

ETHICS IN H2020 PROPOSALS

Overview

Most proposals often contain unrecognized ethical issues which must be addressed appropriately. Proposal should proactively demonstrate that all ethical issues have been considered. Proposals should be ETHICS READY following the “ethics by design” method.

Taking into account ethics in research projects enhances the quality of research and ensures that your work is within the legal framework and will contribute to Responsible Research and Innovation. Remember, only ethical research is excellent research! Ethics should not be misunderstood as hindering the scientific progress and the freedom of research. In truth, the main ethical principles in research include respect for human dignity and integrity, privacy and confidentiality, minimization of harm and maximization of benefits, respect and protection of the environment. The compliance with the highest standards of research integrity (i.e. avoiding fabrication, falsification, plagiarism, questionable research practices, double funding, etc.) is beyond doubt and should always be considered and addressed.



How to complete your ethics self-assessment

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

1. **Ethics Self-assessment**
2. **Ethics Review** consisting of **Ethics Pre-Screening/Screening and Ethics Assessment**
3. **Ethics Checks and Audits**



Ethics – Online manual

Ethics Appraisal Procedure	Who?	When?	How?
Ethics self-assessment	Applicant	Application phase	Consideration of ethical issues of the proposal
Ethics Pre-screening/Screening	Ethics experts and/or qualified staff	Evaluation phase	Review of application material
Ethics Assessment (severe intervention on humans)	Ethics experts	Evaluation/Grant preparation phase	Review of application material
Ethics Check/Audit	Ethics experts	Implementation phase	Review of project deliverables/interview with applicants

ETHICS SELF-ASSESSMENT

When preparing a proposal, you must complete the **Ethics Issues Table (Part A)** and subsequently, when needed, an **Ethics Self-Assessment (Part B)** in which you:

- will describe how the proposal meets the national legal and ethical requirements of the country(ies) where the tasks raising ethical issues will be performed;
- should provide a copy of any opinion or notification or regulatory approval obtained by your ethics committee or by, the competent national or local authority;
- should discuss in detail how the ethics issues identified in the ethics issues table, will be addressed, in particular in relation to:
 - research objectives (study of vulnerable populations, dual use, etc.);
 - research methodology (consent procedures, protection of data collected etc.);
 - design of the research project from an ethics point of view;
 - potential impact of the research (questions related to dual use, environmental);
 - damages, population stigmatization, political/financial retaliation, benefit sharing, malevolent use);
 - how the ethics requirements set out in the work programme will be fulfilled;



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The **ethics self-assessment** will become part of your **grant agreement** (in Annex 1, as description of the action, ethics requirements, etc.) and may thus lead to binding obligations that may be checked later on **during ethics checks, reviews and audits**.

The time that you invest in this self-assessment is therefore not wasted, and will in fact improve your research results and:

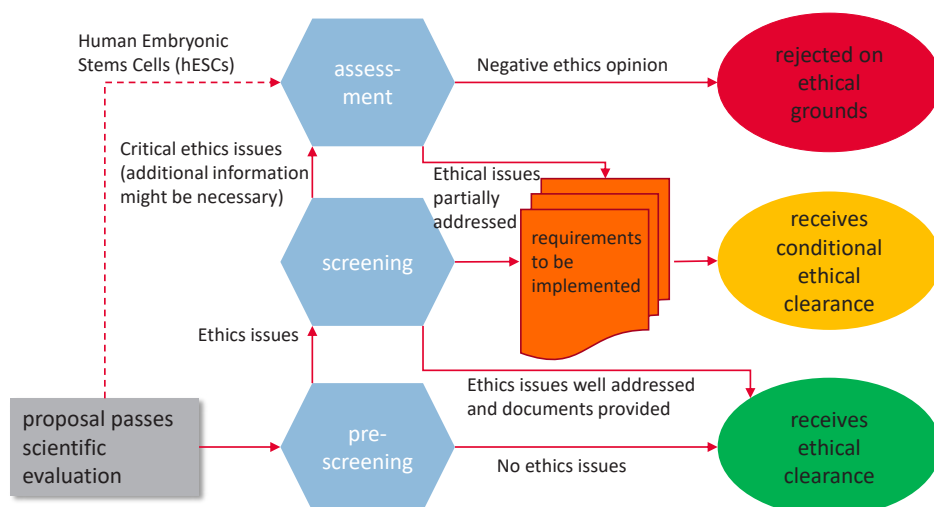
- your proposed research will be compliant with applicable international, EU and national law;
- your proposal will be more rapidly processed during the H2020 proposal selection procedure;
- the results of your research can be more easily published in internationally refereed journals;
- you will contribute to the responsible conduct of research, thereby increasing its social acceptance;

ETHICS REVIEW

Under H2020, in addition to their scientific merit and impact, all shortlisted proposals are evaluated on their ethical impact. **THE ETHICS REVIEW PROCEDURE** (which should result in the decision „ethics ready“) consists of:

- **Ethics Screening** (soon after the scientific evaluation and concerns only proposals shortlisted for funding): during ethics screening, proposals that raise no immediate ethics issues are pre-screened to identify any potential issues of this nature. If such issues arise, the proposals are then fully screened to check whether applicants are giving due consideration to these potential problems;
- **Ethics Assessment** (an in-depth analysis of the ethical issues): for a limited number of proposals with complex ethical issues (e.g. severe intervention on humans, etc.) or where ethical issues have not been addressed properly the screening panel can recommend an Ethics Assessment prior to the signature of the GA;

ETHICS REVIEW WORKFLOW



RESULTS OF ETHICS REVIEW

1. **No ethics clearance**
2. **Conditional ethics clearance**
3. **Request for additional information (intermediate outcome)**
4. **No ethics issues (clearance)**
5. **Ethics clearance**

ETHICS CHECKS AND AUDITS

After the signature of the grant agreement and during the life-time of the selected projects Ethics checks and audits are executed. The objective of the procedure 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.

We recommend to elaborate carefully on any ethical issues in section 5 of your proposal. Do not mistakenly believe you have no ethics issues to address when not dealing with the obvious dual-use or human/animal studies. This notion is not correct, and in fact all H2020 Research proposals deal in some way with ethical issues. For this purpose use the EC guide **“How to complete your ethics self-assessment”** that gives well-structured tips for almost all situations and helps you to process all ethical aspects of your proposal correctly.

According to the ethical guide the following ethical issues should be considered:

1. **Human embryos & fetuses**
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**