



MSCA POSTDOCTORAL FELLOWSHIPS

MANUAL FOR ETHICS EXPERTS 2024

European Research Executive Agency

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Key Message:

The ethics appraisal in Horizon Europe is a risk-based process: focus only on serious and complex cases.

Ethics appraisal. What it is:

Exercise to identify ALL serious and complex cases. Only these ones will go to assessment. hESC and hE will go to assessment automatically.

Ethics appraisal. What it is NOT:

It is not a full legal review of the proposals. Ethics requirements are not meant to replace the legal compliance of the proposal to national/EU requirements.

1. GENERAL ASPECTS

1.1. Introduction



This guide will help experts through their work as “ethics experts” for the 2024 Marie-Skłodowska-Curie Postdoctoral Fellowships (HORIZON-MSCA-2024-PF) **ethics screening**.

Ethics Experts have the important task of screening proposals from among Europe’s best and most promising researchers.

Every proposal goes first through a scientific evaluation. Subsequently, those selected for funding undergo an ethics screening before grant agreement signature.

Ethics experts do not perform a scientific evaluation of proposals. Their role is to ensure that the research carried out **complies with the ethics rules of Horizon Europe**.

The **aim** of the Horizon Europe ethics screening exercise is **to detect and to filter out proposals with the highest ethics risks**. There should only be few of them, and it is very likely that not all experts will screen one of these proposals.

The vast majority of proposals should receive ethics clearance. N.B. Clearance means that

no serious and/or complex ethics issues have been identified. This does NOT imply that the proposal is ethically cleared.

The ethics screening has several possible **Ethics Opinions** as an outcome:

- **Ethics Clearance** – this should be **the outcome for most proposals in this call**. No ethics requirements are formulated. In exceptional cases, an ethics check/review to be performed during the lifetime of the project can be recommended and/or the appointment of an ethics mentor.

- **Conditional Ethics Clearance** - **appoint an independent ethics advisor**. In this case there could be some sensitive ethics issues identified. Appointing an independent ethics advisor/board is the only possible requirement in this screening exercise.

- **Ethics Assessment** – **ONLY** for proposals **with serious or complex ethics issues**, and for all proposals involving the use of hESC or hE. This extra step involves additional ethics experts, and it takes place after the ethics screening.

1.2. Ethics guiding principles under Horizon Europe

The ethics appraisal process for MSCA-PF in Horizon Europe (HE) must be conducted in accordance with **Article 19 of Regulation (EU) 2021/695** establishing Horizon Europe, and **Article 14 & Annex 5 of the Model Grant Agreement (MGA)**. MSCA-PF projects should be implemented by adhering to the 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.

When implementing actions under HE, host institutions shall comply with the following ethical guiding principles:

- the principle of proportionality
- 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
- the need to ensure protection of the environment
- the need to ensure high levels of human health protection.

The following **research activities are NOT funded under HE** (Article 18 of Regulation (EU) 2021/695, Article 14 & Annex 5 of the MGA):

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

(d) activities leading to the destruction of human embryos (for example, for obtaining stem cells).

Furthermore, no funding shall be provided, within or outside the Union for research activities that are prohibited in all Member States. No funding shall be provided in a Member State for a research activity which is forbidden in that Member State.

In accordance with Article 7 of Regulation (EU) 2021/695, **activities under the action must have an exclusive focus on civil applications.**

Actions which do not fulfil the ethics requirements specified in Article 19 of Regulation (EU) 2021/695 and are therefore not ethically acceptable, shall be rejected or terminated once the ethical unacceptability has been established.

Research on human stem cells, both adult and embryonic, may be financed depending both on the contents of the scientific proposal and the legal framework of the Member States involved.

All actions involving the use of human embryonic stem cells or human embryos shall be subject to an ethics assessment (Articles 19 of Regulation (EU) 2021/695, Article 14 and Annex 5 of the MGA).

1.3. Obligations of host institutions

In line with Article 19 – Regulation (EU) 2021/695 legal entities participating in an action funded under HE shall obtain all approvals or other mandatory documents from the relevant national, local ethics committees or other bodies, such as data protection authorities, before the start of the relevant activities.

Those documents shall be kept on file and provided to the European Research Executive Agency (REA) upon request. 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 include the conclusions of the committee or authority concerned, if applicable (Article 14 & Annex 5 – Model Grant Agreement (MGA)).

Furthermore, applicants shall provide in Part A of the proposal:

- an ethics self-assessment identifying and detailing all the foreseeable ethics issues related to the objective, implementation and likely impact of the activities to be funded, including a confirmation of compliance with the ethical principles and a description of how it will be ensured;
- a confirmation that the activities will comply with the European Code of Conduct for Research Integrity as well as applicable international and national law, including the Charter of Fundamental Rights of the EU and the European Convention on Human Rights and its Supplementary Protocols;
- for activities carried out outside the Union, a confirmation that the same activities would have been allowed in a Member State; and
- for activities making use of human embryonic stem cells, as appropriate, details of licensing and control measures that shall be taken by the competent authorities of the Member States concerned as well as details of the ethics ap-

provals that shall be obtained before the activities concerned start.

1.4. The different roles in the process

The European Research Executive Agency (REA) uses independent experts for the ethics screening of proposals. These experts have different roles, namely:

- **Ethics Experts:** responsible for drafting the Ethics Individual Report (EthIR). The expert may also be asked to act as Rapporteur. In this case they are responsible for drafting and finalising the Ethics Consensus Report (EthCR).
- **Ethics Vice-Chairs (VC)** to support the experts and monitor the ethics screening process. Each expert has a VC allocated to them. The VCs are themselves ethics experts with substantial experience.

1.5. Working conditions

Place of work: all the work of the ethics experts is performed remotely and may be carried out at home or place of work. The screening of proposals is performed through **SEP**, a web-based electronic tool.

Conflict of Interest (Col): REA will not appoint an expert to screen proposals if they have a vested interest that could influence their review.

An expert has Col if they:

- were involved in the preparation of any proposal submitted to the same topic/other topic within the same call budget-split;
- are a director/trustee/partner or involved in any way in the management of an applicant (or linked third parties or other third parties involved in the action);
- are employed or contracted by one of the applicants (or linked third parties or other third parties involved in the action);
- stand to benefit directly/indirectly if any proposal submitted to the topic/other topic within the same call budget-split is accepted or rejected;

- have a close family/personal relationship with any person representing an applicant legal entity (or third party) involved in the preparation of the proposal;
- are a member of an advisory group set up by the EU to advise on the preparation of work programmes or work programmes in an area related to the call in question;
- are a National Contact Point (NCP), or are working for the Enterprise Europe Network (EEN);
- are a member of a programme committee.

Experts must inform REA as soon as they become aware of a COI. This can happen before the signature of the contract, upon receipt of proposals, during the course of the work.

If there is a COI for a certain proposal the expert cannot screen it neither individually, nor in the consensus group. REA will determine if there is a COI on a case-by-case basis and decide the course of action to follow.

More details are available in the [Expert Code of Conduct](#) which forms an integral part of the contract signed by the experts.

Remuneration: experts are entitled to a fee per task, up to a maximum amount. Please consult the contract for details.

Work schedule and volume: participation in the MSCA-PF ethics review **does not imply** consecutive or 9-to-5 working days, but **flexible working hours** according to the deadlines (please see the **timetable** on page 35). The number of proposals each expert will be asked to screen largely depends on the number of proposals likely to be funded that have been received in their area of expertise.

Experts are requested to **follow the instructions of the appointed Vice-Chair on how to prioritise their tasks**. This guidance will be given using either e-mail or the IT system SEP. Depending on the circumstances, the Vice-Chair may intervene to guide the expert during the ethics screening process by leaving comments in SEP to help submit individual and consensus reports on time.

Guiding principles as ethics expert:

1. Independence

Experts are screening/assessing in a personal capacity. They represent neither their employer nor their country.

