

Bridge2HE: A transition from H2020 to HorizonEurope for NCPs

ETHICS REQUIREMENTS AND PROCESS IN HORIZON EUROPE

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BRIDGE2HE

Bridge2HE is the follow-up project to the NCP Academy and is intended as a bridge project to ensure the transfer of NCP project networks from Horizon 2020 to Horizon Europe.

Targets:

- Maintain continuity with current NCP structures and network coordination.
- Integration of NCP networks under a common HE NCP portal.

Added Value:

- Trainings for NCPs
- Development and provision of materials and service concepts for NCP work
- Support for applicants, brokerage events
- Optimisation and adaptation of NCP networks to HE



Horizon Europe regulation (2021/695) (rules for participation)

Article 19

Ethics

1. Actions carried out under the Programme shall comply with ethical principles and relevant Union, national and international law, including the Charter and the European Convention for the Protection of Human Rights and Fundamental Freedoms and its Supplementary Protocols.

Particular attention shall be paid to the principle of proportionality, to the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and to the need to ensure protection of the environment and high levels of human health protection.

prgf. 2: requirements for participants,

prgf. 3: requirements for Commission/funding bodies,

prgf. 4: timeframe for documents

6. Actions which do not fulfil the ethics requirements referred to in paragraphs 1 to 4 and are therefore not ethically acceptable, shall be rejected or terminated once the ethical unacceptability has been established.



MGA – Model Grant Agreement – Article 14

Article 14.1:

The action **must** be carried out in line with the highest ethical standards and the applicable **EU, international and national law** on ethical principles.

Specific ethics rules (if any) are set out in Annex 5.



MGA Annex 5 (Article 14)

Before starting an action task raising ethical issues, the beneficiaries must have obtained all approvals or other mandatory documents needed for implementing the task, notably from any (national or local) ethics committee or other bodies such as data protection authorities.

The documents must be **kept on file** and be submitted **upon request** by the coordinator to the granting authority.

If they are not in English, they must be submitted together with an **English summary**, which shows that the documents **cover the action tasks in question** and includes the **conclusions** of the committee or authority concerned (if any).



MGA – Model Grant Agreement – Article 9

Article 9 — Other participant involved in the action

9.1 Associated partners

9.3 Subcontractors

9.4 Recipient of financial support to third parties

“, the **beneficiaries must ensure** that their contractual obligations under Articles ---, 14 (ethics) --- also apply to the ---”

AGA: “It is the beneficiaries’ responsibility to ensure that these obligations are accepted by the XXX

(e.g. via contractual arrangements, consortium agreement, etc).”

(e.g. via call conditions or contractual arrangements, scholarship agreement, rules of contest, etc).”



MGA – Model Grant Agreement – Chapter 5

Chapter 5 Consequences of non-compliance

- ✓ Article 28 – Grant reduction
- ✓ Article 29 – Payment deadline suspension
- ✓ Article 30 – Payment suspension
- ✓ Article 31 – Grant agreement suspension
- ✓ Article 32 – Grant agreement or beneficiary termination
- ✓ Article 33 – Damages
- ✓ Article 34 – Administrative sanctions and other measures



All research activities must respect:

- ✓ the principle of **proportionality**
- ✓ the right to privacy
- ✓ the right to the protection of personal data
- ✓ the right to physical and mental integrity of all persons
- ✓ the right to equality and non-discrimination
- ✓ high levels of protection of the environment and human health.



Ethics review introduced by the Commission



Ethics review

Same criteria as in H2020

For all activities funded, ethics is an **integral part** of research from beginning to end, and **ethical compliance** is essential to achieve real research excellence. An ethics review process is carried out systematically in all Horizon Europe proposals, based on a **self-assessment** included in the proposal.

Ethical research conduct implies the application of fundamental ethical principles and legislation in all possible domains of research. This includes the adherence to the highest standards of **research integrity** as described in the **European Code of Conduct for Research Integrity**.

Adapted following lessons learnt

- Focus mainly on complex/serious cases
- Reduce number of ethics requirements in funded projects.



Ethics Appraisal Procedure

HE Programme Guide p. 21-26

- ✓ Ethics review procedure before the project start
 - ✓ Self-assessment
 - ✓ Ethics review by independent ethics experts (above threshold)
 - ✓ Ethics screening (if no ethics issues = approved), otherwise =>
 - ✓ Ethics assessment
 - ✓ may lead to contractual obligations (to grant agreement)
 - ✓ Ethics clearance
 - ✓ Conditional ethics clearance
 - ✓ Serious or complex ethics issues => additional information

- ✓ Ethics Checks, Reviews and Audits



Ethics Appraisal Procedure

HE Programme Guide p. 21-26

Activity	Who?	When?	How?
Ethics Self-assessment	Applicant	Application phase	Consideration of ethical issues of the proposal
Ethics Screening	Ethics experts (and/or qualified staff in case a pre-screening is conducted)	Evaluation phase	Review of application material
Ethics Assessment (for proposals involving hESC/hE or flagged as serious or complex)	Ethics experts	Evaluation/ Grant preparation phase	Review of application material
Ethics check/review/audit	Project Officer and/or Ethics officer and/or Ethics experts	Implementation phase	Review of project deliverables/interview with applicants/onsite visit



Ethics Self-Assessment

[how-to-complete-your-ethics-self-assessment_en.pdf \(europa.eu\)](https://ec.europa.eu/euipo/how-to-complete-your-ethics-self-assessment_en.pdf)

The results of the self-assessment need to be included to the proposal Part A point 4 – Ethics and Security.

Proposal template Part A:

4 – Ethics and Security

Ethics issues table

This table should be completed as an essential part of your proposal. Please go through the table and indicate which elements concern your proposal by answering 'Yes' or 'No'. If you answer 'Yes' to any of the questions,

- *indicate in the adjacent box at which page in your full proposal further information relating to that ethics issue can be found, and*
- *provide additional information on that ethics issue in the Ethics Self-Assessment section.*

For more information on each of the ethics issues and how to address them, including detailed legal references, see the guidelines '[How to Complete your Ethics Self-Assessment](#)'.



How to complete your ethics self-assessment

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How to complete your ethics self-assessment

Structure in all sections:

1. Background
2. How to address the issues
3. Ethics issues checklist (example Humans)

2 HUMANS		YES/ NO		Information to be provided in the proposal	Documents to be kept on file and provided on request
Does your activity involve human participants?		<input type="checkbox"/>	<input type="checkbox"/>	Please provide information in one of the subcategories below	
If YES:	Are they volunteers?	<input type="checkbox"/>	<input type="checkbox"/>	1) Details on recruitment, inclusion and exclusion criteria and informed consent procedures. 2) Details on unexpected findings policy.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.

4. Background documents & further reading



The ethics review covers issues as:

- ✓ human rights and protection of human beings
- ✓ animal protection and welfare
- ✓ data protection and privacy
- ✓ health and safety
- ✓ environmental protection
- ✓ artificial intelligence

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.



Ethics review procedure in Horizon Europe

- ✓ Due to the self-assessment the ethics experts will assess the given documents and inform the ethics results through Coordinator to the participants. Results will be available in *Document library* of the project in question.
- ✓ If the review leads to requirements, these requirements need to be completed immediately
- ✓ If the review shows complex issues, another assessment begins
- ✓ Become deliverables to DoA Part A (by the PO)
- ✓ Generate an additional Ethics WP
- ✓ May require changes to DoA Part B (by the Coordinator)



Serious and complex ethics issues

Guide on [Identifying serious and complex ethics issues in EU-funded research](#)

- ✓ The seriousness and complexity of the ethics issues are assessed on a **proposal-by-proposal** basis.
- ✓ If the activities are **standard practices**, with a clear legal/ethics framework, the related ethics issues should not in the meaning of Horizon Europe be considered as serious or complex as they should be addressed by at **local, regional and national level**, should receive appropriate ethics approval/s and should not undergo an ethics assessment. In such cases of standard practices, there should be no need of ethics advisors or advisory boards.



When the approvals & mandatory documents need to be obtained?

- Before the start of the **relevant** activities, task in question
- ✓ The applicants & participants need to keep all the documents on (their own) file and provide them to the Coordinator to be handed over to the Commission/funding body when they request.



Ethics WP in short

- ✓ Ethics assessment may lead to a situation where ethics WP is necessary
- ✓ Ethics requirements due after project start will be ethics deliverables
- ✓ For ethics deliverables will be created automatically an ethics WP
- ✓ Normally the last WP in project



Negative result of ethics assessment

After the ethics assessment, if your proposal is not given ethics clearance, it is **not eligible for funding** and will be rejected.

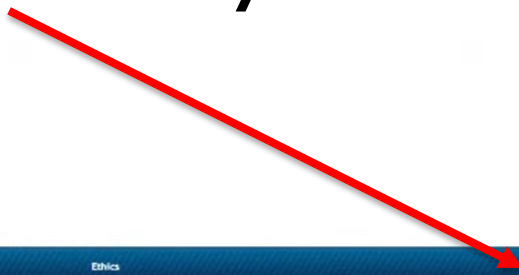
You will be informed of

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

The project may also be terminated/task suspended if the ethics issues fail during the project duration



Do NOT click the *Ethics info* ready before a permission



The screenshot shows the 'Ethics' section of the Grant Management system. The top navigation bar contains various tabs, with 'Ethics Info' highlighted and marked with a yellow warning icon. Below the navigation bar, the 'Ethics' section displays 'Ethics categories/issues identified during the Ethics Review' with icons for categories such as HEP, HUMAN, HCT, POPD, ANIMALS, AI, and OTHER ETHICS. There are also sections for 'Ethics requirements' and 'Ethics Reports'.

- Ethics screen is available as read only
- Before a final Opinion is encoded by Ethics experts in the Ethics evaluation process, at times, additional information may be requested from the applicant.
- The Consortium or its representative has to upload the requested information in Grant Management application in the Funding & Tenders Portal, under section 'Additional Information request'



Tips

- ✓ Ethics review procedure may take **time** = start early
- ✓ Rely on the experts in your **own organisation** (or local/national authorities)
- ✓ **Communicate** immediately to the ethics expert if needed => ethics reviews are case-by-case assessments
- ✓ If some document/approval will be delayed, justify it and give **time estimation**
- ✓ Be active, be proactive



Sources of information

HE Programme Guide pages 21-26

European Code of Conduct for Research Integrity of ALLEA

<https://allea.org/code-of-conduct/>



Ethics Guidelines for Trustworthy AI, published by the European Commission's High Level Expert Group on Artificial Intelligence, published 8 April 2019

<https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines#Top>

Ethics in Horizon Europe

Key changes to the Ethics Appraisal Process, identifying serious and complex issues, and addressing ethics of Artificial Intelligence

[Horizon Europe: key changes to the Ethics Appraisal Process – YouTube](#)

By Commission

Ethics Review Helpdesk

[Research Enquiry Service | European Commission \(europa.eu\)](#)

➔ Select 13 Ethics from the box “Subject”





Bridge2HE: A transition from H2020 to HorizonEurope for NCPs



Thank You

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70 4D4P7 70
CH4NG3
- 573PH3N H4WK1NG

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our online feedback form