European Commission

H2020-ITN-2015 Coordinators Day

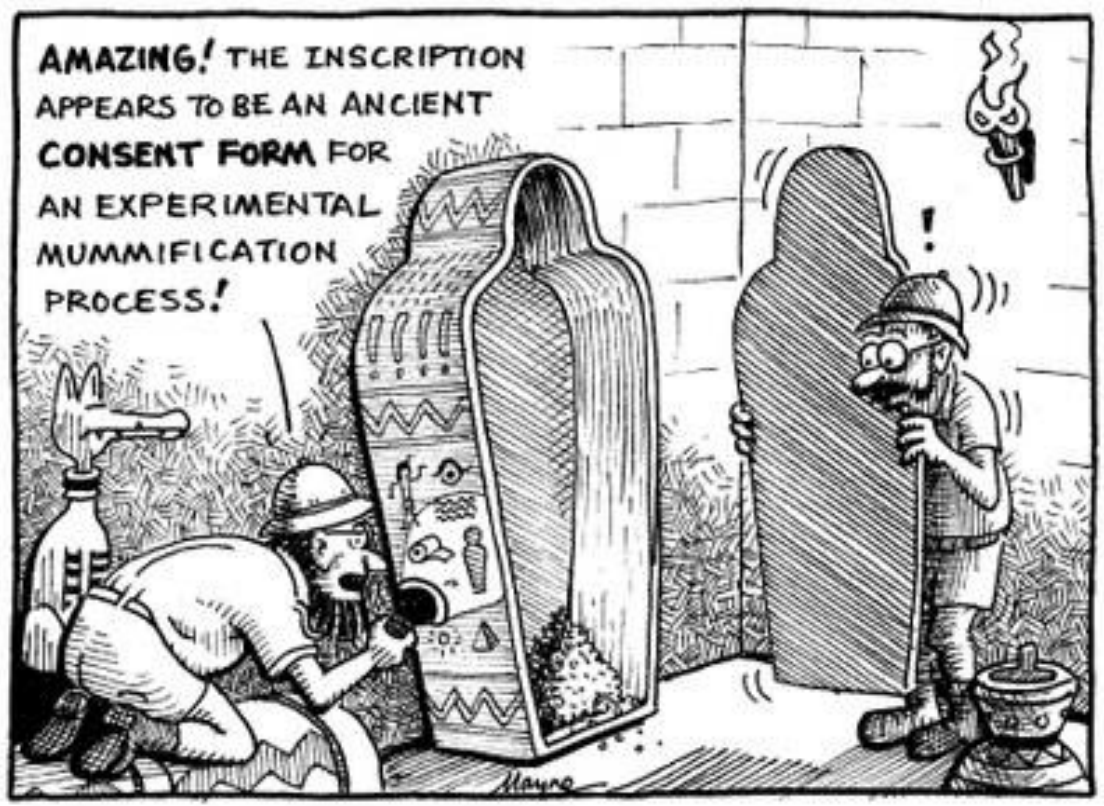
Ethics & Research Integrity

Timea BALOGH

Research Executive Agency
Unit REA-A1

Research Executive Agency

European Commission



Research Executive Agency

European Commission

Rules for Participation of Horizon 2020

Article 13 – Proposals

Article 14 – Ethics Review

Article 18 – Grant Agreement

Article 23 – Implementation of Actions

Research Executive Agency

European Commission

Horizon 2020
Model Grant Agreement

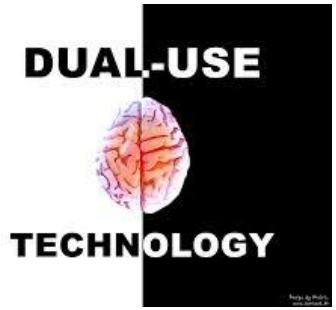
Article 34 – Ethics

- **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

Research Executive Agency

Importance of Research Ethics in H2020



- ✓ **Research ethics** is crucial for **all scientific domains** (NOT only in Life Sciences). For example:
  - **Data protection & Privacy**
  - **Dual use** issues
  - **Environmental risks and safety** issues
  - **Research integrity** aspects

- ✓ In Horizon 2020, **all proposals** considered for funding will be submitted to an **Ethics Review** procedure.

Ethics Self-Assessment Guidance

European Commission

Key document for applicants and beneficiaries

⚠

Regularly updated

3. Human cells/tissues

This section refers to research using, producing or collecting human cells or tissues.