2. Impartiality

Experts must treat all proposals equally and screen/assess them impartially on their merits, irrespective of their origin or the identity of the applicants.

3. Objectivity

Experts screen/assess each proposal as submitted; meaning on its own merit, not on its potential if certain changes were to be made.

4. Consistency

Experts apply the same standard of judgment to all proposals.

Confidentiality:

Experts must:

- Not discuss evaluation matters (content of proposals, evaluation results, opinions, etc.) with anyone (including other experts or Commission/Agencies staff or any other person not directly involved in the evaluation of the proposal).
- Not contact partners in the consortium, sub-contractors or any third parties.

- Not disclose the names of the fellow experts. The Commission publishes the names of the experts annually – as a group, but no link can be made between an expert and a proposal.
- Maintain the confidentiality of documents (paper or electronic) at all times (on-site or remotely). Return, destroy or delete all confidential documents (paper or electronic) upon completing the work, as instructed.

1.6. Overview of the different MSCA-PF schemes

The goal of the MSCA Postdoctoral Fellowships (PFs) is to enhance the creative and innovative potential of researchers holding a PhD to acquire new skills through advanced training, international interdisciplinary and inter-sectoral mobility.

MSCA-PFs are open to excellent researchers of any nationality. The scheme also encourages researchers to work on research and innovation projects in the non-academic sector.

As an ethics expert, you will screen two types of Postdoctoral Fellowships:

a. European Postdoctoral Fellowships (EFs)

EFs are hosted in EU Member States or Horizon Europe Associated Countries for 12 to 24 months and are open to researchers holding a PhD of any nationality either coming to Europe from any country in the world or moving within Europe.

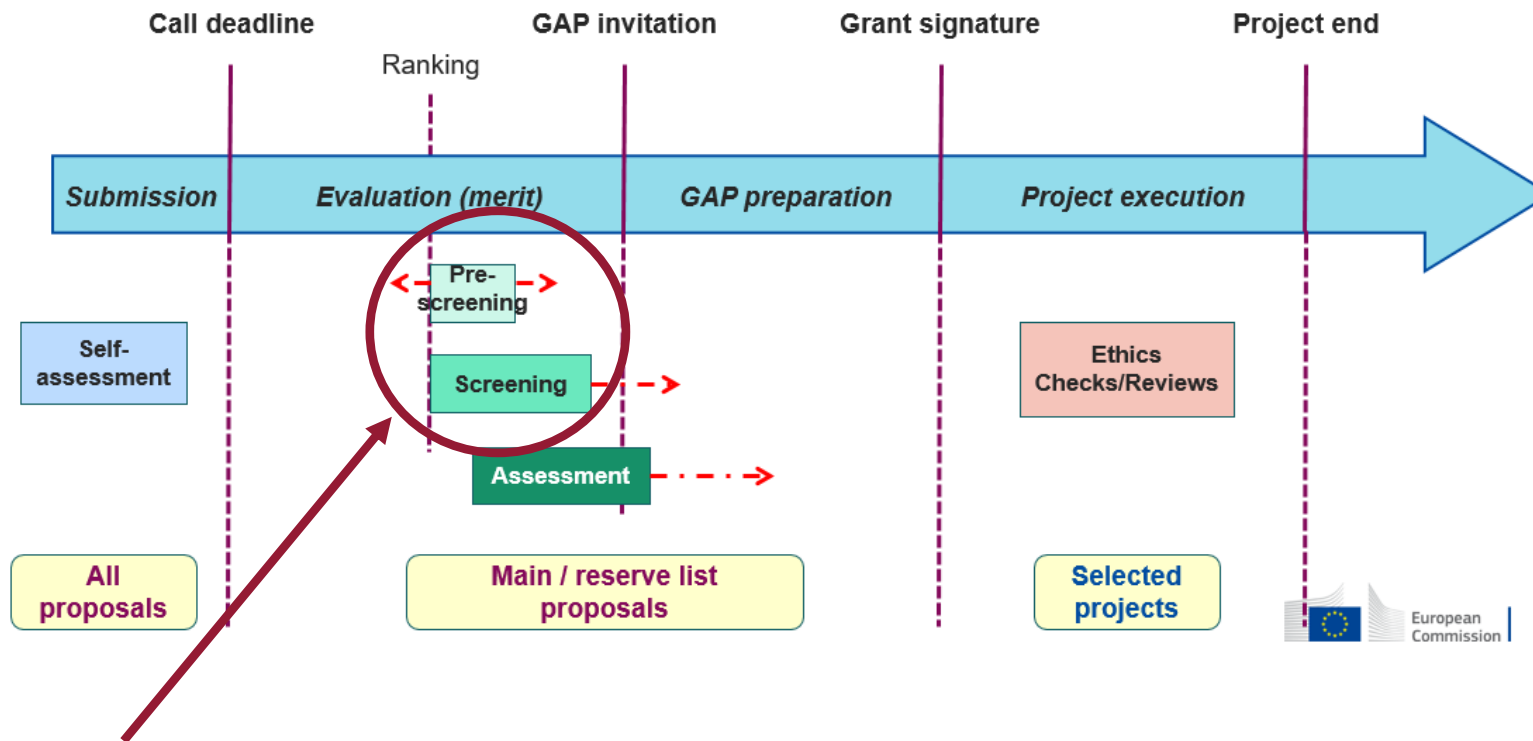
b. Global Postdoctoral Fellowships (GFs)

GFs are based on a 12 to 24-month stay in a Third Country outside Europe followed by a mandatory 12-month return period to a European host institution in an EU Member State, or a Horizon Europe Associated Country.

The **definition of Horizon Europe Associated Countries** is available in the [Horizon Europe Programme Guide](#) (8. International Cooperation and Association). Please see the [List of Participating Countries in Horizon Europe](#) for an up-to-date list of countries with which the association agreements have started to produce legal effects (either through provisional application or their entry into force).

2. THE ETHICS APPRAISAL PROCESS IN PRACTICE

2.1. The ethics appraisal flow in Horizon Europe

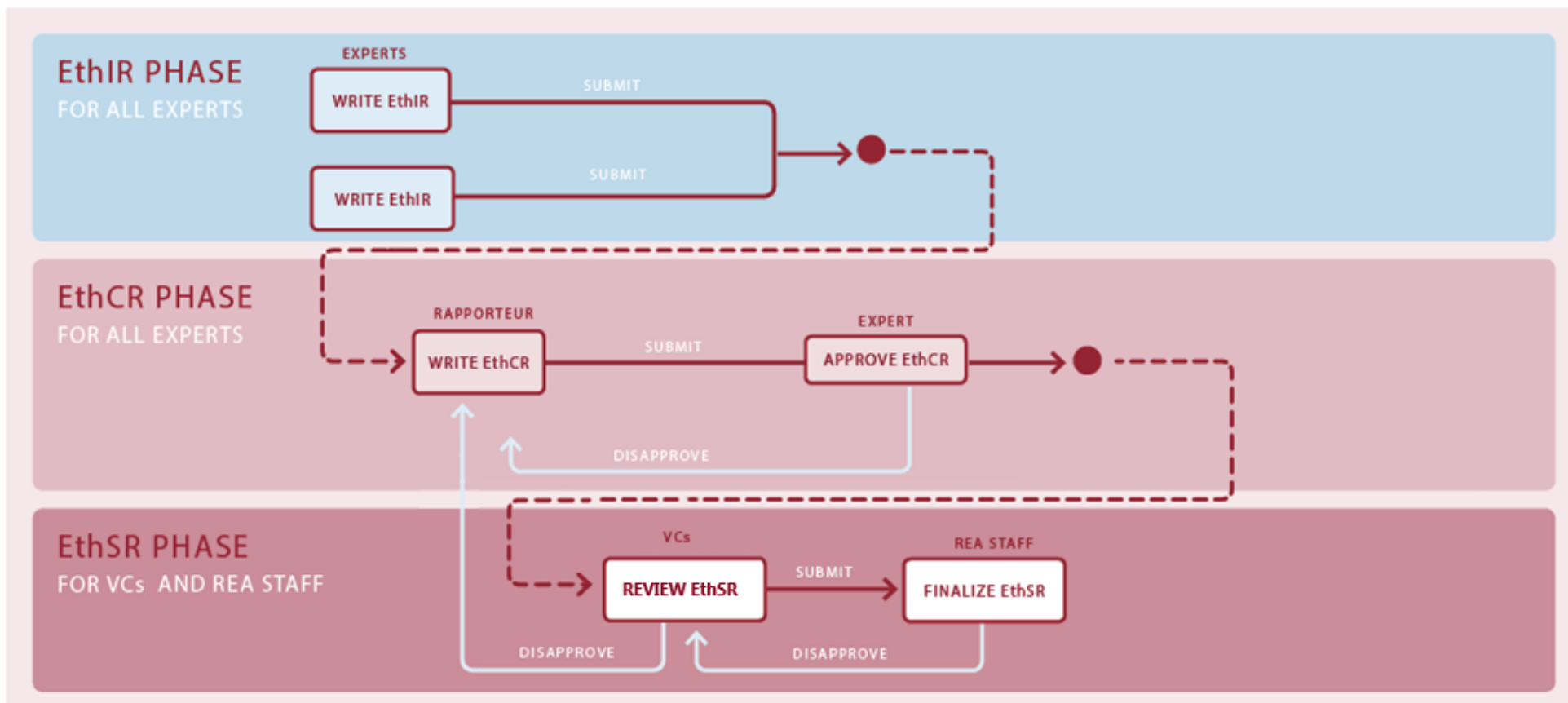
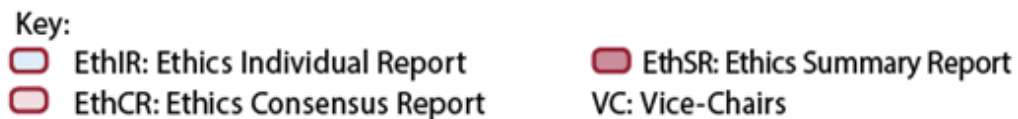


CURRENT EXERCISE

NOTE: Proposals submitted in the scientific panels **Environment & Geosciences (ENV)**, **Life Sciences (LIF)**, **Social Sciences & Humanities (SOC)**, **Information Science & Engineering (ENG)** and **Chemistry (CHE)** will be subject to a full ethics screening, regardless of the applicants' self-assessment.

For the panels **Physics (PHY)**, **Mathematics (MAT)** and **Economic Sciences (ECO)**, the proposals undergo a pre-screening step in case the applicant stated that there are no ethical issues.

2.2 Overview of the ethics screening in SEP



2.3. The ethics screening timing

Remote Phase 7– 31 January 2025

The allocation of proposals to ethics experts depends on their expertise. This also defines the number of proposals to screen. REA staff will try to have a balanced workload among all ethics experts.

The proposal evaluation system SEP will notify the expert by email when they receive a task. The expert should look at the task and accept it. Only in exceptional cases, such as Conflict of Interest (CoI), the expert should decline a task. If experts have screening and pre-screening tasks, they should finish first the pre-screening ones, since these might trigger subsequent screenings. VCs and REA staff will monitor the progress to ensure that all proposals have at the deadline a consensus report (EthCR) approved by the two experts. The EthCR will then become **Ethics Summary Report (EthSR)**.

After the remote phase, REA staff will perform a final screening of the EthSRs to ensure the compliance with HE rules.

2.4. The structure of the MSCA-PF proposals

MSCA-PF proposals have three different parts:

In addition to the abstract and legal data, such as information on researcher, host and supervisor, the **Part A** contains the “Ethics & Security” section with an “Ethics Issue table”, followed by the “Ethics self-assessment”. In the latter, the applicant must discuss the ethical dimension of the objectives, methodology and likely impact as well as describe compliance with ethical principles and relevant legislations.

Part B1 describes the research proposed and its length is limited to 10 pages.

Part B2 contains the CV of the researcher, information on the host institution, and **relevant ethics related information provided by the applicant**, if relevant.

All three parts can contain information on ethics. A good starting point is to look first at the ethics self-assessment in part A and verify what ethics relevant information is already present in part B2.

2.5. The different ethics categories and compliance

In Horizon Europe the applicants have to fill in their ethics self-assessment for the following different ethics issues categories in Part A of the proposal:

1. Human Embryonic Stem Cells and Human Embryos
2. Humans
3. Human Cells / Tissues (not covered by section 1)
4. Personal Data
5. Animals
6. Non-EU Countries
7. Environment, health & safety
8. Artificial Intelligence

9. Other ethics issues

The **Ethics issue table and the ethics self-assessment are presented in the next page.**

All necessary information on these ethics categories and guidance on how the ethics issues should be addressed can be found in the document: [“How to complete your ethics self-assessment”](#).

Knowing the content of the aforementioned document is essential for ethics experts.

Experts should mark those ethics self-assessments that contain erroneous statements and provisions that may not be copied into the grant agreement without further scrutiny.

In the context of the ethics appraisal, Third Country refers to a non-EU country (a country that is not a Member State). Please note that in the framework of the ethics review, Associated Countries are considered as Third Countries. However, for the purpose of this ethics screening, one should take into account that countries like Norway and Switzerland have mostly aligned their legislation and policies with the EU.

Cross-Cutting Issue:

- **Misuse from the security perspective** is covered by the Security Screening (e.g., research activities that could generate knowledge, materials and technologies that could be adapted for criminal/terrorist activities; or result in the development of chemical, biological, radiological or nuclear (CBRN) weapons and the means for their delivery.);

- **Misuse not related to the security dimension** will be analysed as part of the relevant ethics sections (humans, personal data, animals, environment, health and safety, artificial intelligence) or as ‘other ethics issue’ (e.g. the development of surveillance technologies that could curtail human rights and civil liberties).

2.6. Ethics Issues Table

Ethics Issues Table	
1. Human Embryonic Stem Cells and Human Embryos	Page
Does this activity involve Human Embryonic Stem Cells (hESCs)?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Does this activity involve the use of human embryos?	<input type="radio"/> Yes <input checked="" type="radio"/> No
2. Humans	Page
Does this activity involve human participants?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)	<input type="radio"/> Yes <input checked="" type="radio"/> No
3. Human Cells / Tissues (not covered by section 1)	Page
Does this activity involve the use of human cells or tissues?	<input type="radio"/> Yes <input checked="" type="radio"/> No
4. Personal Data	Page
Does this activity involve processing of personal data?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Is it planned to export personal data from the EU to non-EU countries? Specify the type of personal data and countries involved	<input type="radio"/> Yes <input checked="" type="radio"/> No
Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country? Specify the type of personal data and countries involved	<input type="radio"/> Yes <input checked="" type="radio"/> No
Does this activity involve the processing of personal data related to criminal convictions or offences?	<input type="radio"/> Yes <input checked="" type="radio"/> No
5. Animals	Page
Does this activity involve animals?	<input type="radio"/> Yes <input checked="" type="radio"/> No
6. Non-EU Countries	Page
Will some of the activities be carried out in non-EU countries?	<input type="radio"/> Yes <input checked="" type="radio"/> No
In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues?	<input type="radio"/> Yes <input checked="" type="radio"/> No
It is planned to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Is it planned to import any material (other than data) from non-EU countries into the EU or from a non-EU country to another non-EU country? For data imports, see section 4.	<input type="radio"/> Yes <input checked="" type="radio"/> No
Is it planned to export any material (other than data) from the EU to non-EU countries? For data exports, see section 4.	<input type="radio"/> Yes <input checked="" type="radio"/> No
Does this activity involve <u>low and/or lower middle income countries</u> , (if yes, detail the benefit-sharing actions planned in the self-assessment)	<input type="radio"/> Yes <input checked="" type="radio"/> No
Could the situation in the country put the individuals taking part in the activity at risk?	<input type="radio"/> Yes <input checked="" type="radio"/> No
7. Environment, Health and Safety	Page

