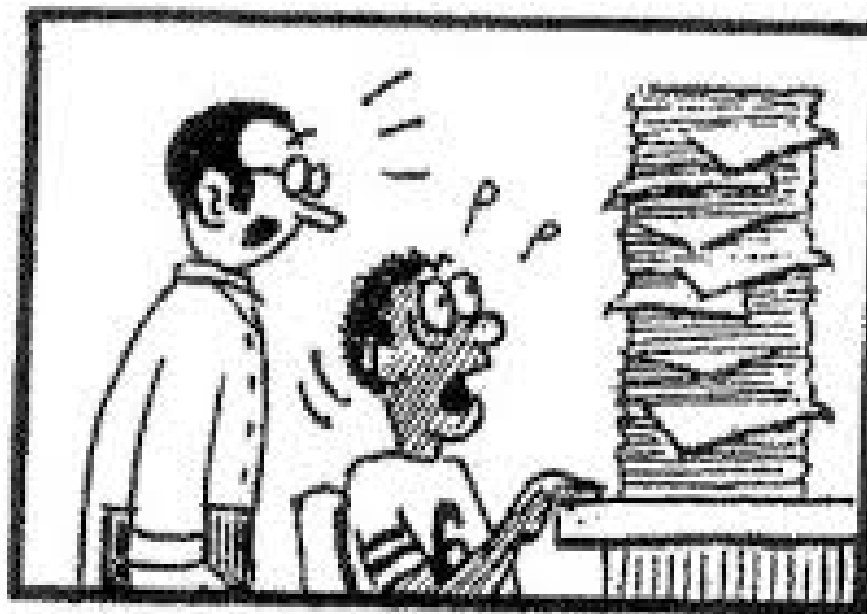
- The Research Proposal involving the use of hESC
- Scientific justification from the evaluation panel/committee stating that "Use of human embryonic stem cells is necessary to achieve the scientific objectives set out in the proposal"
- Ethics review report
- Proof of registration of the HESC lines concerned in the European hESC registry or a signed statement that the registration will be done before the start of the project
- Copies of local ethics approvals/ authorisations



Horizon 2020 Ethics Documents

- ✓ **Participant Portal H2020 Ethics section:**
http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm
- ✓ **Ethics issues Self-Assessment Guidance:**
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf
- ✓ **Link to the Ethics Issues Table template:**
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/ethics-eit_en.pdf
- ✓ **H2020 Online Manual:**
http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

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*"The biggest risk in this study is just
reading the consent form!"*