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H2020-ITN-2016 Coordinators Day

Ethics & Research Integrity

Timea BALOGH

Research Executive Agency
Unit REA-A1

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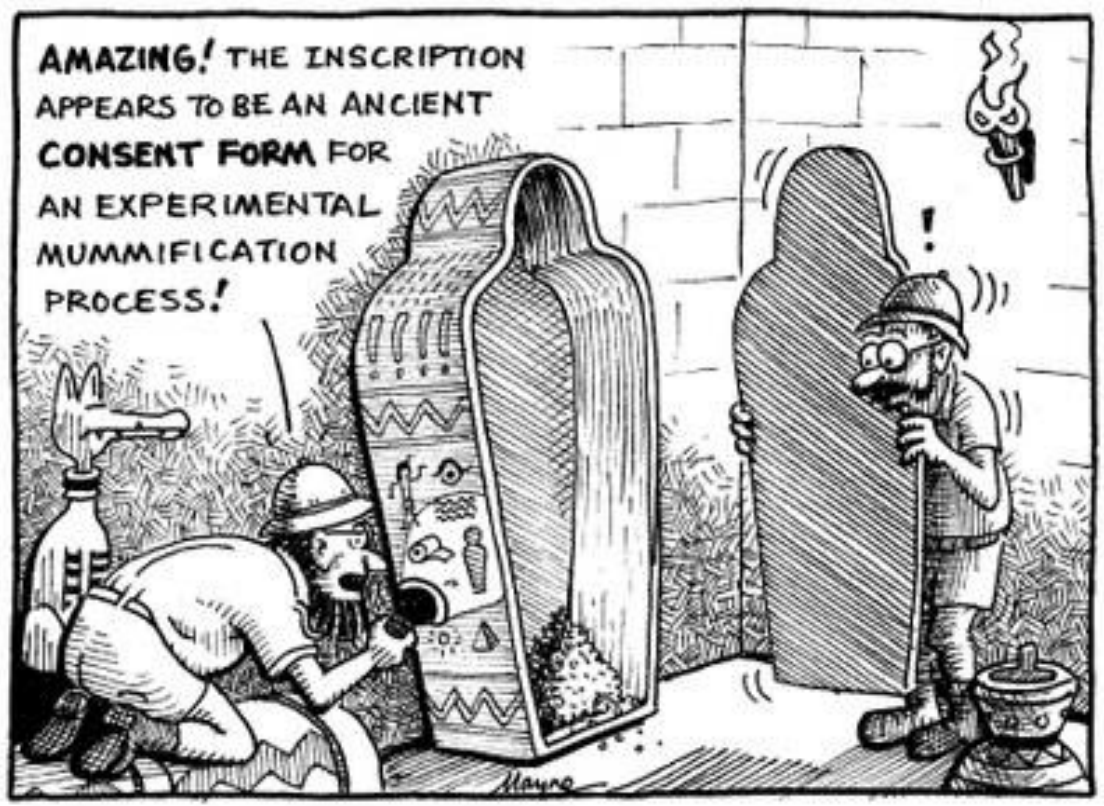

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Rules for Participation of Horizon 2020

(EU REGULATION No. 1290/2013)

Article 13 – Proposals

Article 14 – Ethics Review

Article 18 – Grant Agreement

Article 23 – Implementation of Actions

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Horizon 2020 Grant Agreement

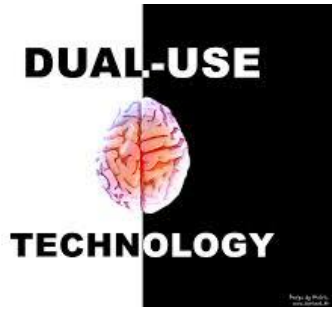
Article 34 – Ethics

- **34.1** – Obligation to comply with ethical principles
- **34.2** – Activities raising ethical issues
- **34.3** – Activities involving human embryos or human embryonic stem cells
- **34.4** – Consequences of non-compliance

Article 39 – Processing of Personal Data

- **39.3** – Consequences of non-compliance

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.

