European Commission

H2020-RISE-2017 Coordinators Day

Ethics & Research Integrity

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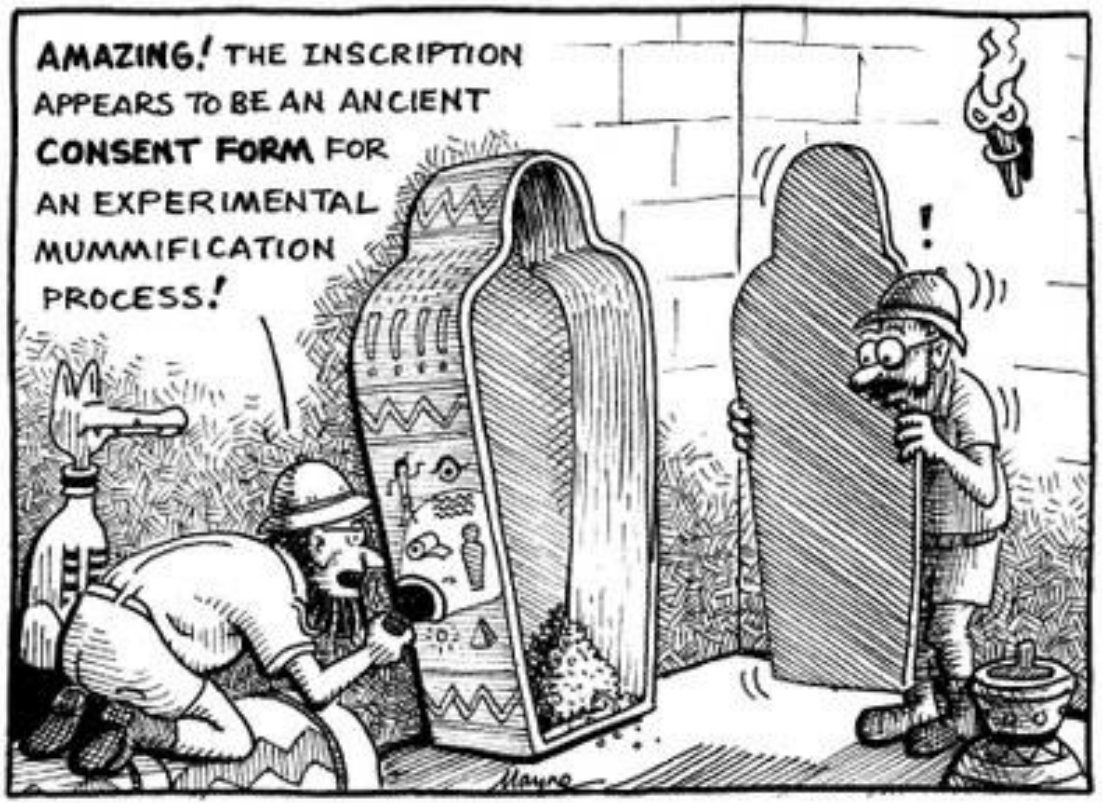
Research Executive Agency

