Guidelines for ensuring compliance with ethical principles in Horizon 2020

– from proposal to Grant Agreement

Project Management Working Group

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Introduction

At the stage of submitting project proposals for Horizon 2020 scientists are obliged to describe the ethically relevant issues of the project. Therein they must demonstrate how these issues will be considered and handled in the envisaged project.

Article 19 of Regulation (EU) No 1291/2013 establishing Horizon 2020 [1] describes the basic ethical principles (see Annex). Article 34 of the Annotated Model Grant Agreement [2] describes the basic ethical principles that are based on ten main ethical principles. These must be addressed as relevant to the research activity in the project:

Article 34 GA Ethics – Main ethical principles

1. Respecting **human dignity and integrity**

2. Ensuring **honesty and transparency** towards research subjects and, notably, getting free and informed consent (as well as assent whenever relevant)

3. Protecting **vulnerable persons**

4. Ensuring **privacy and confidentiality**

5. Promoting **justice and inclusiveness**

6. **Minimising harm and maximising benefit**

7. **Sharing the benefits** with disadvantaged populations, especially if the research is being carried out in developing countries

8. **Maximising animal welfare**, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research

9. Respecting and protecting the **environment and future generations**

10. Following the **highest standards of research integrity** [3] (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct)

The EU wants to ensure compliance with basic ethical principles as well as institutional, regional and national procedures of the respective organisations in the framework of research projects. **Eligible projects will therefore undergo an ethics assessment procedure by the EU Commission.**
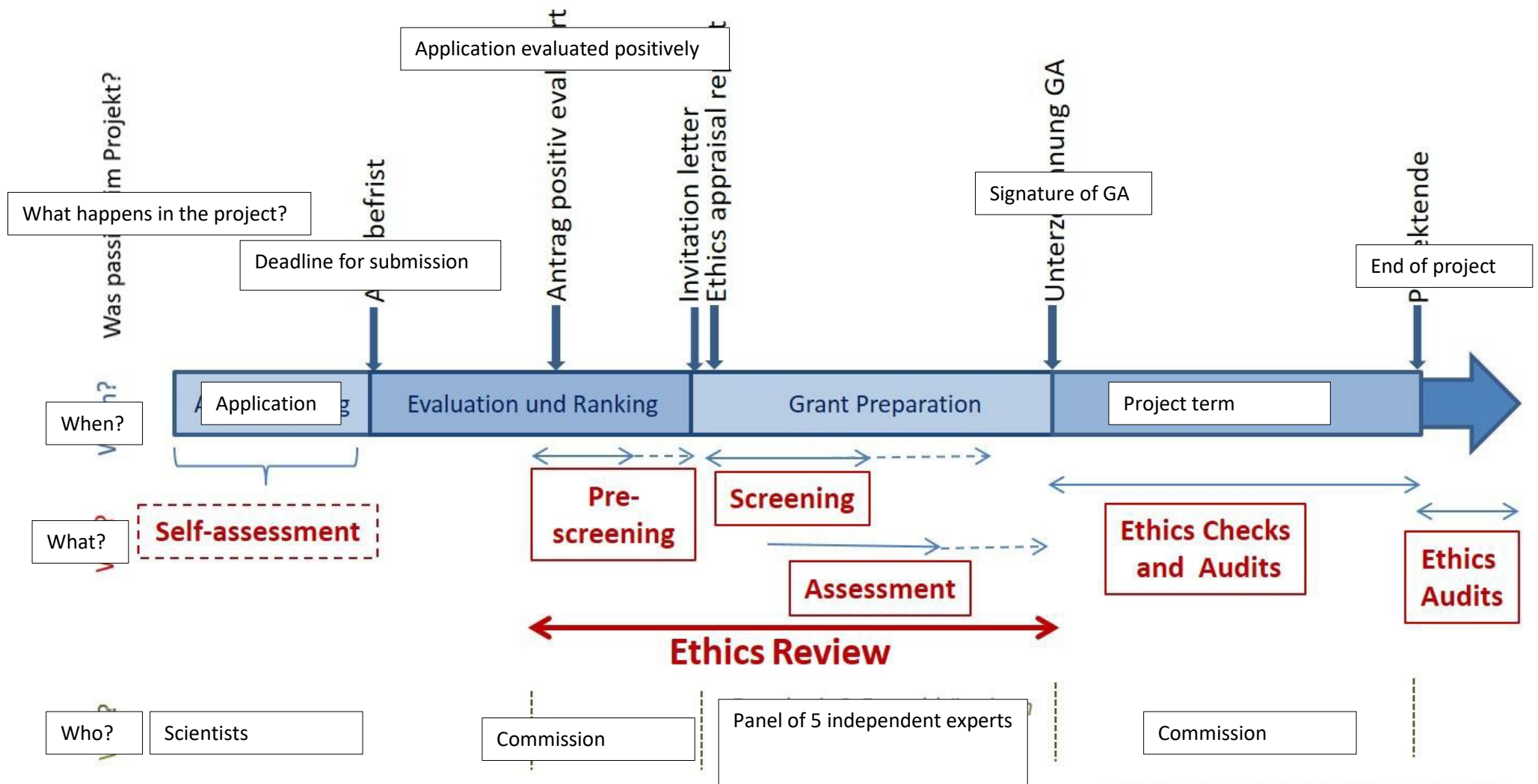
Ethics assessment procedure of projects under H2020