Does this activity involve the use of substances or processes that may cause harm to the environment, to animals or plants (during the implementation of the activity or further to the use of the results, as a possible impact)?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Does this activity deal with endangered fauna and/or flora / protected areas?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Does this activity involve the use of substances or processes that may cause harm to humans, including those performing the activity (during the implementation of the activity or further to the use of the results, as a possible impact)?	<input type="radio"/> Yes <input checked="" type="radio"/> No
8. Artificial Intelligence	Page
Does this activity involve the development, deployment and/or use of Artificial Intelligence? (if yes, detail in the self-assessment whether that could raise ethical concerns related to human rights and values and detail how this will be addressed).	<input type="radio"/> Yes <input checked="" type="radio"/> No
9. Other Ethics Issues	Page
Are there any other ethics issues that should be taken into consideration?	<input type="radio"/> Yes <input checked="" type="radio"/> No

I confirm that I have taken into account all ethics issues above and that, if any ethics issues apply, I will complete the ethics self-assessment as described in the guidelines [How to Complete your Ethics Self-Assessment](#)

ETHICS SELF-ASSESSMENT

If you have entered any issues in the ethics issue table, you must perform an ethics self-assessment in accordance with the guidelines "How to Complete your Ethics Self-Assessment" and complete the table below.

Ethical dimension of the objectives, methodology and likely impact
<p>Explain in detail the identified issues in relation to:</p> <ul style="list-style-type: none"> – objectives of the activities (e.g. study of vulnerable populations, etc.) – methodology (e.g. clinical trials, involvement of children, protection of personal data, etc.) – the potential impact of the activities (e.g. environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.)
Compliance with ethical principles and relevant legislations
<p>Describe how the issue(s) identified in the ethics issues table above will be addressed in order to adhere to the ethical principles and what will be done to ensure that the activities are compliant with the EU/national legal and ethical requirements of the country or countries where the tasks are to be carried out. It is reminded that for activities performed in a non-EU countries, they should also be allowed in at least one EU Member State.</p>

3. WORKING IN SEP

3.1. Accept the task in SEP

As soon as a task is allocated to an expert, they will receive a notification via email and will be given access to SEP. The expert will see the proposal abstract and the name of the host institution, so that they can declare (if any) a conflict of interest (CoI).

In absence of CoI or any other reason which prevents the expert from working on the proposal, they must confirm to accept to screen each pro-

A dialog box with a title bar that says "I agree to work on this task" and a checkbox. Below the title bar, the text reads: "I declare that, to the best of my knowledge, I have no conflict of interest in the evaluation of this proposal." At the bottom of the dialog, there are two buttons: "OK" and "Cancel".

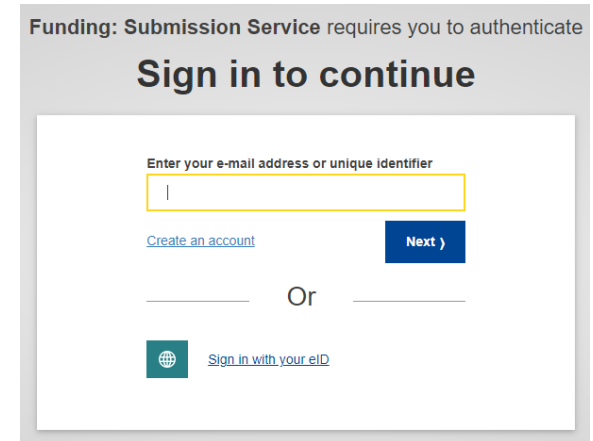
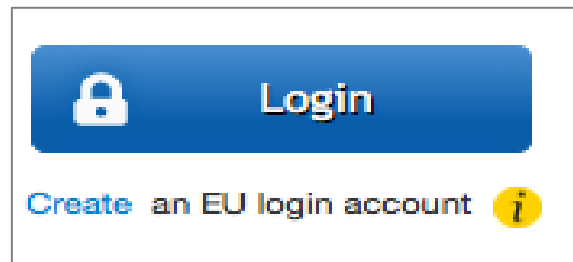
posal assigned to them in SEP.

It is important for the timely completion of the ethics screening that experts accept the tasks without unnecessary delay.

How to access SEP?

<https://ec.europa.eu/research/participants/evaluation/>

Use the EU-Login (formerly ECAS) credentials:



Experts will be asked to screen proposals in their specific field of expertise, according to the keywords they have previously selected and their profile. Given the multi-disciplinary approach of some proposals, experts may also be requested to screen proposals not closely linked to their specific field of expertise, but more broadly linked to their general expertise.

3.2. Accessing Tasks in SEP:

1. Go to **Active Tasks**
2. The type of task is indicated for each proposal
3. As soon as the task is assigned, experts can access it
4. Click **Edit** to access the relevant task

The screenshot shows the 'Evaluation Service' interface. At the top, there is a navigation bar with the European Commission logo and the text 'Evaluation Service'. Below this, there are several tabs: 'Evaluations', 'Search users', 'Search proposals', 'Proposals', 'Active Tasks', and 'All Tasks'. A red arrow points to the 'Active Tasks' tab.

Below the tabs, there are several filter fields for 'Call', 'Panel', 'Task', 'Proposal', 'Acronym', 'Status', and 'Threshold', each with a 'Type to filter' dropdown and a search button. There is also a 'Reset' button.

The main content is a table with the following columns: Panel, Task, Proposal, Acronym, Owner, Deadline, Status, Score, and Action. The table contains two rows of data:

Panel	Task	Proposal	Acronym	Owner	Deadline	Status	Score	Action
LIF	Write EthIR	6912	ERROR	[Redacted]	26 Jun 2015 23:59	Assigned		Edit Decline
LIF	Write EthIR	6912	OBoDo	[Redacted]	26 Jun 2015 23:59	Assigned		Edit Decline

Below the table, there is a pagination control showing 'Displaying 1 to 2 of 2' and a page number '1'. There is also a 'Page size' selector with options 10, 25, 50, and 100. Red arrows point to the 'Write EthIR' task in the second row, and the 'Edit' buttons in the 'Action' column of both rows.

4.ETHICS PRE-SCREENING

This phase does not concern all scientific panels and involves only **one expert** per proposal. The pre-screening stage is a **factual check** without a consensus discussion. The aim is to confirm if a proposal has ethics issues or not.

Confirmation of no ethics issues means "**ethics clearance**" of the proposal. The process is then completed.

If one or more ethics issues are identified, the proposal goes to **Ethics Screening**.

Please note that only a limited number of experts will receive Pre-screening tasks. In this case, experts should complete them as a priority.

For Section 6: NON-EU COUNTRIES, experts should flag the proposal **ONLY** if activities undertaken in these countries raise **potential** ethics issues.

Panel	Task	Proposal	Acronym	SI
ENV	Review EthSR	7 [redacted]	[redacted]	Fi
ENV	Review EthSR	7 [redacted]	[redacted]	Fi
ENV	Review EthSR	79 [redacted]	CA [redacted]	Fi
CHE	Review EthSR	79 [redacted]	[redacted]	Fi
CHE	Write EthCR	7 [redacted]	[redacted] nm	Fi
CHE	Write EthIR	7 [redacted]	[redacted] nm	Fi
CHE	EthPR Final Check	7 [redacted]	Chi [redacted]	C:
CHE	EthPR Check 1	[redacted]	[redacted]	Fi

Note: in SEP experts need to confirm twice the clearance of the same proposal. That is, when the expert submits the **EthPR Check 1** task of a proposal with no ethics issues, they will receive another task **EthPR Final Check** to confirm their review.