Such cells or tissues may:

- be obtained from commercial sources
- originate from another laboratory, institution or biobank
- be produced or collected by you during previous research activities or
- be produced or collected by you as part of this research project.

3.1 Ethics issues checklist

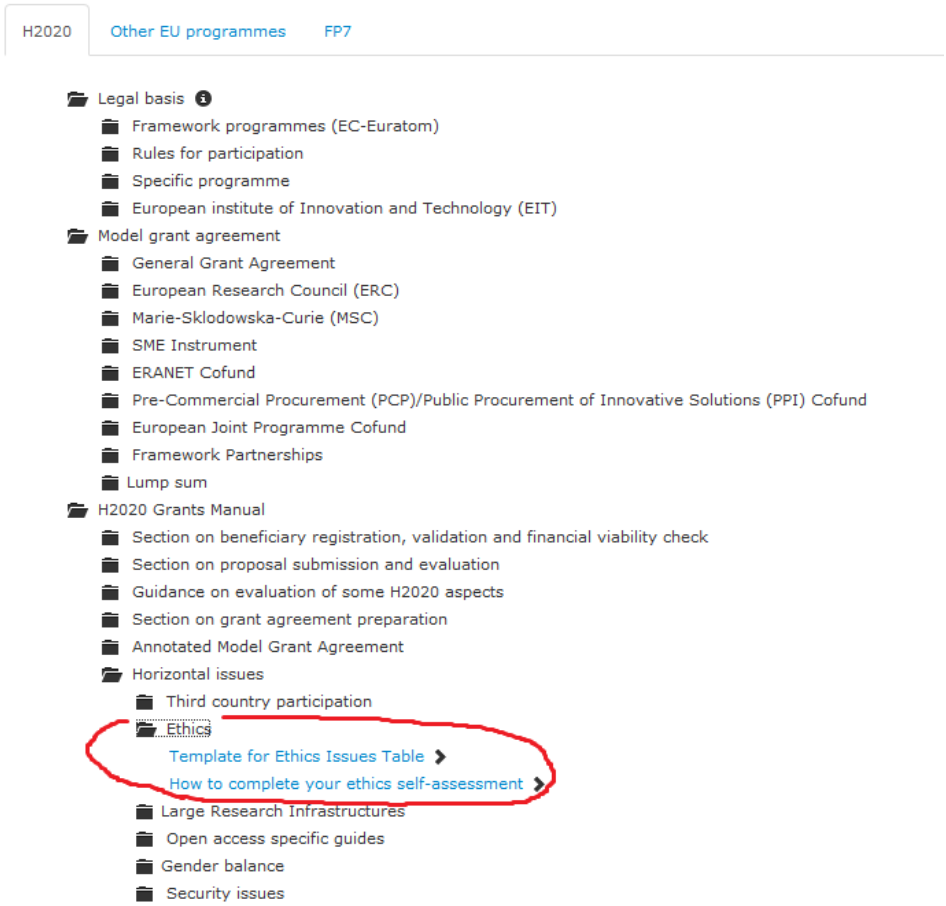
Section 3: HUMAN CELLS / TISSUES	YES/ NO		Page	Information to be provided	Documents to be provided
Does your research involve human cells or tissues (other than from Human Embryos/Foetuses, *see section 1*)?	☐	☐		Details of the cells/ tissue types. **plus:**	Copies of relevant Ethics Approvals. Copies of accreditation/designation/authorisation/ licensing for using, processing or collecting the human cells or tissues (if required), **plus:**

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

Research Executive Agency

Where to find the Ethics Self Assessment Guidelines

On the Participant Portal…



Agency

Main ethics issues

The main areas that are addressed during the Ethics Appraisal procedure and in the **Ethics Self-Assessment guidance** document include:

1. **Human embryos and foetuses**
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)**

European Commission

1-Ethics issues Checklist:

Section 1: HUMAN EMBRYOS/ FOETUSES		YES/NO		Page	Information to be provided	Documents to be provided
Does your research involve Human Embryonic Stem Cells (hESCs)?		☐	☐			
If **YES:**	- Will they be directly derived from embryos within this project?	☐	☐		*Research cannot be funded.*	*Research cannot be funded.*
	- Are they previously established cells lines?	☐	☐		Origin and line of cells. Details on licensing and control measures by the competent authorities of the Member States involved.	Copies of Ethics Approval. 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.

2- How to deal with the issues

3- What do the applicants/beneficiaries need to provide ?

4- Documents and links

Research Executive Agency

European Commission

Third Countries (Non-EU countries)

Only applicable when Ethical issues are raised

✓ **Possible ethical issues:**

non-compliance with Horizon 2020 ethics rules, health and safety risks for researchers & staff, potential exploitation of research participants and/or local resources in low/lower middle income countries

✓ **Information to be provided:**

details on activities carried out in non-EU countries, type of local resources to be used and modalities for their use, type of materials or data to be exported/imported, benefit sharing measures, responsiveness to local research needs, procedures to facilitate effective capacity building (for low income countries), safety measures, confirmation that the activities implemented in Third Countries comply with Horizon 2020 ethics rules

✓ **Documents to be provided:**

if applicable: copies of relevant Ethics Approvals and other authorisations or notifications, Material Transfer Agreement and copies of any authorisations, authorisation for export from EU, insurance cover

✓ **Applicable legislation:**

- Declaration of Helsinki: http://www.wma.net/en/30publications/10policies/b3/
- Convention on Biological Diversity: http://www.cbd.int/ and Nagoya Protocol: http://www.cbd.int/abs
- Commission decisions on the adequacy of the protection of personal data in Third Countries: http://ec.europa.eu/justice/data-protection/document/international-transfers/adequacy/index_en.htm
- Data transfer to the US: Safe Harbour Agreement is invalid

Environmental Protection

- ✓ **Possible ethical issues:**
  harm to the environment can occur as part of the experimental design of the research and as the result of undesirable side-effects of the technologies.

- ✓ **Information to be provided:**
  details on risk-benefit analysis, *if applicable*: demonstrate the application of the precautionary principle

- ✓ **Documents to be provided:**
  safety classification of laboratory, *if applicable*: GMO authorisation and specific approvals, *if applicable*: specific authorisations if dealing with endangered fauna and/or flora/protected areas

- ✓ **Applicable legislation:**
  - The precautionary principle: http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm
  - Council Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0043:EN:HTML
  - Council Directive 79/409/EEC on the conservation of wild birds: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31979L0409:en:HTML
  - Council Regulation (EC) 338/97 on the protection of species of wild fauna & flora by regulating trade therein: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997R0338:en:NOT
  - Directive 2009/41/EC on the contained use of genetically modified micro-organisms: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009L0041:en:NOT
  - Cartagena Protocol on Biosafety: http://bch.cbd.int/protocol/

Dual Use/Misuse/Exclusive Civilian Focus

Please refer to the three notes:

- ✓ Dual Use

http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-dual-use_en.pdf

- ✓ Misuse

http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-misuse_en.pdf

- ✓ Exclusive Civilian Focus

http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-civil-apps_en.pdf

Export Control

PLEASE CHECK THE RISK TABLE IN THE MANAGEMENT SECTION OF THE DoA!

Specific Ethics Issues

✓ Humans

- This ethics issue refers to the individuals participating in the research (i.e., patients, healthy volunteers), NOT to the researchers
- Do not confuse "volunteers for social or human sciences research" (question 1.1) with "healthy volunteers for medical studies" (question 1.6)

