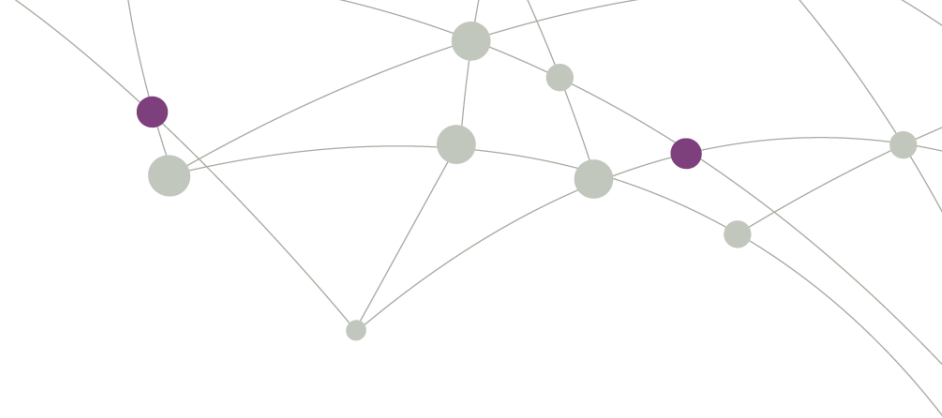




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Ethics requirements in Horizon2020

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Briefly about Horizon 2020

Horizon 2020 is the biggest EU Research and Innovation programme ever with nearly €80 billion of funding available over 7 years (2014 to 2020)

It is implemented mainly through calls for proposals; proposals are evaluated by independent experts

Ethics is an integral part of all research activities funded by the European Union.

Ethics in Horizon 2020

The broad topic of ethics in research is considered from different aspects:

- Research integrity
- „Ethics-ready“ proposals
- Ethics monitoring during the implementation of projects
- Funding of ethics research
- Responsible research and innovation (RRI)

Ethics requirements in Horizon2020

Overview of the **procedures** before, during and after evaluation

Relevant **documents** and where to find them

Some **examples**

Legal background:

Horizon 2020 - Regulation of Establishment: Ethical principles (Article 19)

Horizon 2020 Rules for Participation: Ethics Reviews (Article 14)

Model Grant Agreement: Ethics (Article 34)

See more at:

http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

Ethics Appraisal Procedure

The process to assess and address the ethical dimension of activities funded under Horizon 2020 is called the **Ethics Appraisal Procedure**.

Ethics Self-assessment

Application phase – by the applicant

Ethics pre-screening / screening

Evaluation phase – by ethics experts

Ethics assessment

Evaluation / grant preparation
phase – by ethics experts

Ethics check / audit

Implementation phase – by ethics
experts

Ethics Self-Assessment (1)