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Where to find the Ethics Self Assessment Guidelines

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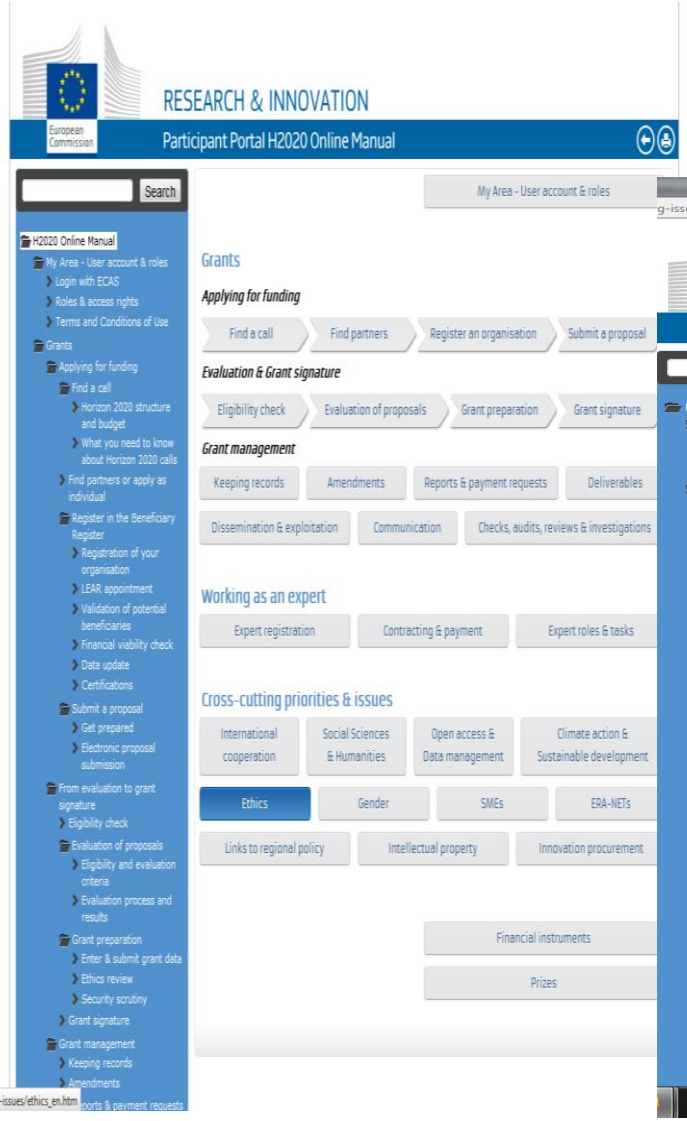
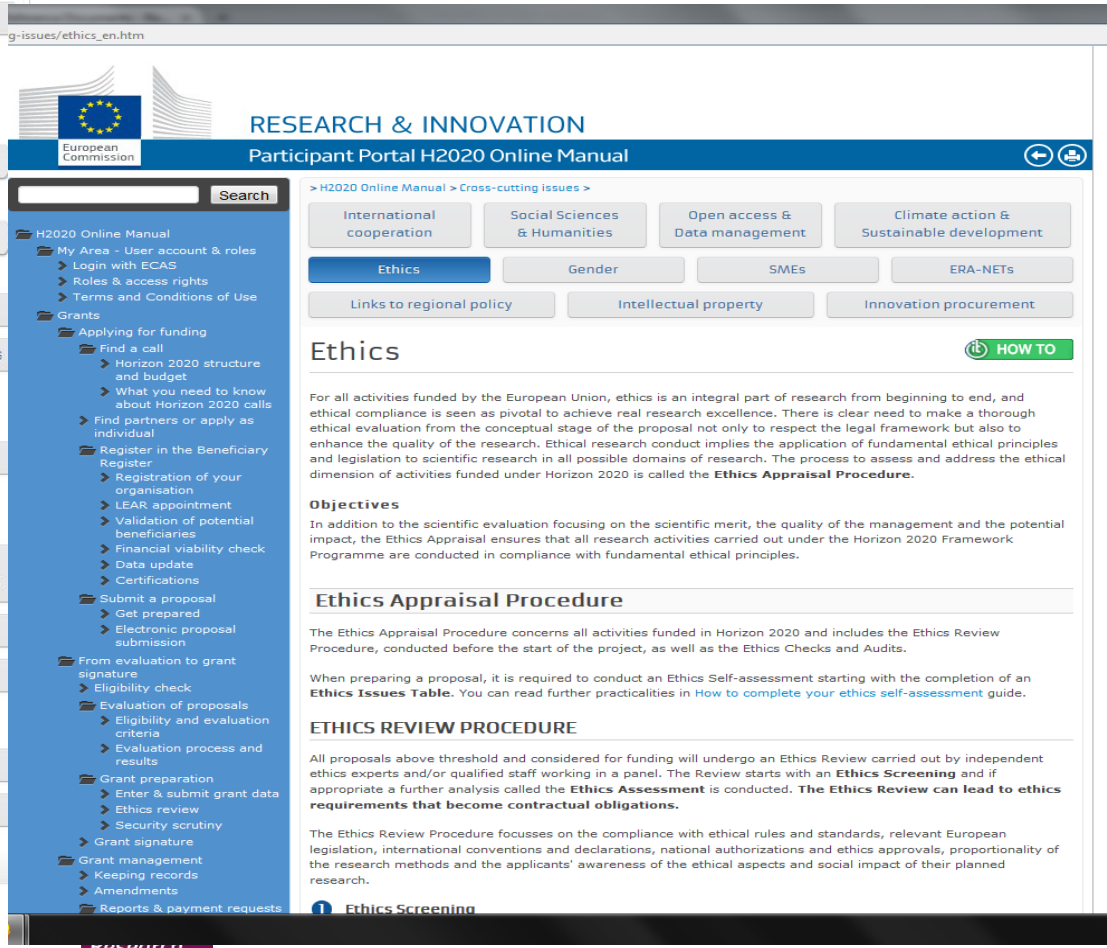
In the Online Manual on the Participant Portal





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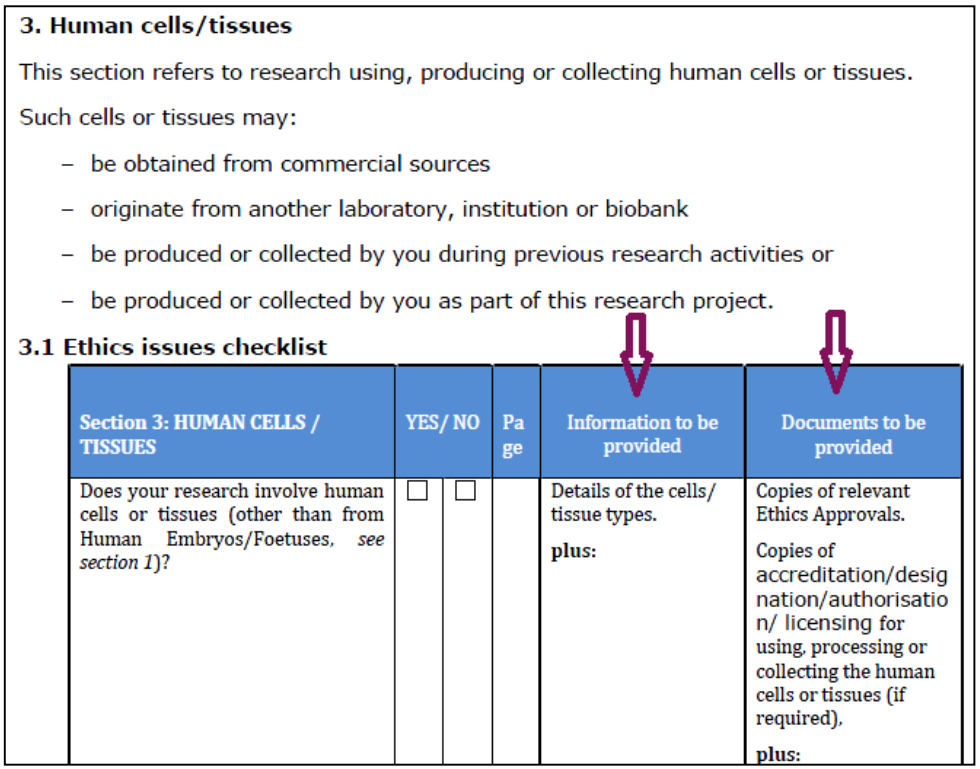
Ethics Self-Assessment Guidance

Key document for applicants and beneficiaries

Regularly updated

Version 5.2

12 July 2016



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

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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. **Human beings**
3. **Human cells or tissues**
4. **Personal data**
5. **Animals**
6. **Non-EU countries**
7. **Environment, health & safety**
8. **Dual use**
9. **Exclusive focus on civil applications**
10. **Potential misuse of research results**
11. **Other ethics issues**

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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 do I deal with the issues?