✓ Data Protection

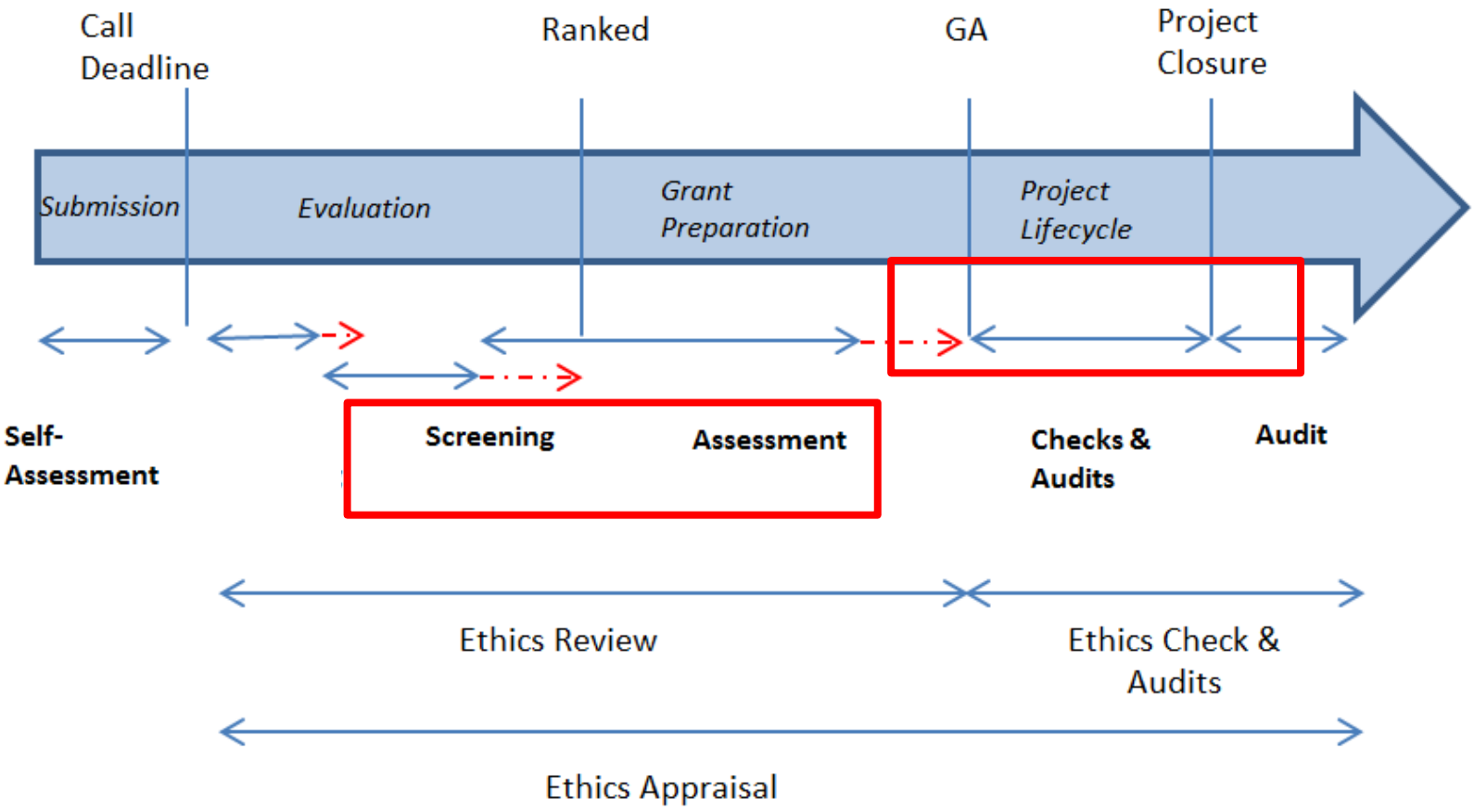
- Scientific Workshops organised by the project with the participation of researchers do NOT raise ethical issues and should not be flagged
- Beneficiaries should comply with Art 39.2

Ethics appraisal in H2020

All mainlisted proposals are carefully verified by ethics experts to see if there are any ethics issues raised in the proposal.

The implementation of ethics issues is monitored during the entire project life cycle

Ethics appraisal



How to deal with ethics issues…

During the Grant Agreement Preparation:

- You received an Ethics Summary Report
- All the requirements should be in Sygma as deliverables (contractual obligation) and in the ethics section of your DoA
- All ethics requirements should have been addressed

How to deal with ethics issues…

During project implementation:

- You should send your PO a copy of all Ethics documents/authorisations/animal licences for all partners at the latest before the start of the research work related to the ethics issues (if not done during the GAP)
- In case of any update of your Ethics documents, you should send REA a copy of the updated document no later than the start of the research work related to the Ethics
- You should confirm by email that the updated ethics documents are valid for the work done within your project
- If applicable, you should appoint an ethics Adviser

How to deal with ethics issues…

During reporting periods (Progress and Periodic reports):

- In case of any update of your Ethics documents, you should send REA a copy of the updated document
- You should confirm by email that the updated ethics documents are valid for the work done within your action
- If an ethics adviser/ethics advisory board has been appointed, he should send to REA an ethics report together with your periodic report
- Check if all ethics issues are cleared, otherwise it can block your Interim or Final Payment

Researcher Misconduct

Research Integrity

The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.

Situation that may create confusion with respect to **fabrication, falsification, plagiarism** or other **research misconduct**:

- Missing the appropriate citation and references
- Using the same text in different proposals or ongoing projects - if it is the case provide the appropriate explanation/citation
- Missing the indication about the provenience of the text used in the proposal

Research Executive Agency

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

- ✓ **H2020 Online Manual:**
  http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

European Commission

Thank you for your attention

Research Executive Agency