Project proposals will be assessed in accordance with the following steps:

1. **Ethics Self-assessment** (by scientists upon application submission)
2. **Ethics Review** (prior to the finalisation of the Grant Agreement initiated by the EU Commission)
   a. Ethics Pre-screening
   b. Ethics Screening
   c. Ethics Assessment
3. **Ethics Check and Ethics Audit** (in certain projects, after signing the Grant Agreement)

Every project proposal will be checked for its ethical relevance. The process begins with the Ethics Self-assessment (Ethics Self-assessment) performed by the scientists themselves in the form of an Ethics Issues Table – Checklist in the administrative Part A of the application. If the applicants specify ethically relevant issues in the checklist, the consideration of these issues must be described in the majority of funding models in Part B, Section 5 (Ethics and Security). With MSCA applications the ethics issues are described in Part B2, Section 6 of the application. With ERC applications there is no separate annex; here the explanations must be freely formulated and uploaded as an annex to the application in the Participant Portal.

If a project is recommended for funding, an **Ethics Review** takes place. First the Commission reviews the information provided in the application (**Ethics Pre-screening**). If ethical concerns exist, an **Ethics Screening** is performed. In the case of complex ethics contexts, an **Ethics Assessment** is initiated. All projects in which services must be demonstrated in regard to ethical questions shall undergo regular **Ethics Checks** and, when appropriate, an **Ethics Audit**.

Figure 1: Timeline of an Ethics Review – decision-making steps from application submission to the end of the project

Steps in the Ethics Review process of an application/project under Horizon 2020

In the following table and figure the processes are marked with traffic light colours according to their level of approval; green = Ethical clearance; orange = Under review; red = No clearance given; PI = Project manager in the respective institution

	Step	What?	Checked by the EU	Tips – help – documents
1	ETHICS SELF-ASSESMENT (PI)	The scientist fills out the **Ethics Table** in Part A of the application (SEP) • YES / NO – answers If answer is **YES**: state explanations for the ethics issues		Help of the EU-Commission in filling out forms: How to complete your ethics self-assessment
		Opinion on: 1. human embryos/fetuses, 2. humans, 3. human cells/tissues, 4. protection of personal data, 5. animals, 6. non-EU countries, 7. environmental protection, 8. Dual Use, 9. misuse (e.g. of knowledge, algorithms for propaganda), 10. other ethics issues.	Attention: In **research with embryonic stem cells** the **Ethics Review/Pre-screening** (step 2) is initiated automatically	The applicants should be **proactive** and demonstrate that ethics issues were considered. In the Ethics Table refer to the description of the ethically relevant activities in Part B (page number, short explanation). Upload a comprehensive, clear presentation under **Section 5 Ethics and Security**, in **MSCA Section 6** and **a written document in ERC**, with the application in the Participant Portal as a separate annex (number of pages not limited!). TIP: • Even if you marked NO in the table, it can be useful to explain this in Section 5, Section 6 or in the Ethics Annex. This helps to show the experts and assessors that you considered the ethical aspects.

	Step	What?	Checked by the EU	Tips – help – documents
1		The scientist fills out the **Ethics Table** in Part A of the application (SEP) • YES / NO – answers If answer is **YES**: state explanations for the ethics issues		• Ask about procedures in your own institution. Is there a local ethics committee? • When **working in non-EU countries**: Explain that international, EU and national principles are respected, e.g. Benefit Sharing. • In case of complex ethics issues, define **Ethical Screenings** as deliverable and/or appoint an Ethics Adviser to consult the consortium; apply for funds for project monitoring when possible.
			Attention: In research with embryonic	
2a		All projects proposed **for funding** undergo the **Pre-screening process**	Formal review of the information provided in the table performed by REA employees	Pre-screening occurs even if the scientists only answered NO in the Ethics Self-assessment.
			Case A: **No** ethically relevant activities are identified, only NO answers were given *ETHICS CLEARANCE* No further review is necessary	
			Case B: **Ethically relevant activities are identified** > **at least one** question in the table was answered with YES	