On the other hand, if the expert flags the proposal for full ethics screening, the second task will be cancelled.

Usually, the expert performing the pre-screening will be also involved in the full screening.

Ethics Pre-Screening Form in SEP Simplified version of Ethics Issues Table

- Section 1: HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS
Current status: _____
 No Yes
- Section 2: HUMANS
Current status: _____
 No Yes
- Section 3: HUMAN CELLS/TISSUES (not covered by section 1)
Current status: _____
 No Yes
- Section 4: PERSONAL DATA
Current status: _____
 No Yes
- Section 5: ANIMALS
Current status: _____
 No Yes
- Section 6: NON-EU COUNTRIES
Current status: _____
 No Yes
- Section 7: ENVIRONMENT, HEALTH AND SAFETY
Current status: _____
 No Yes
- Section 8: ARTIFICIAL INTELLIGENCE
Current status: _____
 No Yes
- Section 9: OTHER ETHICS ISSUES
Current status: _____
 No Yes

5. ETHICS SCREENING

5.1 Introduction

What is an EthIR?

The Ethics Individual Report (EthIR) is the report that experts draft for each of their allocated proposals by flagging identified ethics issues and reflecting on their seriousness and complexity. This can be performed directly in the online tool SEP. Please note that SEP is a corporate tool and is not specifically tailor-made for the MSCA-PF call. Therefore, we encourage you to carefully follow the specific instructions given in this Manual.

The aim is to obtain two EthIRs written by different experts for each proposal.

The EthIRs will serve as the working basis for the drafting of the Consensus Report.

The **ethics screening** step in the ethics appraisal involves **two independent experts**. It is a flagging exercise that **aims to identify proposals with serious and/or complex ethics issues**.

Compared to H2020, in Horizon Europe, no specific requirement is formulated, except the possible appointment of an ethics advisor, if needed.

The actors of the EthIRs phase

In the EthIRs phase, all **Experts** perform their tasks on their own under the supervision and with the support of their **Vice-Chair**

5.2 How to proceed?

On 7 January 2025 you will gain access to SEP, where supporting documents such as this manual, the “how to complete your ethics self-assessment”, and guidance on how to use SEP are all available.

Please make sure that you have read this Manual before you start the screening process, following the steps below:

1 As soon as you gain access to SEP, you must check whether your specific or general expertise is appropriate to assess each proposal, and that you don't have a conflict of interest.

You will see the proposals assigned to you in the Dashboard. For each of those proposals, before ac-

cepting the task, please click on the View button where you will be able to see:

- a. The abstract of the proposal.
- b. The name of the Researcher.
- c. The name of the Supervisor.
- d. The name and address of the host organisation (“Coordinator”).

If you have a Col, please either decline the task (DECLINING A TASK) in SEP or contact your Vice-Chair.

2 If you have no apparent Col, please accept the task immediately (ACCEPTING A TASK). It is important that you accept the tasks without unnecessary delay unless you detect a Col. By accepting the task, you will gain access to the whole proposal.

3 After opening each proposal, please check if your name or institution are cited by doing a keyword search through the whole proposal. If your name or institution are cited (e.g. consortium, collaboration, publication or else), please consult your Vice-Chair before proceeding, as there may be a Conflict of Interest. Otherwise, please continue.

4 You are advised to skim through your assigned proposals to get a general idea of their content and quality. This is a good practice and will allow you to identify proposals that are “ethically” weak and/or missing certain elements while at the same time noticing more ‘complete’ (i.e. better developed) proposals. This may help you to calibrate your way of assessing.

5 You are invited to **proceed in alphabetical order of the proposal acronyms** (as they appear in SEP). This will allow everyone to start the following phase (consensus) in an efficient and timely manner. Start by checking:

- a. The host institution can be based either in a EU Member State or in an Associated Country.
- b. The type of action of the proposal (European or Global Fellowship) before assessing it. Global Fellowships include a compulsory stay in a third country.
- c. Whether it contains secondment(s) in Third or Associated Countries.

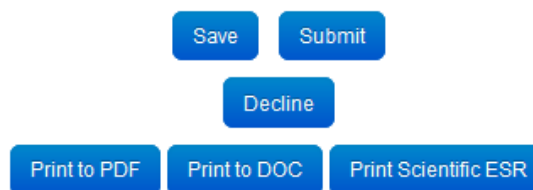
6 After the initial verifications and your overall assessment of a proposal, you should **draft your indi-**

vidual report for each proposal directly in the **SEP Evaluation Report Form**.

You should follow the assessment workflow as illustrated in the next page. Please remember that you must read and assess the proposals independently, without discussing them with anybody else, except your Vice-Chair (if necessary).

While assessing each proposal, please **consider all the information in Part A, Part B1 and Part B2** of the proposal.

7 While assessing each proposal, you may need to have a look at the scientific Evaluation Summary Report, where evaluators have commented on the robustness of AI-based systems and/or techniques, and/or on the use of hESC/hE. At the bottom of the form, click “Print Scientific ESR” to download the document.



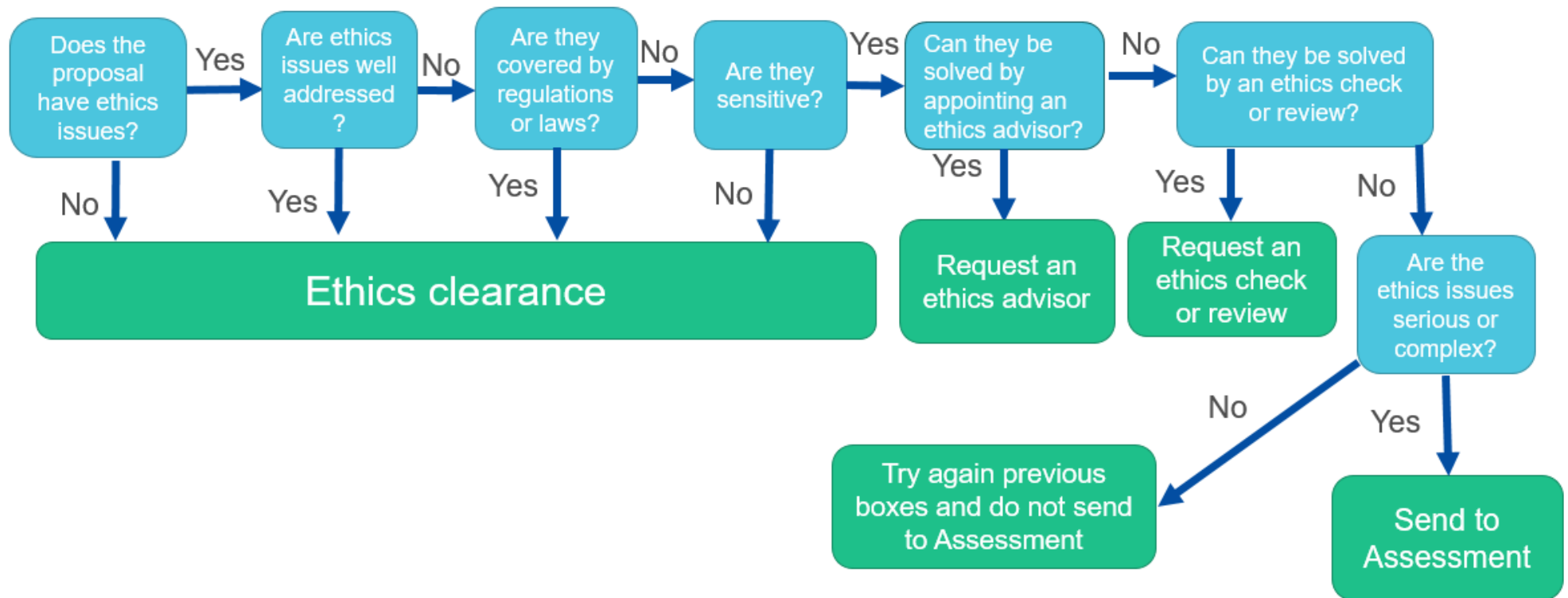
8 Please **notify** your Vice-Chair by email in case of doubts or if you need **feedback**.

9 **When your EthIR is ready, please submit it in SEP.**

If you have submitted an EthIR by mistake and/or wish to reopen it, please contact us.

Please remember that the EthCR phase can only start when the two EthIRs for any given proposal are submitted. Any delay on your side in delivering your work may slow down the whole process.

Decision Flow Chart



5.3 What is the consensus phase?

Once the 2 experts have submitted their EthIRs for a proposal, the consensus phase for that proposal begins. During this phase, the two experts discuss and agree first on seriousness and complexity of the ethics issues, and then on the outcome of the screening. The consensus phase is conducted in SEP through the discussion box, with support from the Vice-Chair. In exceptional cases, a teleconference may be organised. Further practical information on how to perform EthCR tasks in SEP is available in Completing a consensus report.

The consensus discussion is limited to a minimum, as the ethics issues table in SEP has a simplified version compared to Horizon 2020.

The actors of the Consensus Phase:

Rapporteur

The role of the Rapporteur is to prepare the Consensus Report and lead the discussion with the fellow expert to reach an agreement on the ethics issues to flag (or not), on their seriousness/complexity, and whether the appointment of an ethics mentor/advisor or an ethics check is needed.

Expert

The role of the expert is to actively participate in the consensus discussion with the rapporteur, and to formally approve the EthCR once the consensus is reached.

Vice-Chair

The role of the Vice-Chairs is to supervise and monitor this phase. They check the fairness, objectivity and accuracy of the Consensus Report and make sure that the process respects all applicable rules.

The aim of the consensus phase is to give:

- a clear and substantiated assessment of the ethics issues of the proposal.
- an explanation of the mandate of the ethics mentor / advisor, if relevant
- an explanation of the reason for asking an ethics check / review and identification of documents the beneficiary will need to submit, if relevant.

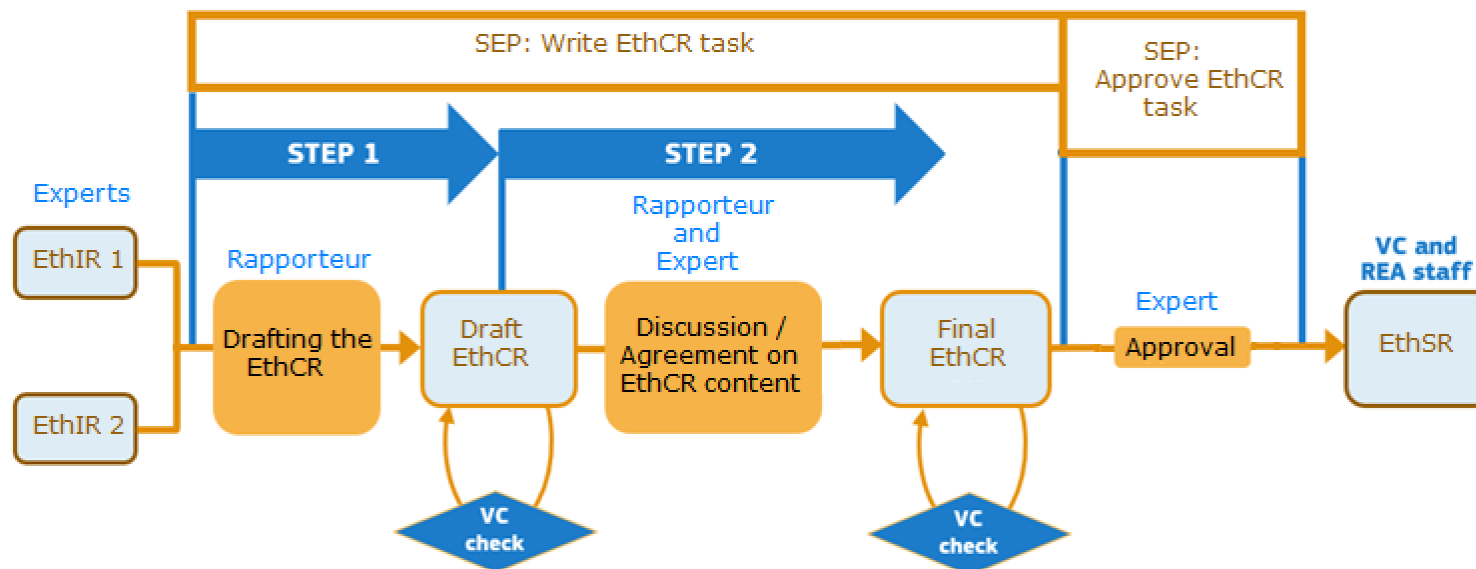
The quality of the EthCR is crucial, as the text will be included as such in the Ethics Summary Report, which is sent to the applicant. Feedback to applicants is taken very seriously.

5.4 Step 1: Drafting the Consensus Report

The starting points for the initial EthCR draft to be prepared by the Rapporteur are the 2 EthIRs. The Rapporteur should not try to impose their views when preparing the EthCR draft: each EthIR carries the same weight.

This step is performed exclusively by the **Rapporteur**, with support of the **Vice-Chair**.

The scheme below presents a detailed overview of the whole Consensus Phase, including how the different steps relate to the two EthCR tasks for a proposal in SEP: Write CR (assigned to the Rapporteur) and Approve CR (assigned to the Expert).



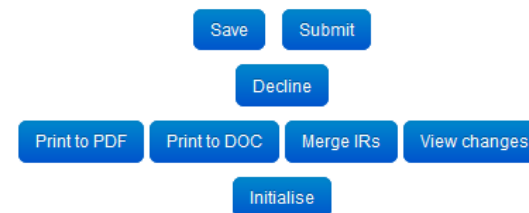
How to proceed?

The **Rapporteur** opens the ‘Write EthCR task’ in SEP, which is created once all EthIRs are submitted, (check the link [COMPLETING A CR](#)). After accepting the task, the Rapporteur can start working on the EthCR by clicking on the ‘**Initialise**’ button. Two options can be chosen:

- Click on ‘**Blank form**’ to manually draft the EthCR;

or

- Click on ‘**New form with expert’s assessments**’ and ‘**all available reports**’ to merge the 2 EthIRs. Click on ‘**OK**’ and then on the ‘**Merge IRs**’ button to combine the two EthIRs into one report. **Save** the report.



At any stage of the EthCR draft preparation, the ‘**View changes**’ option will show the changes be-

tween the current and the previous versions of the EthCR.

When the EthCR is ready the rapporteur informs the other Expert via a notification through the SEP comment box, writing: “Please provide your comments”.

If in doubt about this process, please contact your Vice-Chair.

5.5 Step 2: Discussion / Agreement on EthCR content

The consensus must be a collaborative process with commitment from the Rapporteur and the Expert to find the solution that best reflects the opinion of the group. **The consensus discussion takes place through the SEP comment box.** You are encouraged to use the relevant comment categories provided in SEP for the discussion.

The Rapporteur and the Expert discuss the proposed outcome until an agreement is reached. If an Expert is not responsive at this stage, the Rapporteur should notify the Vice-Chair.

After all the Evaluators have agreed, the **Rapporteur** submits the EthCR. The Expert receives an “Approve EthCR” task for a final check. They can either “approve” the EthCR, or **Disapprove (NOT decline!)** leaving a comment in the EthCR discussion comment box with their reasons.

Before disapproving, the expert should explain the reason(s) in the “Task Comments” box. When leaving a comment, do not forget to tick the “send notification” box, so that the fellow expert is notified about the reason why the EthCR was disapproved.



Please remain available until the closure date indicated in your contract.

Once the CR is approved by the second Expert, the Ethics Summary Report (EthSR) phase is initiated.