Step 1: Ethics issues table

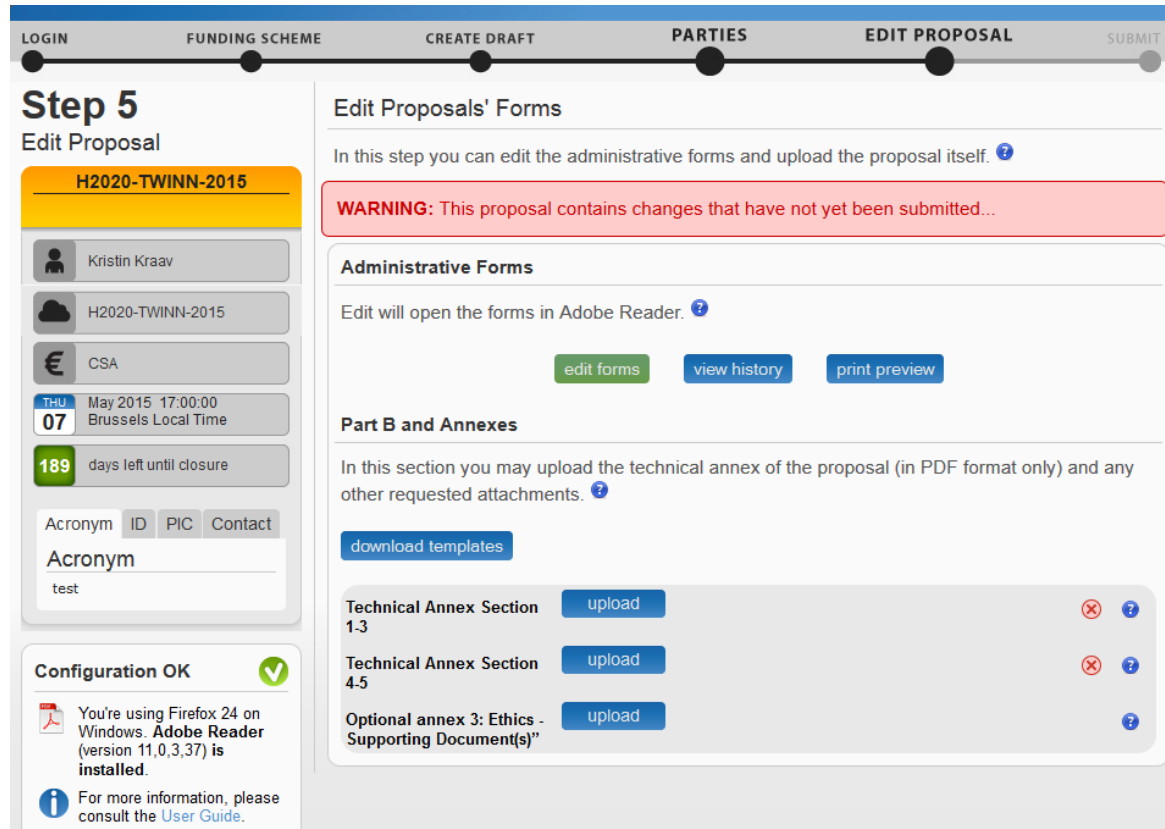
1. Human embryos/foetuses
2. Humans
3. Human cells/tissues
4. Personal data
5. Animals
6. Third countries
7. Environment & health and safety
8. Dual use
9. Misuse
10. Other

Proposal ID	Acronym	Go to
4 - Ethics issues table		
The applicable legislation is the Horizon2020 legislative acts (i) (see legal references at the end of the section).		
This Table should be completed as an essential part of your proposal. Answer "Yes" or "No" to all of the questions below. If an answer is "Yes", then indicate in the adjacent box at which page in your full proposal further information relating to that issue can be found.		
For further explanation on the questions see " How to Complete your Ethics Self-Assessment " or, for ERC calls, the "Information for applicants" (Annex 3 - Specific Guidance Related to Ethics).		
As explained in these documents, please note that if you answer YES to any of the questions below, you are requested to provide additional information and documentation.		
1. HUMAN EMBRYOS/FOETUSES		Page
Does your research involve Human Embryonic Stem Cells (hESCs) ?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Will they be directly derived from embryos within this project?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they previously established cells lines?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Does your research involve the use of human embryos?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Does your research involve the use of human foetal tissues / cells?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
2. HUMANS		Page
Does your research involve human participants?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they volunteers for social or human sciences research?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they persons unable to give informed consent?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they vulnerable individuals or groups?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they children/minors?	<input checked="" type="radio"/> Yes <input type="radio"/> No	

Ethics Self-Assessment (2)

Step 2: Ethics section in Part B

- Demonstrate awareness of ethics issues
- Address ethics issues in the **design** of your project:
 - objectives
 - methodology
 - impact
 - risk assessment
- Demonstrate compliance with national and EU legislation
- Describe procedures for acquiring necessary permits / provide existing documentation
- Free text, no page limits



LOGIN FUNDING SCHEME CREATE DRAFT PARTIES EDIT PROPOSAL SUBMIT

Step 5

Edit Proposal

H2020-TWINN-2015

Kristin Kraav

H2020-TWINN-2015

€ CSA

THU 07 May 2015 17:00:00 Brussels Local Time

189 days left until closure

Acronym ID PIC Contact

Acronym
test

Configuration OK

You're using Firefox 24 on Windows. Adobe Reader (version 11.0.3.37) is installed.