(First column vertical label: **ETHICS PRE-SCREENING ETHICS SELF-ASSESSMENT (PI)**)

2b	ETHICS REVIEW	In the ethics table **at least one question was answered with YES,** and ethically relevant **activities were referred to in Part B**.	**The Ethics Review** process is initiated > the **PI is notified**	Takes place **before** the Grant Agreement is signed; begins already during the Assessment.
		ETHICS SCREENING	• is performed by 2-3 members of the Ethics Panel • occurs during the scientific discussion or soon thereafter • identification of ethics issues that were not recognized by the PI	In collaborative projects: Every partner that processes ethically relevant questions must describe, respect and confirm local and national standards. TIPS: • Depending on the circumstances, the applicant should involve local ethics committees or experts to give recommendations. If there is no local jurisdiction, submit other documents. • Ethically relevant issues must be worded clearly; misinterpretations must be prevented. • In case of **complex ethics issues,** establish an **Ethics Board** for the project or designate an **independent ethics adviser** to monitor the project.
			A. *CONDITIONAL CLEARANCE* Further obligations > **the necessary procedures** are **automatically** incorporated in the Grant Agreement as **Work Package and Deliverable**!	The PI is in regular contact with the Ethics Panel. Additional possibility: the experts issue remarks and recommendations.

			> An **Ethics Adviser** may be required.
2c	ETHICS ASSESSMENT	In case of **complex** ethics issues:	**B. ETHICS ASSESSMENT** An Ethics Assessment is carried out by at least 5 independent experts. (Ethics Panel: interdisciplinary committee; ethicists and usually also a person with the relevant expert background)

i. ETHICS CLEARANCE
>PI submits all the necessary explanations/documents

> **Grant Agreement is signed**

ii. CONDITIONAL CLEARANCE

Ethics Panel is set up: 5 independent experts
> An **Ethics Adviser** may be required.

Further obligations
> **the necessary procedures** are **automatically** incorporated in the Grant Agreement as **Work Package and Deliverable**!

> obligations are fulfilled:
ETHICS CLEARANCE

Online Manual ERC: If remarks were given, these must be processed as **Deliverable.**

Additional possibility: The experts issue remarks and recommendations.

3	ETHICS CHECKS AND AUDITS	Even after the Grant Agreement is signed the commission may initiate further reviews (MGA Article 22).	EU is in regular contact with the PI.
		The PI is eventually invited to Brussels for further talks; a visit to the institution is also possible.	⇨ **iii. a second *ETHICS ASSESSMENT is demanded*** > the ethics assessment procedure starts anew
			⇨ **Rejection of a project/subproject**

ATTENTION: In the event of unclear facts, Checks and Audits can bring the entire project to a halt!

These guidelines are meant to stress the relevance of ethics issues in the application procedure and possibly during the project implementation. The Ethics Self-assessment is not part of the assessment, nonetheless you should always address ethics issues in the application where they are appropriate.
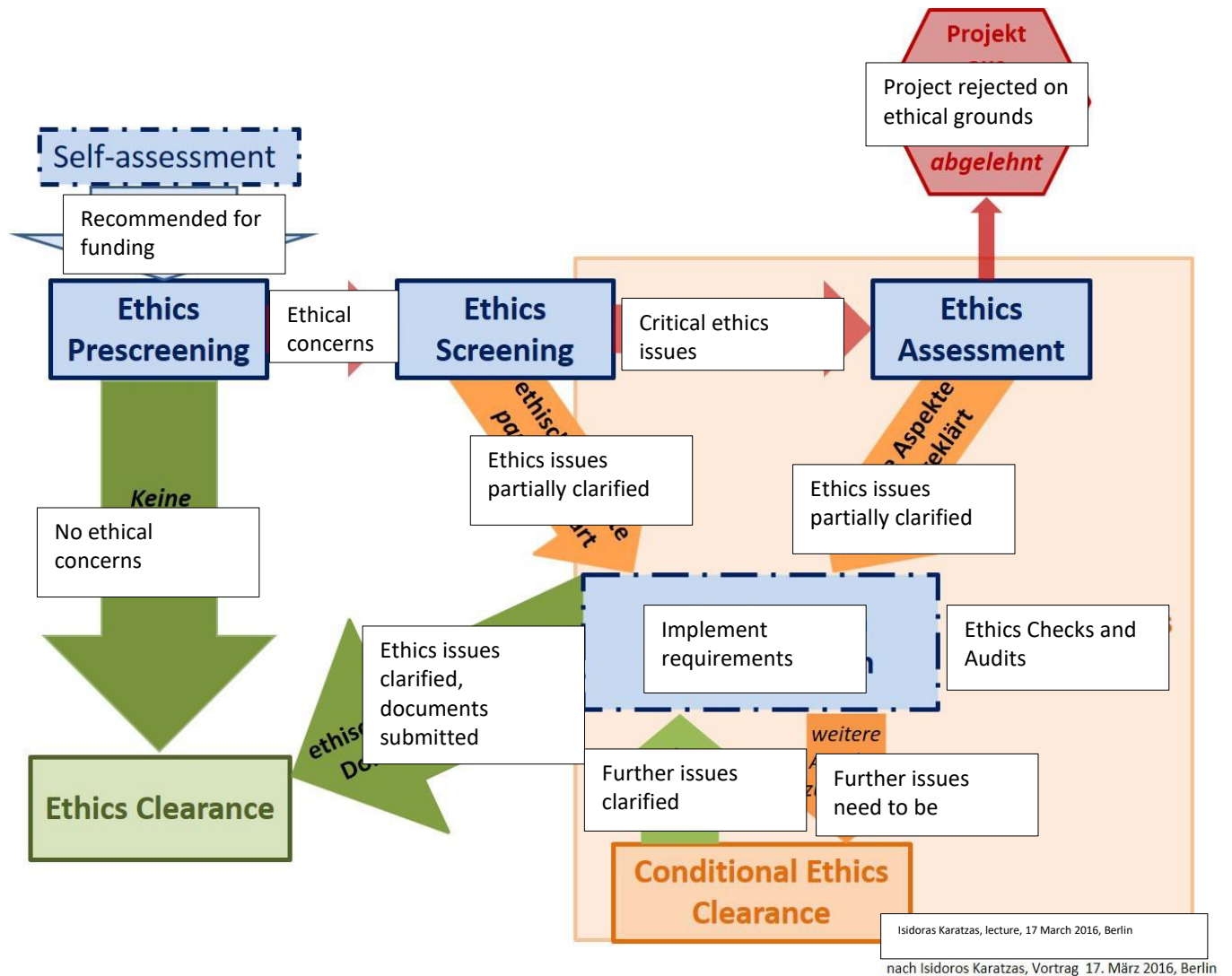

