H2020 Programme

AGA – Annotated Model Grant Agreement

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ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

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34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

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 or for activities which destroy human embryos (for example, for obtaining stem cells).

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.

In addition, the beneficiaries must respect the fundamental principle of research integrity — as set out in the European Code of Conduct for Research Integrity[49].

This implies notably compliance with the following fundamental principles:

- reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;
- honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;
- respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
- accountability for the research from idea to publication, for its management and organization, for training, supervision and mentoring, and for its wider impacts

and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply.

[49] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the *[Commission][Agency]* (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

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, in addition to Article 34.1, 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.

1. Ethical principles

The beneficiaries must carry out the action in compliance with:

- ethical principles (including the highest standards of research integrity) and
- 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

The key sources 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 Protocols (for other texts). Another important source is the UN Convention on the Rights of Persons with Disabilities (UN CRPD).

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

- ethics *self*-assessment (by the applicants, in their proposal)
- 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 guidance on ethics, *see How to complete your ethics self-assessment, Research involving dual use items, Research focusing exclusively on civil applications, Potential misuse of research results and more generally, the Funding & Tenders Portal Online Manual.*

2. Activities carried out outside the EU

Activities carried out in a non-EU country must comply with the laws of that country AND be allowed in at least one EU 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 the research results cannot peripherally 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 prohibited. However, activities that *focus* on military applications will NOT be funded.

4. Research integrity

In order to ensure the necessary level of research integrity, the beneficiaries must follow principles listed in this Article and ensure that the persons carrying out research tasks comply with the European Code of Conduct for Research Integrity[54] (i.e. follow the good research practices listed in this Code and refrain from any research integrity violations it describes).

Fundamental research integrity principles:

- **reliability** in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources

[54] Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf.

- **honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way
- **respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment
- **accountability** for the research from the idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.

The Code constitutes a general reference framework and takes into account the legitimate interests of the beneficiaries (i.e. regarding IPRs and data sharing).

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply. In addition, beneficiaries should rely on local, national or discipline-specific guidelines, if such documents exist and are not contrary to the Code.

3.0 The detailed research integrity obligations were introduced with GA version 3.0. For older grant agreements, these obligations were however already implicitly included in Article 34 (which already provided for the more general obligation to comply with the highest standards of research integrity and the European Code of Conduct for Research Integrity).

5. Activities raising ethics 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 as **deliverables** in Annex 1 of the GA.

> ***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*.
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> ***Examples (ethics deliverables):*** *to submit to the Commission/Agency a report on certain ethics issues during the course of the action*.

Other ethics requirements may have been required already before GA signature.

> ***Examples (other ethics requirements):*** *confirmation that the research data of this study will not be transferred outside the EU.*

In addition, the beneficiary must obtain — before the start of the activity for which it is needed — all the necessary **ethics opinions, notifications** and **authorisations** *(e.g. to ethics committees, data protection authorities, dual-use authorities, etc.).*

> **Best practice:** When preparing the applications for such opinions/notifications/ authorisations, beneficiaries should request the assistance of ethics experts, research ethics departments/committees and of their organisation's data protection officer (DPO).

⚠ **Record-keeping —** The documents no longer need to be submitted before the start of the action, but the beneficiary must keep them on file and provide them on request to the Commission/Agency *(e.g. in case of ethics reviews, checks or audits; see Article 18).*

The beneficiary must be able to show that the opinions/authorisations/notifications cover the tasks to be undertaken in the context of the action.

If the documents are not in English, the beneficiary may be asked to provide an English summary.

This summary should show that the opinions/authorisations/notifications cover the action activities and should include conclusions, recommendations and, if applicable, conditions imposed *(e.g. the use of animals is authorised but limited to a certain number)*.

Translation costs may (exceptionally) be charged to the action *(see Article 6.2.D.3)* — at the rate of non-official translations.

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

6. Activities involving human embryos (hE) or human embryonic stem cells (hESC)

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

- they comply with the Statement of the European Commission related to research activities involving human embryonic stem cells[55] (in particular, do NOT result in the destruction of human embryos)

and

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval by the Commission/Agency.

These activities raise ethics issues and must comply with the rules above (and in particular the ethics requirements set out in Annex 1; *see point 5*).

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