NOTE: if Rapporteurs submit an EthCR by mistake at any step of the Consensus phase, they can simply ask the second expert to disapprove it in SEP. This will reopen the Rapporteur’s “Write EthCR” task.

5.6 After the Consensus Phase: The ESR Phase

Once the final EthCR version is submitted, the Vice-Chair receives a “Review EthSR” task in SEP and per-

forms a quality check. A second quality check is then performed by REA staff, concluding the proposal evaluation process.

The report may be sent back by the Vice-Chair from the EthSR phase to the Consensus phase for revision.

In case this happens, the Rapporteur should revise the EthCR by taking into consideration the comments from the Vice-Chair and restart the consensus process with the other expert.

Screening Form in SEP

Ethics Issues
<i>Simplified version of Ethics Issues Table</i>
Serious or Complex Ethics Dimension?
External Independent Ethics Advisor/Board?
Ethics Check or Review during the Project?

Simplified version of Ethics Issues Table

- Section 1: Human embryonic stem cells and human embryos No Yes
- Section 2: Humans No Yes
- Section 3: Human cells/tissues (not covered by section 1) No Yes
- Section 4: Personal data No Yes
- Section 5: Animals No Yes
- Section 6: Non-EU countries No Yes
- Section 7: Environment, Health and Safety No Yes
- Section 8: Artificial intelligence No Yes
- Section 9: Other ethics issues No Yes

5

5.7 Outcomes of the ethics screening

1st Possible Outcome: Cleared

- 1. Serious or complex ethics dimension

Current status:

Based on the proposal, including the ethics self-assessment, do you consider that this activity can be qualified as serious or complex from an ethics perspective and should therefore undergo a complete ethics assessment?

- Your judgment should be consistent with the guidelines on [Serious and complex ethics issues](#)

- If you find that the proposal involves the use of human embryos (hE) or human embryonic stem cells (hESC) please answer 'Assessment'. In this case the proposal must undergo an ethics assessment.

- If 'Assessment', please summarise your concerns taking into account the ethics issues identified above.

*

CLEARED ASSESSMENT

COMMENTS:

Comments box NOT ACTIVE when proposal is Cleared!

2nd Possible Outcome: Assessment

Ethics assessment should be recommended on an exceptional basis (only for proposals with complex and serious ethics issues), and it must be duly justified!

- 1. Serious or complex ethics dimension

Current status:

Based on the proposal, including the ethics self-assessment, do you consider that this activity can be qualified as serious or complex from an ethics perspective and should therefore undergo a complete ethics assessment?

- Your judgment should be consistent with the guidelines on [Serious and complex ethics issues](#)

- If you find that the proposal involves the use of human embryos (hE) or human embryonic stem cells (hESC) please answer 'Assessment'. In this case the proposal must undergo an ethics assessment.

- If 'Assessment', please summarise your concerns taking into account the ethics issues identified above.

*

CLEARED ASSESSMENT

COMMENTS:

Comments mandatory when proposal is sent to 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.

You should/could also formulate **suggestions** for the experts that will carry out the ethics assessment

0 / 10000 characters

3rd possible outcome: Conditionally Cleared - Ethics Advisor

Opting for Advisor (and not Board!) is the suggested choice for MSCA-PF projects given their budget and duration!

- 2. External Independent Ethics Advisor/Board

Current status:

- In your opinion, would it be necessary to appoint an external independent ethics advisor or an ethics board (with a minimum of three experts) reporting periodically to the Commission/Agency/funding body?
- If yes, your choice between a single ethics advisor and an ethics board should reflect the size of the grant and the significance of the ethics issues. *

NO YES (Ethics Advisor) YES (Ethics Board)

REASONS (Mandatory if the answer is YES): Please detail the reasons and the main elements of the advisor's or board's mandate, including the periodicity and timing of their reports. Note that the advisor or board will be expected to start working at the beginning of the project. The reasons and mandate you provide below will be shared with the applicants.

Mandatory ONLY if answer is YES!

0 / 2000 characters

TIMING (mandatory if YES): Please enter the number of months after project start when the independent ethics advisor or ethics board should start working (e.g., entering the number 1 means the advisor/board will start working at the beginning of the project).

Please detail the **reasons** and the main elements of the advisor' **mandate** and indicate the periodicity and timing of their report(s).

1.a possible outcome: Cleared - Recommend an Ethics Mentor

- 2. External Independent Ethics Advisor/Board

Current status:

- In your opinion, would it be necessary to appoint an external independent ethics advisor or an ethics board (with a minimum of three experts) reporting periodically to the Commission/Agency/funding body?
If yes, your choice between a single ethics advisor and an ethics board should reflect the size of the grant and the significance of the ethics issues. *

NO YES (Ethics Advisor) YES (Ethics Board)

REASONS (Mandatory if the answer is YES): Please detail the reasons and the main elements of the advisor's or board's mandate, including the periodicity and timing of their reports. Note that the advisor or board will be expected to start working at the beginning of the project. The reasons and mandate you provide below will be shared with the applicants.

It is possible to recommend the appointment of an ethics mentor to advise the project participants on ethics issues. Please detail the reason and the main element of the mentor's mandate.

0 / 2000 characters

TIMING (mandatory if YES): Please enter the number of months after project start when the independent ethics advisor or ethics board should start working (e.g., entering the number 1 means the advisor/board will start working at the beginning of the project).

- v

Leave the **TIMING** box empty, since this is not a requirement

Ethics Mentor vs Ethics Advisor

Ethics Advisor

- Independent and free from any conflict of interest.
- They are paid **from the project budget** for this service (via e.g. a service contract).
- Obligation to send independent report(s) to the REA.

Ethics Mentor

- Not independent from the host institution (can be a member of the same department or institution). The mentor provides advice and shares experience and knowledge on how to properly identify and address ethics issues.
- Receives remuneration from the host institution (as regular staff).
- No formal obligation to report to REA, although it is recommended to keep on file a report of the activities performed.

1.b possible outcome: Cleared - Ethics Check/Review

Opting for Check (vs Review) is the preferred option for MSCA-PF projects given their budget and duration!

- 3. Ethics Check or Review during the project

Current status:

- In your opinion, would an Ethics Check or Ethics Review be necessary during the project? An Ethics Check is an internal check by the project officer or ethics officer who may be supported by ethics experts. An Ethics Review is a more elaborate and in-depth procedure carried out by up to 5 external ethics experts.
- If yes, your choice between an Ethics Check and an Ethics Review should reflect the size of the grant and the significance of the ethics issues.
- An Ethics Check or Review may be needed when it is important to reassess the global situation or specific ethics issues during the implementation of the project, or when the self-assessment in the proposal does not contain the necessary elements. *

NO YES (Ethics Check) YES (Ethics Review)

REASONS (Mandatory if the answer is YES): Please detail the reasons and the main elements of the Ethics Check/Review mandate:

Mandatory ONLY if the answer is YES!

0 / 2000 characters

TIMING (Mandatory if the answer is YES): Please enter the number of months after project start when the check or review should be carried out (e.g., entering the number 12 means the check/review will be carried out in month 12 of the project).

Ethics Check vs Ethics Review in Horizon Europe

During the lifetime of the project, an ethics check, or an ethics review may be requested to:

- **assist the host institution** to deal with the ethics issues raised by their research and if necessary
- to take preventive or/and corrective measures

The expert must indicate in the *REASONS* box which document(s) (necessary authorisations / licences / certificates, etc.) must be submitted in order to carry out the check/review.

Ethics Check: internal check performed by a REA project officer, possibly with the support of external ethics experts.

Ethics Review: more elaborate and in-depth procedure carried out by up to 5 external ethics experts.

The choice between Ethics Check and Ethics Review should reflect the size of the grant and the seriousness/complexity of the ethics issues. Therefore, as a general rule, for PF projects we suggest asking for an Ethics Check. However, if experts believe that ethics issues are serious/complex to justify an Ethics Review, we suggest sending the proposal to Ethics assessment.