Figure 2: Ethics assessment – decision-making processes within the Commission

Annexes

Ethical principles

Article 19.1: All the research and innovation activities carried out under Horizon 2020 shall comply with **ethical principles** and **relevant national, European 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.

Article 19.2: Research and innovation activities carried out under Horizon 2020 shall have an exclusive focus on **civil applications**.

Article 19.3: The following fields of research shall not be financed:

- research activity aiming at **human cloning for reproductive purposes**;
- research activity intended to **modify the genetic heritage of human beings** which could make such changes **heritable**;
- 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.

In-text references

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11. 11 December 2014, page 114
http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-establact_de.pdf

[2] Annotated Model Grant Agreement
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/amga/h2020 - _amga_en.pdf

[3] European Code of Conduct for Research Integrity www.allea.org/publications/joint-publications/

Documents and additional information

How to complete your Ethics Self-assessment – Guidelines of the EU Commission; an important document that provides instructions for answering ethics questions of during the application:
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2 0 20_hi_ethics-self-assess_en.pdf

Example table and Checklist for the Ethics issue table, to be filled out as in Part A of a H2020 application (here ITN):
https://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-msca-itn-2014/1597698-itn_2014_-_ethics_issues_checklist_en.pdf

Ethics Helpdesk (Participant Portal):
http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

Assistance from the commission on questions of ethics, inter alia.

➤ In questions regarding Dual Use:
http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-dual-use_en.pdf
➤ Question on possible misuse of research data:
http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-misuse_en.pdf
➤ If research projects involve military organisations and/or the defence industry *as research focusing on civil application:*
http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-civil-apps_en.pdf
➤ In research on refugees, asylum seekers and migrants:
http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-refugees-migrants_en.pdf

General information on data protection

➤ Guidance on transatlantic data transfer: http://ec.europa.eu/justice/newsroom/data-protection/news/151106_en.htm
➤ Link to data-protection bodies:
http://ec.europa.eu/justice/data-protection/bodies/index_en.htm
➤ Data protection documentation, Article 29 "Internet of Things":
http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2014/wp223_en.pdf

Additional information

SATORI – EU project developing a common European ethics assessment framework for research and innovation offers a wide range of information: http://satoriproject.eu/the-project/

Leopoldina and DFG: Joint Committee for dealing with security-relevant research – tasks and activities of the committee, progress regarding the implementation of recommendations in dealing with security-relevant research. Contains **model statutes** for **ethics committees for security-relevant research (KEF)**:
www.leopoldina.org/uploads/tx_leopublication/2016_GA_Taetigkeitsbericht.pdf

The Research Ethics Guidebook – a resource for social scientists: Stresses compliance with ethical aspects already in the planning phase: www.ethicsguidebook.ac.uk.