



European
Commission

The EU Framework Programme
for Research and Innovation

HORIZON 2020



AGA – Annotated Model Grant Agreement

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Research and
Innovation

ARTICLE 34 — ETHICS

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34.1 Obligation to comply with ethical principles

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 Integrity⁴⁷ — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and
- (b) applicable international, EU and national law.

Funding will not be granted for **activities carried out outside the EU** if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:

- (a) aim at human cloning for reproductive purposes;
- (b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or
- (c) intend 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.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the ‘ethics requirements’ set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the [Commission][Agency] copy of:

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

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

⁴⁷ The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf



1. Ethical principles

The beneficiaries must carry out the action:

- in compliance with ethical principles and
- respecting applicable international, EU and national law.

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations
- Following the highest standards of research integrity (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct; see also *the European Code of Conduct for Research Integrity*⁵³).

The key source texts of **EU and international law** are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights (ECHR) and its Supplementary Protocols (for other texts, see *the Science in Society e-library*⁵⁴).


Compliance to the ethical principles and legislation is ensured by the Commission's '**H2020 ethics appraisal scheme**' (i.e. the European Commission's general approach on ethics issues in research), which includes all of the following:

- 'ethics self-assessment' (by the applicants, in their proposal; see *the proposal templates and the Guidance — How to complete your ethics self-assessment*)

⁵³ Available at http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

⁵⁴ Available at <http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1407>

- two-stage 'ethics review', with an ethics screening and, if necessary, an 'ethics assessment' (by the Commission/Agency, during the selection procedure)
- if necessary, ethics checks, reviews and audits (during the implementation of the action and up to two years afterwards; see *Article 22*).

 For more information on ethics in research, see *the Online Manual*.

2. Activities carried out outside the EU

For activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of a third country; the activities must ALSO be allowed in at least one Member State.

The beneficiaries must confirm in the 'ethics self-assessment' section of their proposal that this condition is met.

3. Exclusive focus on civil applications

Activities under the action must have an exclusive focus on civil applications.

This does not mean that peripherally, the research results cannot be useful in a military context. Research related to dual-use products or technologies (usually used for civilian purposes but with possible military applications) is not banned. However, activities *focusing* on military applications will not be funded.

4. Activities raising ethical issues

If the ethics review (carried out by the Commission/Agency during the selection procedure) identifies an ethics issue, the Commission/Agency will define 'ethics requirements' and include them in Annex 1 of the GA (in addition to requirements that the consortium must already fulfil before the GA is signed).

Examples (ethics issues): involvement of patients, volunteers, children or vulnerable populations; use of human (embryonic) stem cells; implication of developing countries; collecting and processing of personal data; use of animals; risk of environmental impact; risk of malevolent use or misuse of research results.

In this case, the beneficiaries must comply with the **ethics requirements**.

Examples (ethics requirements): the obligation to appoint a data protection officer, an independent ethics advisor or ethics advisory board.

Moreover, the coordinator must — before the activity starts — submit **copies** of the following,:

- any opinion(s) issued by an ethics committee; and
- any notification(s) or authorisation(s) for activities that raise ethical issues (*e.g. to ethics committees, data protection authorities, dual-use authorities, etc.*).

Best practice: When preparing the documents, beneficiaries should request the assistance of ethics experts, research ethics departments/committees and of their organisation's data protection officer (DPO).

For new opinions, authorisations or notifications: the beneficiaries must include the EU action's title in their requests.

For existing opinions, authorisations or notifications: the beneficiaries must confirm that all the documents submitted cover all the tasks to be undertaken in the context of the action.

If the documents are not in English, the coordinator must submit an English summary that allows the efficient and timely review of the proposal.

This summary should contain the conclusions, recommendations and, if applicable, the conditions imposed.

It is expected that the translation will be made by the beneficiaries. If, exceptionally, there should be translation **costs**, they will be considered eligible (see *Article 6.2.D.3*) — at the rate of non-official translations.

There is NO need to submit copies of requests for opinions or authorisations; the Commission/Agency only needs a copy of the opinion or authorisation.

The Commission/Agency may carry out ethics checks, reviews or audits, to ensure that the beneficiaries have properly implemented the ethics requirements (see *Article 22*).

5. Activities involving human embryos or human embryonic stem cells

Activities that involve human embryos or human embryonic stem cells can only be funded, if:

- they comply with the terms outlined in the Statement of the Commission related to research activities involving human embryonic stem cells⁵⁵ and
- they are set out in Annex 1 or the coordinator has obtained explicit approval by the Commission/Agency.

If they are retained for funding, these activities will be considered as 'activities raising ethical issues' (and must comply with the rules above, including 'ethics requirements' that will be set out in Annex 1; see *point 4*).

⁵⁵ Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF>