RISE 2020 Ethics Evaluation
Expert Briefing Notes

DISCLAIMER: These briefing notes follow with the oral presentation for the experts to prepare the remote and central phases of H2020-MSCA-RISE-2020 ethics evaluation. The information aims to facilitate the work of the evaluators along the key principles of fair, transparent, and high quality evaluation process and outcomes. The notes therefore are provided for information purposes only and are not intended to replace consultation of any applicable legal sources. Neither the European Commission, nor the Research Executive Agency (or any person acting on their behalf) can be held responsible for the use made of these briefing notes. The guidance provided in the H2020 rules and Annotated Model Grant Agreement shall prevail in case of discrepancies.
Welcome to this evaluation!

This briefing video aims to provide you with an overview and understanding of your role as an evaluator. These briefings will target the ethics appraisal timeline and process, the main ethics issues, the ethics self-assessment and the appraisal process in RISE.

As an independent ethics expert, you will assess the ethics of proposals submitted in response to the RISE 2020 call.

The RISE action funds research and innovation projects implemented through the secondments of staff between participants from any country. The applicants can submit proposals in all fields of research covered by the Treaties on the EU and on the functioning of the EU.

Role of experts, Guiding principles, conflict of interest

Role of independent experts
- As an independent expert, you assess the ethics of proposals submitted in response to a given call
- You are responsible for carrying out the screening of the proposals yourself (and you are not allowed to delegate the work to another person!)
- Significant decisions will be made on the basis of your evaluation of the assessment
- You must complete your reports in the electronic system within a given deadline as per your contractual obligations
- Failing to meet the deadlines may result in the reduction or rejection of your allowance/expenses claimed

There are four Guiding Principles
- Independence
  – You are evaluating in a personal capacity
  – You represent neither your employer, nor your country!

- Impartiality
  – You must treat all proposals equally and evaluate them impartially on their merits, irrespective of their origin or the identity of the applicants

- Objectivity
  – You evaluate each proposal as submitted; meaning on its own merit, not its potential if certain changes were to be made

- Consistency
  – You apply the same standard of judgment to all proposals
In terms of Confidentiality, here are some “do’s” and don’ts”

Do:

• Not discuss evaluation matters, such as the content of proposals, evaluation results or opinions of fellow experts, with anyone not directly involved in the evaluation of the call

• Not contact partners in the consortium, sub-contractors or any third parties

• Not disclose names of your fellow experts

• Maintain confidentiality of documents, paper or electronic, at all times, and delete them upon completing your work

Conflicts of interest (COI)

*COI rules are in Annex 1 Code of Conduct of the expert contract

- Experts must inform the Commission/Agency as soon as they become aware of a COI. This can happen:
  o Before the signature of the contract
  o Upon receipt of proposals
  o During the course of your work (during evaluation)

- If there is a COI for a certain proposal the Expert cannot evaluate it:
  o Neither individually
  o Nor in the consensus group
  o The Commission/Agency will determine if there is a COI on a case-by-case basis and decide the course of action to follow

- If you knowingly hide a COI, you will be excluded from the evaluation and your work declared null and void
  o The allowance/expenses you claimed may be reduced, rejected or recovered
  o Your contract may be terminated

ETHICS IN H2020

• For all activities funded by the European Union, Ethics is an integral part of research from beginning to end.

• Ethical compliance is crucial for all scientific domains (not only in Life Sciences).

• In H2020, all proposals considered for funding will be submitted to an Ethics Review.

• All proposals must describe ethical issues raised & how they will be addressed so as to conform to national, European and international regulations.

Only proposals that comply with ethical principles and legislation may receive funding.

As for the ETHICS TIMELINE

- The ethics appraisal procedure of Horizon 2020 starts before the evaluation with the applicant self-assessment and goes on until the project ends, and even after in case of ex post ethics audit.

- For the present exercise, the ethics experts are asked to conduct the Ethics Review, by implementing Ethics Screenings of proposals that are likely to be funded.
PROCESS

- Ethics screening
  - The role of the expert is to check the proposal and confirm if it is cleared for ethics. If the proposal is conditionally cleared, the experts must draft the requirements that the applicants will have to fulfil.
  - Each proposal is checked by two experts separately - both submitting an individual report - which are used to set up a consensus meeting. Following the meeting, a consensus report is drafted and its conclusions are sent to the applicants.

- Ethics Assessment
  - The Assessment is an additional step, that takes place after the Screening, but only for very specific cases. It is NOT PART OF THE CURRENT EXERCISE and will be managed by the ethics services of the European Commission at a later Stage.
  - Therefore, the role of the Experts during this Screening process is to flag when an Assessment is required in the consensus report.

The MAIN ETHICS ISSUES that you will assess include the area of

Human Embryonic Stem Cells (hESC)

- If the project involves hESC, check the applicable ethical issues and select “Ethics Assessment recommended” in the “Ethics Opinion”
- Check with the Ethics Coordinator if the Scientific Evaluators confirmed that the use of hESC is necessary and complete that section of the report

Humans

This ethics issue refers to the individuals participating in the research (i.e., patients, healthy volunteers), NOT to the researchers

Please keep in mind that "volunteers for social or human sciences research" (question 1.1) should not be confused with "healthy volunteers for medical studies" (question 1.6)

Human Cells / Tissues

If the origin of human cells/tissues is not described in the proposal (prospective collection, previously collected, biobank, etc.) use the different requirement options (do not make assumptions)

Data Protection

According to the Grant Agreement Art 39.2, the beneficiaries must process personal data in compliance with applicable EU and national law on data protection.

The new General Data Protection Regulation entered into force on 25 May 2018. Some of the key elements, covered by the updated Regulation are:

- Shift from compliance-based to accountability based approach (record keeping);
- Data protection by design and by default;
- Data minimisation;
- Obligatory appointment of Data Protection Officer (in certain cases);
- Data Protection Impact Assessments (in certain cases);
- Administrative fines.
In the context of scientific research, GDPR provides a number of derogations, aimed at the facilitation of research activities. It also enables Member states to introduce further conditions or limitations with regard to the processing of genetic, biometric and health data and adopt derogations for some of the data subjects' rights. The derogations, pertaining to research are subject to a number of safeguards aimed at ensuring that technical and organisational measures are in place to protect the rights and freedoms of the data subjects. Bear in mind that the principle of data minimisation should be respected at all times and data should be anonymised/pseudonymised (whenever possible).

In the background information, you will find a self-explanatory presentation on the GDPR that focuses on the elements, definitions, etc. As well as the New Ethics and Data Protection Guide released in November 2018.

**TC participation**

- The fact that an organisation from a TC integrates the consortium does NOT raise ethical issues per se. Ethical issues might arise if:
  - Research activities are carried out in a Third Country
  - Human participants or resources come from a Third Country
  - Material is imported/exported from/to a Third Country

- In case data is transferred from EU to a TC, check the Third Countries for which Commission decisions have been published on the adequacy of protection of personal data (https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/adequacy-protection-personal-data-non-eu-countries_en).

The countries covered by adequacy decision provide adequate level of personal data protection. In case personal data are transferred from a non-EU country to the EU (or a third country), the transfer must comply with the laws of the country in which the data has been collected.

**Non-EU Countries**

- *Does your research involve non-EU countries?*
  
  **Yes**, if a participant comes from a non-EU country (USA, Switzerland, Israel, Morocco, etc)

- *If research activities raising ethics issues are performed in non-EU countries*, the applicants must confirm that the research performed outside the EU is compatible with the Union legislation and Horizon 2020 Guidelines
PART II

Ethics Self Assessment

Each applicant is responsible for:

- identifying any potential ethics issues
- handling ethical aspects of their proposal
- detailing how they plan to address them in sufficient detail already at the proposal stage

The proposals include a Part A and a Part B:

- **Section 4 of Part A** is the Ethics Issues Table, which indicates the issues flagged by the applicants. Part A also lists the participants and their country.

- Part B describes in detail the activities proposed by the consortium.
  
  - **Sections 2 to 4 of Part B** contain a detailed description of the work.
  
  - **Section 7 of Part B** is the Ethics section, where applicants describe how the ethics issues identified in Part A will be addressed.

- The ethics evaluators must check both, Part A and Part B of the proposals, for the screening process.

The Ethics Issue Table is the Applicant's self-assessment and can be found in part A.

The Ethics Self-Assessment Guidance

The Ethics Self Assessment Guidance for the applicants is also a key document for the work of the ethics expert. This document contains important details on the different ethics issues, including tables that mention the information and documents applicants must provide. This document supports the experts in looking for the necessary information in the proposals and drafting in their reports the requirements addressing missing items.

The document is available in the participant portal, under the reference documents (Grant Manuals/Horizontal Issues/Ethics):


Appraisal Process in RISE

The Screening is done for those proposals that are likely to be funded and where the applicants or the Scientific Experts flagged at least one ethics issue.

The role of the expert is to check the proposal and confirm if the proposal is cleared for ethics. If the proposal is conditionally cleared, the experts must draft the requirements that the applicants will have to fulfil.
Each proposal is checked by two experts separately and both submit an individual report. The two EthIR are used to set up a consensus meeting. Following the meeting, the consensus report is finalised and its conclusions are sent to the applicants.

Types of Reports:

There are 2 types of reports:

- Ethics Individual Report (EthIR)
- Ethics Consensus Report (EthCR)

Ethics Screening Reports must be clear, concise and project specific

Please, remember that all ethical issues identified in the proposal need to be addressed in the report

Do NOT base your evaluation on the proposal Self-Assessment Table only: check the entire proposal

Requirements

- The Experts should edit the predefined requirement text, whenever it is appropriate to do so. The requirements should be concise and project specific.

- Clarifications and confirmations must be addressed before the signature of the Grant Agreement.

- Authorisations / approvals from local/national competent bodies must be obtained before the start of the relevant research. The Experts must indicate in the respective requirement which organisations of the consortium must provide them.

- When a requirement is linked to obtaining a document (ethics approval, authorisation, etc.) the Experts must indicate in the text of the requirement that it must be fulfilled before month X of the project. To define month X the Expert must check the WP “Start Month” in the “Work Package List” table of Part B.

- Be reminded that according to the revised Art. 34.2, opinions, notifications and authorisations must be kept on file by the project coordinator and be submitted only upon request by the Agency (see Article 52).

    - You are kindly requested to revise the wording in the requirements concerning the approvals in SEP and re-write when necessary with the following sentence “the opinions, notifications/ authorisation must be obtained, kept on file and be submitted upon request”

- If applicable, Experts may request necessary adaptation of the methodology to comply with the ethical principles and relevant legislation.

Opinion

- The experts must select one of the following three “Ethics Opinion” options, according to the situation of the proposal.

- Please note that the option “additional information needed” is not applicable to RISE.
• The "Ethics Clearance" is given when the proposal is already fully compatible with Article 34 of Horizon 2020 Grant Agreement.

**Ethics Assessment**

• The Assessment is an additional step, that takes place after the Screening, but only for very specific cases. During the assessment, a larger panel of ethics evaluators (3-5) checks the proposal. It is NOT PART OF THE CURRENT EXERCISE and will be managed by the ethics services of the European Commission at a later Stage.

• The role of the Experts during the present exercise is to indicate in the consensus report when an Assessment should be performed. Only very specific cases should be sent for Assessment: serious ethics issues, such as severe interventions on humans, lack of appropriate ethics framework in the country where the research is conducted, etc. For the case of hESC, it is mandatory to send the proposal for Assessment.

• Please list in the Screening report any additional information or documents that the applicants should provide prior to the Ethics Assessment to facilitate its conduct. Note that the Assessment will take into account, the analysis of the Screening.

• If you think a proposal should be sent for Assessment, please inform the Ethics Correspondent, following the consensus meeting of the respective proposal and do not put requirements.

• In principle not more than 1% of proposals should go to assessment.

**Ethics Check**

In specific cases, the Experts might recommend an Ethics check, which will be implemented during the project.

When a check is requested, the Expert must indicate the timing for the check (month of the project when the check should be done) and must include a justification for the implementation of an ethics check.

In principle not more than 10% of proposals should have an ethics check

**Sensitive Flag**

Even if a proposal receives clearance, the ethics issues may be highly sensitive. If the high sensitivity flag is selected, please include a justification.

**SEP**

**EthIR**

During the EthIR Phase, experts will receive the task: Write EIR

• Draft the Ethics individual Report (EthIR)
• 2 experts per proposal
• The EthIR should be ready by **Wed, 8 July 2020**.

During this phase the Vice Chairs follow-up the work of the experts and provide them with support if they need some.
EthCR

- The rapporteur writes the Ethics Consensus Report (EthCR)
- The Task EthCR is active only after the submission of both EthIRs.
- The rapporteur will be able to merge the two EthIRs.
- We would kindly ask the Rapporteurs to draft the EthCR by Friday, 10 July 2020. Please don’t submit.
- At the end of this phase, all experts need to approve the EthCR.

Check if your comments are included and avoid contradictions.
If something is missing, include a comment in the comments box and reject the report back to the rapporteur.
The EthCR can be sent back to the rapporteur either by the second expert or by the vice-chair.

KEY MESSAGES

- Include ONLY requirements NOT already fulfilled in the proposal.
- If there are requirements, choose conditional clearance.
- Please check the completeness and accuracy of your comments and make sure you include a justification for the requirements.
- The EthSR will be sent to the applicants.
- If you come across sensitive proposals according to your experience, let us know for reinforced monitoring.