3- What do you need to provide?

4- Background documents and further reading

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Non-EU countries

Applicable when ethical issues are raised

- ✓ **This is the case where:** research activities are conducted, partially or wholly, in a non-EU country, participants or resources come from a non-EU country, material is imported from or exported to a non-EU country

- ✓ **Possible ethical issues:** exploitation of research participants, exploitation of local resources risks to researchers & staff, research which is prohibited in the EU, transfer of data (NB: Commission decisions on the adequacy of the protection of personal data in third countries)

Research carried out in a non-EU country — for activities carried out outside the EU, it is not enough for that the activity to be accepted and comply with the legal obligations of a non-EU country; the activities must ALSO be allowed in at least one Member State

Horizon 2020 funding cannot be granted for activities carried out outside the EU if they are prohibited in all Member States

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Environmental Protection

- ✓ **Possible ethical issues:**

  Research that may adversely affect the environment or the heal of the researchers involved.

  This may be due to the experimental design of the research itself or undesirable side-effects of the technologies used

- ✓ **Information to be provided:**

  details on risk-benefit analysis, *if applicable*: demonstrate the application of the precautionary principle, safety measures to be taken

The precautionary principle requires that where there is plausible scientific evidence for serious risks, you must prove that a new technology will not harm the environment.

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

- ✓ Potential misuse of research

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_re apps_en.pdf

Specific Ethics Issues

✓ Human beings

- 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

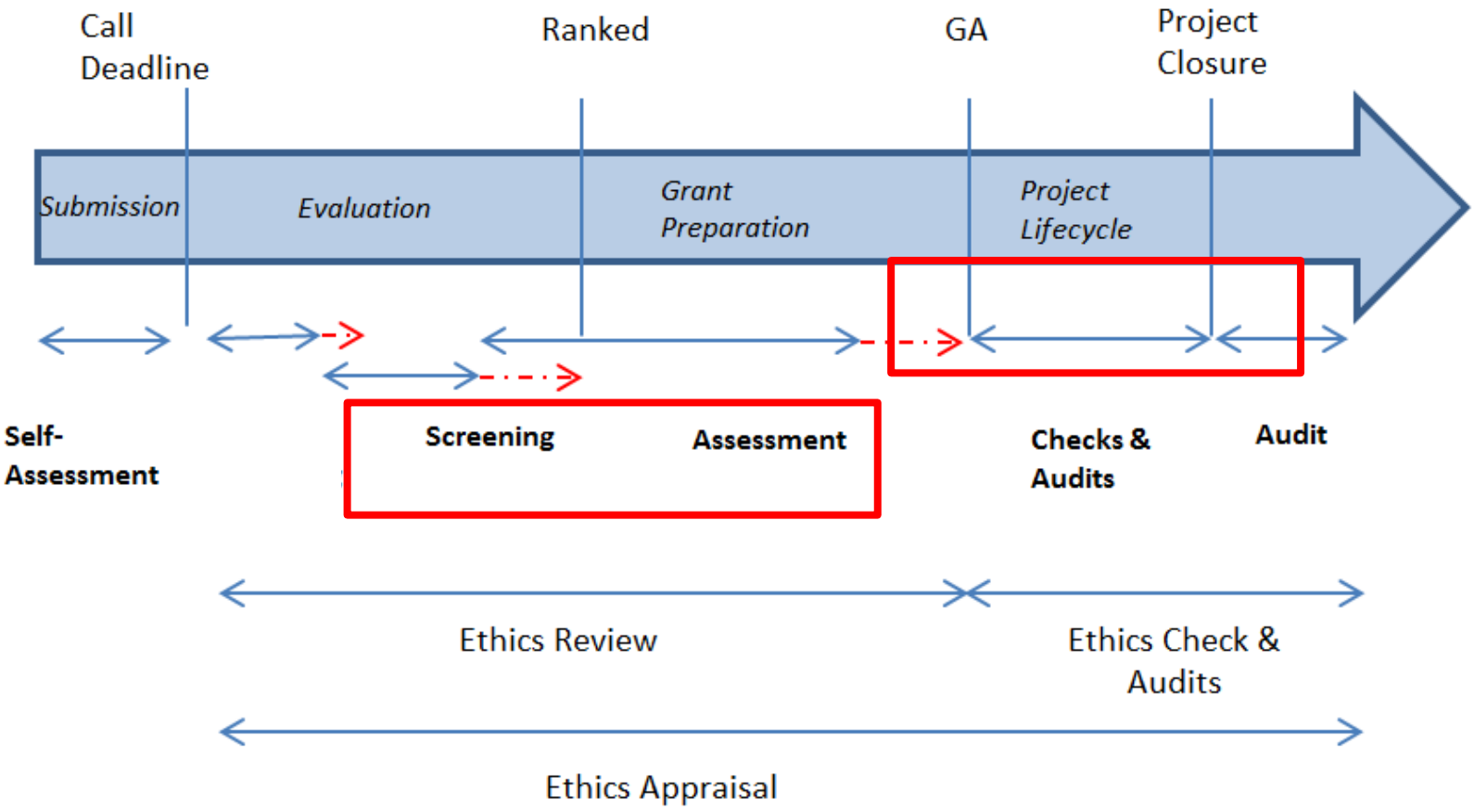
- Scientific Workshops organised by the project with the participation of researchers do NOT raise ethical issues and should not be flagged
- Beneficiaries should comply with Art 39.2

Ethics appraisal in H2020

All shortlisted 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 lifecycle

Ethics appraisal



How to deal with ethics issues…

During the Grant Agreement Preparation:

- You received an Ethics Summary Report;
- All the ethics requirements have been transferred into 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 **obtain and keep in the file** any ethics ethics committee opinion required under national law, any notification or authorisation for activities raising ethical issues required under national and/or European law for all partners at the latest before the start of the research work related to the ethics issue.

- **Confirmation that the documents are in place if required** (by uploading a declaration in Sygma as a Deliverable)

- **Upon request by the Agency, you have to submit the required ethics documentation.** If they are not in English, a summary is requested, which shows that the tasks in question are covered and includes the conclusions of the committee or authority concerned.

How to deal with ethics issues…

During reporting periods (Progress and Periodic reports):

- In case of any **update of your Ethics documents**, you should obtain (and submit upon request) a copy of the updated document no later than the start of the research task in question
- You should confirm that the obtained ethics documents are **valid for the work done within your action**
- If an **ethics adviser/ethics advisory board** has been appointed, a **report** has to be sent to the REA together with the periodic report
- Check if all ethics issues are cleared, otherwise it can block the interim or final payment

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

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Horizon 2020
Model Grant Agreement
Article 34

34.1 – Obligation to comply with ethical principles

The beneficiaries must **respect the highest standards of research integrity.** This implies notably compliance with the following essential principles:

honesty; reliability; objectivity; impartiality; open communication; duty of care; fairness and responsibility for future science generations

Ethics Legal Basis

This means that beneficiaries must ensure that persons carrying out research tasks:

- present their research goals in an honest and transparent manner
- design the research carefully and conduct it in a reliable fashion
- use appropriate techniques and methodologies (including for data management)
- exercise due care for the subjects of research
- ensure objectivity, accuracy and impartiality while disseminating
- make the necessary references
- refrain from plagiarism, data falsification or fabrication
- avoid double funding, conflicts of interest and misrepresentation of credentials

Horizon 2020
Model Grant Agreement
Article 34

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) and the Agreement or **participation of the beneficiary may be terminated** (see Article 50). Such breaches may also lead to any of the other measures described in Chapter 6.

Horizon 2020 Ethics Documents

- ✓ **Participant Portal Online Manual 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

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Thank you for your attention!

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