For more information, please consult the [User Guide](#).

Edit Proposals' Forms

In this step you can edit the administrative forms and upload the proposal itself. ?

WARNING: This proposal contains changes that have not yet been submitted...

Administrative Forms

Edit will open the forms in Adobe Reader. ?

edit forms view history print preview

Part B and Annexes

In this section you may upload the technical annex of the proposal (in PDF format only) and any other requested attachments. ?

download templates

Technical Annex Section 1-3 upload

Technical Annex Section 4-5 upload

Optional annex 3: Ethics - Supporting Document(s)" upload

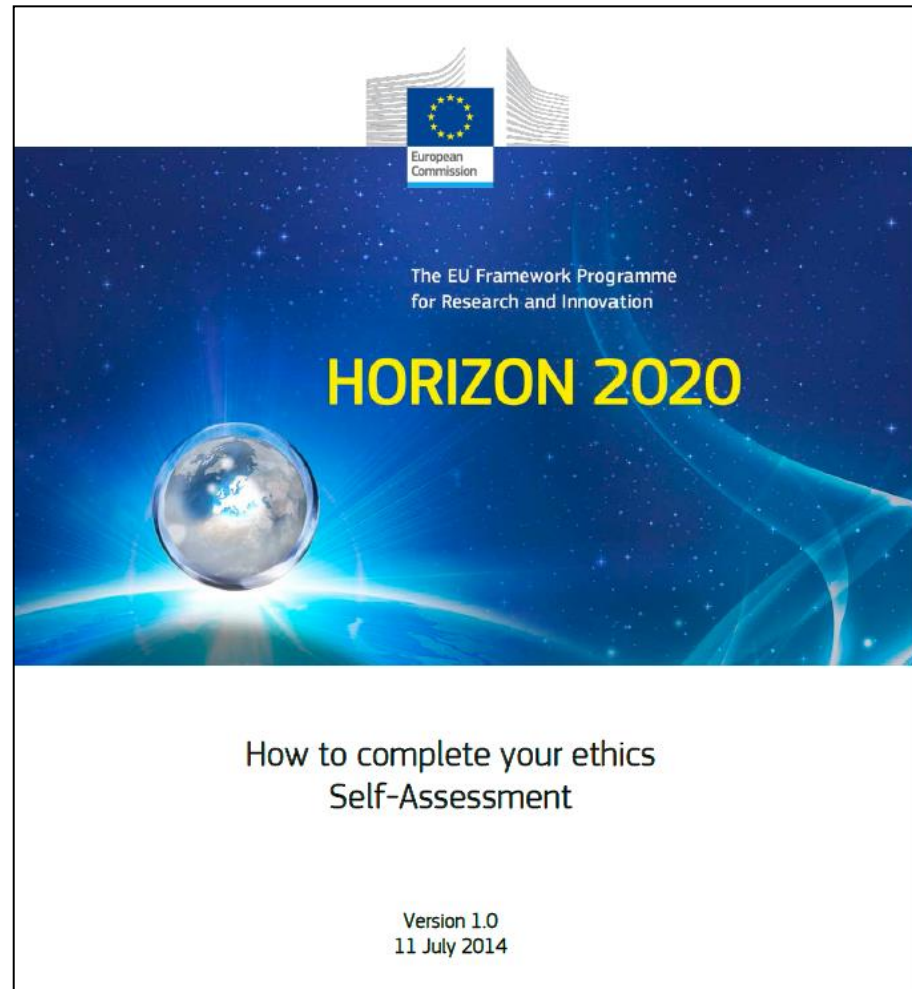
Typical questions of applicants

- What can be considered as an **animal**?
- **Observing** non-human primates is an ethics issue?
- If not collecting names, birth dates and addresses are the **pictures or videos** subject to data protection?
- Is an authorisation needed, to do **secondary use of data/samples** previously collected by another researcher?
- The use of **nanotechnology** should be mentioned? How to address it?
- How to deal with **benefit sharing arrangements** when researching in third countries?

Ethics Self-Assessment (3)

„How to complete your ethics Self-Assessment“

- what needs to be described in the proposal
- which additional documents have to be provided
- Practical, straightforward and (almost) comprehensive



Ethics Self-Assessment (4)

Domain-specific guidance notes: mostly made for FP7, but fully relevant today

- [Guidance Note for Researchers and Evaluators of Social Sciences and Humanities](#)
- [Guidance Note - Ethics and Food-Related Research](#)
- Research on Human embryos/foetuses
- [Ethics for Clinical Trials on Medicinal Products Conducted with Paediatric Population](#)
- [Data protection and Privacy](#)
- [Informed Consent](#)
- ICT Ethics Resources
- [Research on Animals](#)
- Research Involving Developing Countries
- Dual Use
- Research Ethics in Ethnography/Anthropology
- Misuse/Malevolent use Guidance Notes

Ethics screening

Ethics pre-screening / screening

Evaluation phase – by ethics experts

The ethics experts first perform an **Ethics Pre-Screening** taking into account the Self-assessment. The objective of the pre-screening is to list the (potential) ethical issues but not to assess them.

When there is at least one confirmed ethical issues, the proposal is subject to a complete Ethics Screening:

- assessment of the **ethical aspects of its objectives, methodology and potential impact**
- **identification all proposals that require (ethical) approval** at the national level
- Ethics experts may also recommend an **Ethics Assessment**. Proposals involving the use of Human Embryonic Stems Cells (hESCs) automatically proceed to the Ethics Assessment.

Typical shortcomings

- Limited description of informed consent procedures or commitment to adhere to fundamental ethical principles;
- Mere or superficial reference to some basic EU rules;
- Failure to take into account the special ethical challenges arising from:
 - the involvement of special population groups;
 - the performance of research in conflict zones or areas where no ethics infrastructure exists

Cases: recommended ethics assessment (1)

The objectives of the proposed research are the determination of the **impact of an alternative approach to vocational training program pedagogy** when applied to **entrepreneurship training for persons with disabilities**.

Due to the special nature of the proposed research, the lack of certain pieces of information **and the involvement of a large number of people with disabilities**, the project will benefit from an Ethics Review undertaken by experts in the field of disability studies.

An Ethics Review is recommended given **the involvement of children** (18 months-3 years) and **the nature of the proposed research** (filming of children in relation to their language abilities and collection of video data in order to help foster psycholinguistic research and speech-therapist practice).

Cases (2)

Due to the special **nature of the proposed research, the lack of information on specific aspects of the research and the involvement of a large number of people** that would be asked to answer questions regarding their role and life as employees, the project will benefit from an Ethics Review undertaken by experts in the field of employment research

An Ethics Review is recommended considering that the researcher is planning to organise **focused interviews** not only with key actors - judges, prosecutors, defence counsel and legal officers but also with other stakeholders, including **accused persons, victims**, United Nations and Government officials and NGOs

Ethics Assessment

Ethics assessment

Evaluation / grant preparation
phase – by ethics experts

- Individual reading of the proposals
- Meeting as an ethics review panel : discussion for a consensus
- Production of an Ethics Review Report (sent to the participants)
- The Panel's requirements become contractual responsibilities for the Project participants
- The Ethics Review report may indicate the need to organise a follow-up review/audit at a later stage of the project.

Ethics checks and audits

Ethics check / audit

Implementation phase – by ethics experts

During the Ethics Screening or the Ethics Assessment, the experts identify the projects that need an **Ethics Check**, which are executed during the course of the research project. The procedure can also be initiated by the Commission services.

