

Ethics review

ETHICS REVIEW (ETHICS SCREENING & ASSESSMENT)

Background

Neither the EU nor Euratom fund proposals that violate ethical principles.

Our ethics appraisal scheme includes:

- an ethics **self-assessment** (in your proposal)
- an **ethics review** (see below)
- ethics **checks and audits** (during the project and up to 2 years afterwards if necessary).

Each proposal considered for funding is subject to an ethics review.

For more information on ethics, see the [ethics section of the manual](#).

Where does the ethics review fit in? When are proposals reviewed?

The ethics review starts while the project is being scientifically assessed, or soon after. The grant agreement cannot be signed until the review is complete and the required conditions met.

How are proposals screened for ethics issues?

Projects are assessed to see whether they raise ethics issues and, if so, whether these are adequately addressed (while the project is being carried out, as well as at other times).

The ethics review is an **independent assessment**. Opinions issued by local or national ethics bodies as part of a proposal will be taken into account, but will not prejudice the outcome of the ethics review.

The ethics review focuses on issues as:

- human rights & protection of human beings
- animal protection & welfare
- data protection & privacy
- environmental protection
- malevolent use of research results

- compliance with international, EU & national law.

It may also cover issues of research integrity, including, fabrication, falsification and plagiarism in proposing, performing, or reviewing research or in reporting research results; this includes misrepresenting credentials and improprieties of authorship.

How is the ethics review process organised?

The ethics review falls into 2 stages:

Stage 1 - **Ethics screening**

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.

Stage 2 - **Ethics assessment** (if necessary)

If screening reveals any serious or complex issues that call for more in-depth analysis, they will be subject to an ethics assessment. Ethics experts are involved in both screening and assessment.

Exception

All proposals involving the use of human embryonic stems cells (hESCs) will undergo an ethics assessment.

Funding for research involving hESCs is subject to the conditions set out in the [Declaration of the Commission to the Horizon 2020 Framework Programme](#) (OJ C 373, 20.12.2013, p. 12).

IMPLEMENT THE RESULTS OF AN ETHICS REVIEW

We will let you know the outcome of your ethics review at the beginning of the grant preparation phase or soon after. You will receive an ethics screening or ethics assessment report with an ethics opinion on your proposal. The possible outcomes of the ethics review are:

1. Ethics clearance
2. Conditional ethics clearance
3. Ethics assessment recommended
4. Second ethics assessment recommended
5. No ethics clearance

1. Ethics clearance

Proposals giving rise to ethics issues all of which are appropriately handled are granted 'ethics

clearance'. This means that no further steps have to be taken. The ethics section in the proposal can be transferred unchanged to the ethics section in Part B of the DoA.

2. Conditional ethics clearance

In this case clearance is subject to conditions. Your **ethics report will list one or more 'ethics requirements'** which must be met either before or after the grant agreement is signed. They may include:

- regular reporting to the Commission or the agency concerned
- appointing an independent ethics advisor or ethics board (possibly tasked with reporting to us on compliance with ethics requirements)
- an ethics check
- supplying further information/documents
- adjusting methodology so as to comply with ethical principles and relevant legislation

Ethics requirements will be integrated in the grant agreement and have to be met during or after the lifetime of the grant. We will include them in Part A of the Description of the action.

However, some ethics requirements may have to be met already before the grant agreement can be signed.

Tasks of the coordinator or sole applicant

- comply with all ethics requirements
- update the description of the action (DoA) whenever appropriate to address the ethics requirements and describe how they are to be met in the course of the project
- take into account any recommendations set out in the ethics report.

3. Ethics assessment recommended

If an ethics screening uncovers serious or complex issues, a full ethics assessment may be recommended. Additional information may be needed for this purpose.

Tasks of the coordinator or sole applicant

- provide further information if and as requested in the ethics screening report.

4. Second ethics assessment recommended

If important information is missing from an ethics assessment, experts may be unable to reach a conclusion and issue an ethics opinion. In such cases, a second ethics assessment may be recommended.

Tasks of the coordinator or sole applicant

- provide additional information and address weaknesses as requested in the ethics assessment report.

5. No ethics clearance

- If your proposal is not given ethics clearance, it is not eligible for funding and will be rejected.

You will be informed of

- the decision to reject your proposal
- the reasons for the decision
- how you can appeal against it.