2 March 2017

European Commission



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Ethics Legal Basis

Rules for Participation - Horizon 2020

Article 13 – Proposals

Article 14 – Ethics Review

Article 18 – Grant Agreement

Article 23 – Implementation of Actions

Ethics Legal Basis

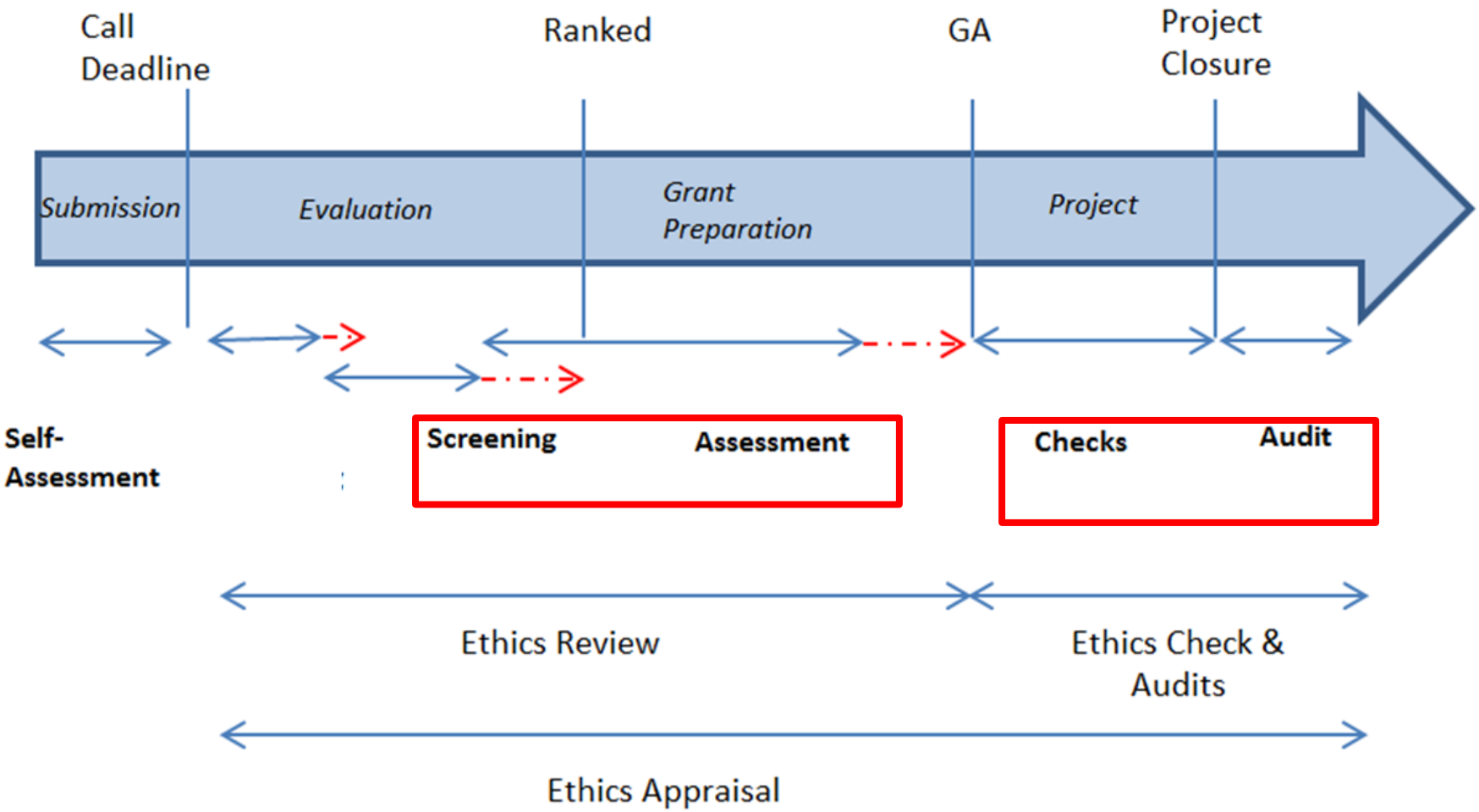
Horizon 2020-Grant Agreement

Article 34 – Ethics

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

Article 39 – Processing of Personal Data

Ethics Appraisal Timeline



Evaluation

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6. Ethics Issues

All research activities in Horizon 2020 should respect fundamental ethics principles, including those reflected in the Charter of Fundamental Rights of the European Union[25]. These principles include the need to ensure the freedom of research and the need to protect the physical and moral integrity of individuals and the welfare of animals.

Research ethics is of crucial importance for all scientific domains. Informed consent and confidentiality are as important for a sociological study as they are for clinical research.

All proposals considered for funding will be submitted to an Ethics Review. The Ethics Review is the core of the H2020 Ethics Appraisal scheme, which concerns all proposals and projects, and also includes the Ethics Checks and Ethics Audit that can be initiated during the project implementation.

In this context, please be aware that it is the applicants' responsibility to identify any potential ethics issues, to handle the ethics aspects of their proposal, and to detail how they plan to address them.

If you have entered any ethics issues in the ethics issues table in Part A of the proposal, you must submit an ethics self-assessment in Part B section 6. For more details on how to correctly address the ethics issues of your proposal, please refer to the Ethics Self-Assessment Guidelines under Horizon 2020[26].

Your self-assessment must:

1) Describe how the proposal meets the national legal and ethics requirements of the country or countries where the tasks raising ethics issues are to be carried out.

Should your proposal be selected for funding, you will be required to provide the following documents, if they are already in your possession:

- The ethics committee opinion required under national law;
- The document that is mandatory under national law notifying activities raising ethics issues or authorising such activities.

If these documents are not in English, you must also submit an English summary of them (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the project, they must include an explicit reference to the project title and each beneficiary concerned must confirm that the respective document(s) covers the tasks described for the project.

2) Explain in detail how you intend to address the issues mentioned in the ethics issues table, in particular as regards:

- Research **objectives** (e.g. study of vulnerable populations, dual use, etc.);

[25] Charter of Fundamental Rights of the European Union, 2000/C 364/01. See also http://www.europarl.europa.eu/charter/default_en.htm

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

ESR

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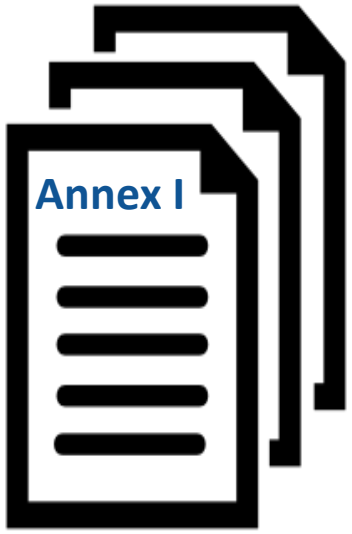
Grant Preparation: Signature

Pre-grant signature requirements:
clarifications, confirmations, informed consent templates, etc.



Post-grant signature requirements:
licenses, authorisations, approvals, opinions, etc.

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Project implementation

H2020-MSCA- RISE Project

Small % of the projects

Project Implementation
Revised Article 34.2

This article defines the **obligations of beneficiaries** in regard to activities raising ethical issues.
It was revised in July 2016 (MGA v3.0).
The revision applies **retroactively to all H2020 grants**:

Beneficiaries must obtain and keep on file the legally required ethics documentation (**ethics opinions, notifications, authorisations**).

You are **no longer obliged to submit** all of these documents by default.

However, you must submit them to the Commission/ Agency if and **as requested**.

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Project Implementation
Revised Article 34.2

34.2 Activities raising ethical issues (AGA)

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

Before the beginning of an activity raising an ethical issue, 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 [Agency] (see Article 52). If they are not in English (…)

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Project implementation for already signed grants

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Post Grant signature requirements

Deliverables

The coordinator must upload a **document** indicating that the consortium has obtained the necessary document(s)

The PO formally approves this approach by accepting the deliverable concerned.

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Document template

Person authorised to submit the declaration via the participant portal,

I declare that the following documents needed for implementing the action tasks described under *project number-acronym* have been obtained prior *to the start of the research activities* and kept on file according to article 34.2 of the GA:

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

Ethics During Project Implementation

- If requested - send the PO a copy of the Ethics authorisations, opinions and notifications.
- In case of check, the PO will request the project all necessary documents.
- If applicable, the appointed Ethics Adviser / Advisory Board must follow-up the handling of ethics issues by the project, must produce a report for each periodic report and must send their report to the REA together with your periodic report

During/ after the project

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Researcher Misconduct & Research Integrity

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

Situations 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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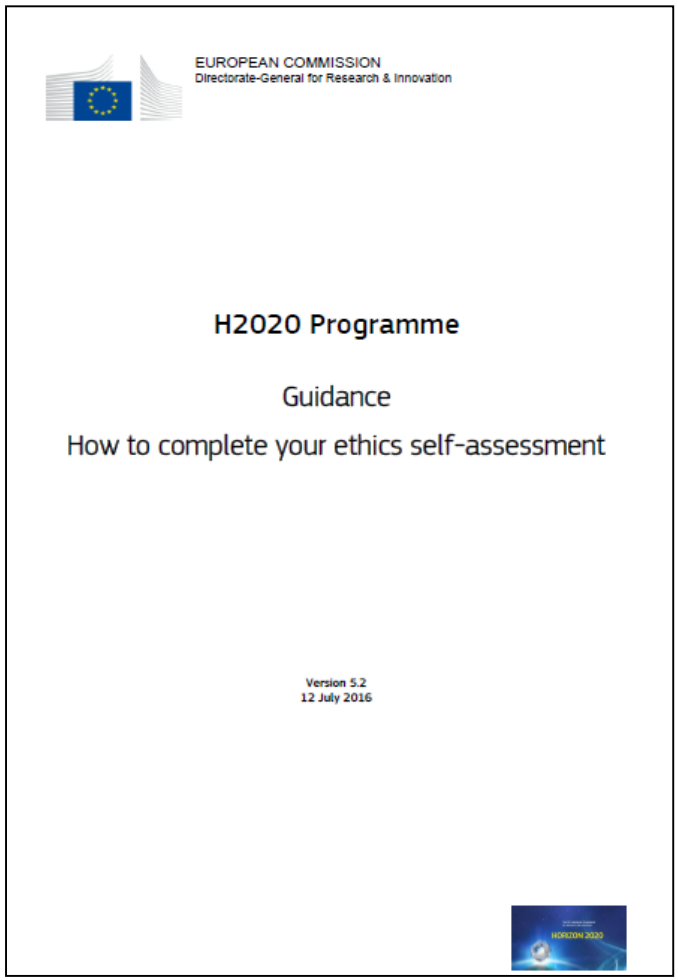
Key documents and links



EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidance

How to complete your ethics self-assessment

Version 5.2
12 July 2016

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6.1 Ethics issues checklist

Section 6: THIRD COUNTRIES	YES/ NO		Page	Information to be provided	Documents to be provided/kept on file
In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues? *Specify the countries involved:*	☐	☐		Risk-benefit analysis. What activities are carried out in non-EU countries? Give details	Copies of ethics approvals and other authorisations or notifications (if required). Confirmation that the activity could have been legally carried out in an EU country (for instance, by submitting an opinion from an appropriate ethics structure in an EU country).
Is it planned to use local resources *(e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?*	☐	☐		What type of local resources will be used and how exactly? Give details.	For human resources: copies of ethics approvals. For animals, plants, micro-organisms and associated traditional knowledge: documentation demonstrating compliance with the *UN Convention on Biological Diversity* *(e.g. access permit and benefit sharing agreement)*

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

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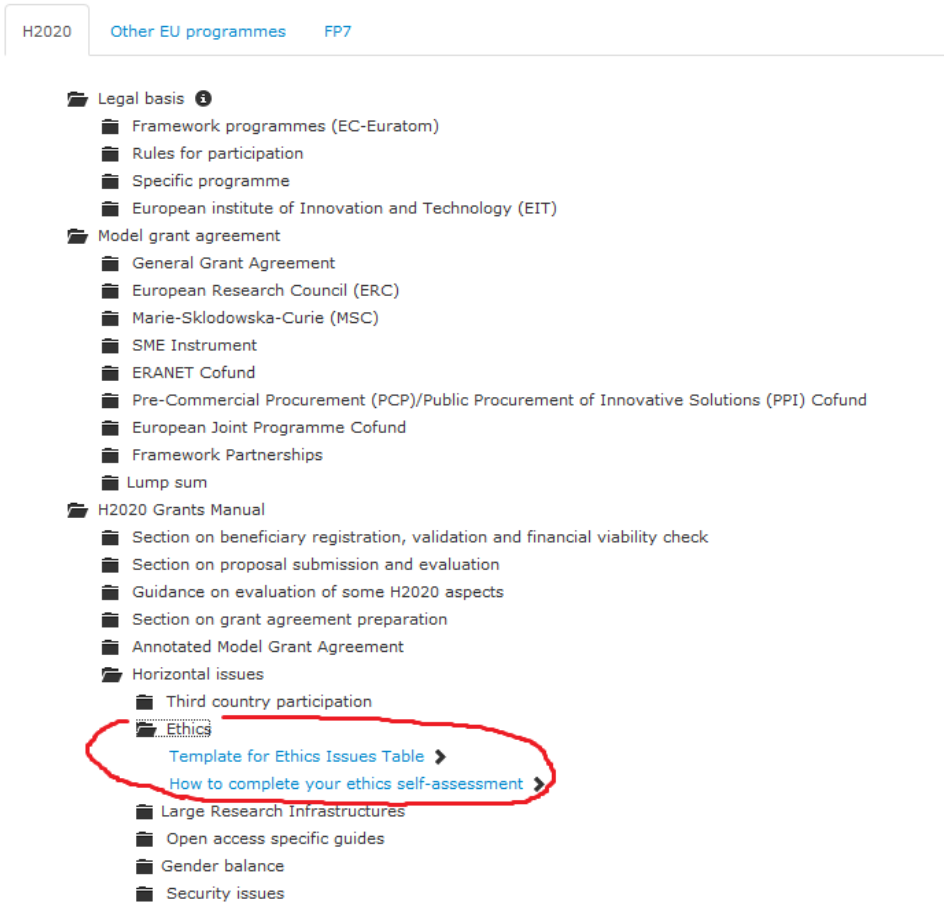
Reference Documents in the Participant Portal



Key links

Horizon 2020 Ethics Documents

- ✓ 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

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Thank you

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