- the aim is to assist the beneficiaries to deal with the ethics issues raised by their research and if necessary to take preventive or/and corrective measures.

In case of substantial breach of ethical principles, research integrity or relevant legislation, the Commission can carry out an **Ethics Audit**.

Ethics Appraisal Procedure

Ethics Self-assessment

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Research integrity

The Model Grant Agreement states:

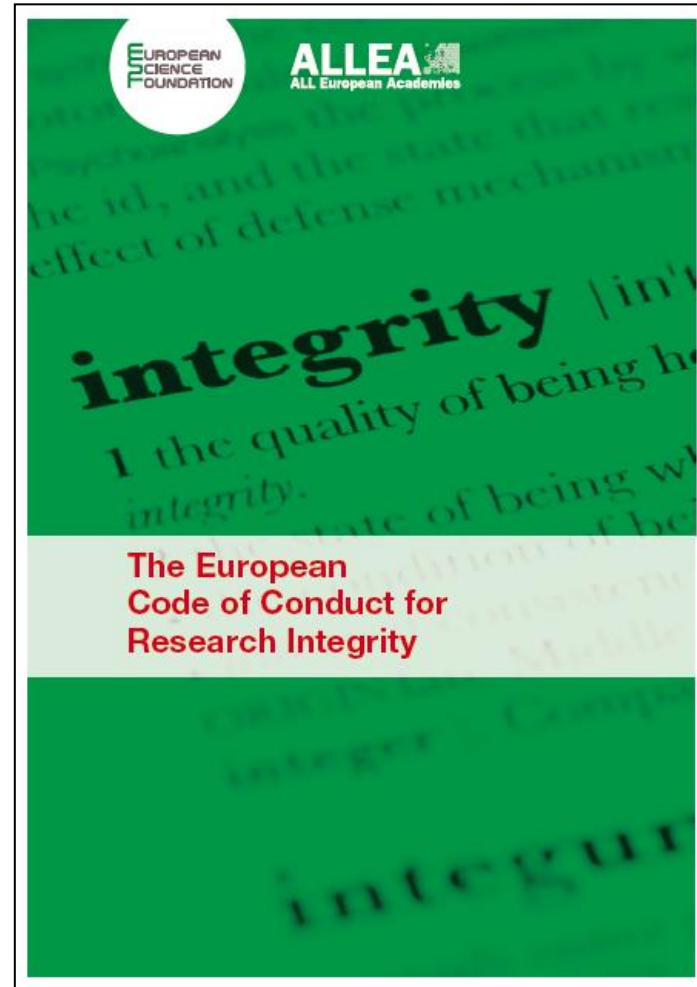
The beneficiaries must carry out the action in compliance with:

- (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.

The European Code of Conduct for RI

The principles of integrity in scientific and scholarly research:

- honesty in communication;
- reliability in performing research;
- objectivity;
- impartiality and independence;
- openness and accessibility;
- duty of care;
- fairness in providing references and giving credit; and
- responsibility for the scientists and researchers of the future.



Responsible Research and Innovation

Responsible Research and Innovation means that societal actors work together during the whole research and innovation process in order to better align both the process and its outcomes, with the values, needs and expectations of European society.

RRI is a cross-cutting issue of Horizon 2020:

- engagement of all societal actors
- gender equality
- science education
- **ethics**
- open access
- governance

Read more at:

<http://ec.europa.eu/research/swafs/index.cfm?pg=home>

Ethics in Horizon 2020

- Research integrity
- „Ethics-ready“ proposals
- Ethics monitoring during the implementation of projects
- Funding of ethics research
- Responsible research and innovation (RRI)

Estonian Research Council (ETAG) is the Estonian National Contact Point for Horizon 2020. Contact us at:

- www.etag.ee
- www.horisont2020.ee (eesti keeles)