When are Ethics Checks / Reviews requested?

- Compliance with specific ethics requirements needs to be checked during the implementation.
- Serious doubts on the how the beneficiary will address the ethics issues during the project.

Please note that the general requirement applicable to all grants already obliges beneficiaries to ensure that all ethics issues related to activities are addressed in compliance with ethical principles, the applicable international and national law, and the provisions set out in the Grant Agreement. Therefore, REA staff should not generally check this.

5.8 Summary of Ethics Screening

- The screening is performed by 2 experts.
- **Main goal:** to decide whether the proposal raises serious or complex ethics issues. Only these proposals should be sent to assessment!
- The experts decide if the project should be subject to an Ethics Check or an Ethics Review during its implementation phase. The choice between Ethics Check and Ethics Review **should always reflect the size of the grant and the seriousness/complexity of the identified ethics issues.**
- The experts decide if the host institution needs to appoint an independent Ethics Advisor to provide guidance on ethics issues during implementation and report to REA (if

yes, this request is formulated as **a requirement!**).

- In the case of cleared proposals where the experts find there is certain lack of ethics awareness, or some ethics issues have not been fully addressed they might recommend the appointment of an Ethics Mentor (not formulated as a requirement, **only as a recommendation!**).
- During the consensus phase, experts should **mark in SEP** those ethics self-assessments that contain erroneous statements and provisions that may not be copied into the grant agreement without further scrutiny. This can be done by leaving a comment in the “Task Comments” box.

Possible outcome of the screening:

- **Ethics Cleared:** the proposal does not raise serious or complex ethics issues.

An ethics check and/or an ethics mentor can still be recommended.

- **Conditionally Cleared:** the host institution should appoint an Ethics Advisor to provide advice on some sensitive ethics issues.
- **Ethics Assessment:** proposals that raise serious or complex ethics issues (and for all proposals involving the use of hE or hESC).

5.9 Ethics Summary Report

The **Ethics Summary Report** is sent to the applicant after the ethics screening.

Ethics Summary Report		
	<i>Call Reference</i>	
	<i>Proposal Number</i>	
	<i>Acronym</i>	
Ethics Issues		
Humans		Yes
Human cells / tissues		Yes
External Independent Ethics Advisor/Board		
In your opinion, would it be exceptionally necessary to appoint an external independent ethics advisor or an ethics board (with a minimum of three experts) reporting periodically to the Commission/Agency/funding body?		Yes (Ethics Board)
Ethics Check or Review during the project		
In your opinion, would an Ethics Check or Ethics Review be necessary during the project?		Yes (Ethics Check)
General requirement applicable to all grants		
The beneficiaries must ensure that all ethics issues related to activities in the grant are addressed in compliance with ethical principles, the applicable international and national law, and the provisions set out in the Grant Agreement. This includes the ethics issues identified in this report and any additional ethics issues that may emerge in the course of the grant. In case any substantial new ethics issues arise, beneficiaries should inform the granting authority. For each ethics issue applicable, beneficiaries must follow the guidance provided in the How to complete your ethics self-assessment .		

6.COMPLEX/SERIOUS ETHICS ISSUES

The main reference document to use to assess if a proposal has serious and/or complex ethics issues is the [Guidelines on “Identifying serious and complex ethics issues in EU-funded research”](#):

6.1 When are the ethics issues serious?

When the proposed research, method(s), or outcome(s):

- have the potential **to violate fundamental rights or freedoms** set out in the EU Charter of Fundamental Rights and European Convention on Human Rights, or **undermine fundamental EU values** such as human dignity, freedom, democracy, equality and the rule of law; or

- have the potential to result in **significant harm** to researchers, research participants, the public, animals or the environment; or
- in light of the European Code of Conduct for Research Integrity, fundamentally **call into question the integrity** of the data and information included in the proposal or the integrity of the practices of the researchers.

6.2 When are the ethics issues complex?

When the proposed research, method(s) or outcome(s):

- involve the development or application of particularly complicated methods or technologies that have not been sufficiently tested and **give rise to uncertainty as regards to the safety of participants** and/or the impact of the

expected results or outcomes on fundamental rights or research integrity; or

- raise **significant ethics issues ‘at scale’** – for example, due to the number of research participants, controversial methods, high-risk technologies or jurisdictions involved; or
- raise **multiple or ‘intersectional’ ethics issues** – meaning that the ethics issues may compound one another to **exacerbate the potential impact on a particular** group (e.g., research into marginalised or vulnerable groups that exposes them to the risk of stigmatisation, exclusion, reprisals or increased marginalisation).

6.3 When are the ethics issues serious and/or complex?

The ethics issues identified in a proposal are serious and/or complex, if:

- the area of research is the **subject of widespread debate** among scientists and ethicists, and the specific methods or techniques involved get to the heart of those debates; or
- there are grave **doubts about the capacity of the researchers or participating institutions** to effectively mitigate the risks arising from the project's execution, affecting humans; or
- there is **a high risk that the research results/findings could be misused**, and adequate measures to mitigate or contain this risk cannot be identified or implemented; or
- there is an objective and **serious lack of awareness of key ethical issues** in the proposal.

6.4 Examples of proposals with serious and/or complex ethics issues

- I. The proposal involves conducting in-depth interviews in prisons and in organisations in charge of the rehabilitation of recently released inmates (a vulnerable population) in a third country. Insufficient information is provided regarding the policy on incidental findings (e.g. evidence of crime and corruption within the prison itself). Furthermore, the applicant confirmed that sensitive personal data will be collected and processed, however, insufficient information is provided on which sensitive data will be collected/processed/stored. Finally, research in prisons and centres for rehabilitation require some consideration of safety measures or proper procedures to be followed, in order to keep the researcher safe.
- II. The proposal studies brain activity in order to design better treatment of chronic pain. The

methodology envisages the infliction of pain and psychological deception techniques (e.g. flickering stimuli). This puts research participants in danger (e.g., there is a potential risk for epileptic seizure episodes among them). The applicant did not address this risk at all, and missed to provide any information on recruiting and consent procedures (screening procedures for previous seizure among the individuals involved is not provided).

III. Research will include vulnerable individuals (e.g. indigenous people in a low-income third country). They will be asked to share sensitive personal data (e.g. health condition, well-being) which will be imported to the EU. No benefit sharing actions were planned. Additionally personal data protection was not addressed. Furthermore, the situation in the country may put the researcher in risk, but this risk is not sufficiently addressed.

IV. The aim of the proposal is to conduct research on LGBTQ+ rights in a country with a

poor human rights record (among others, expressing publicly being LGBTQ+ is a criminal offense). The researcher intends to travel to this country to carry out fieldwork involving contacting and working with local citizens over local state controlled social media.

Access to social media and internet in this country is subject to heavy censorship. The envisaged fieldwork can therefore put the researcher and research participants at a serious risk of being persecuted by local authorities.

e) The proposal aims to develop a cutting-edge invasive technology for female patients with ovarian cancer who have exhausted all other treatment options. The ethics self-assessment in the proposal is very limited, and there is missing information on all ethical issues - e.g., patients, human cell lines, protection of personal data, animals, involvement of third countries, possible environment, health & safety.

6.5 Some examples of proposals with a lower ethics sensitivity

- a) The applicant intends to study food plants and plant model organisms in relation to plant adaptation to more stressful environments, and there are some risks in relation to environmental protection and biosafety. They are properly addressed within the framework of the relevant national and EU legislation.
- b) The project will use human tissues that will be obtained from biobanks and commercial vendors. Furthermore, use of radioactive materials and lasers, and handling of cell cultures and tissues is going to take place in the proposed research. These will be authorised by the competent national bodies supervising such activities in line with the relevant national/EU legislation.
- c) A proposal will perform sensory testing of printed foods containing nanoparticles of functional compounds. The developed products

will be compared with products without the flavouring added through the nanostructured layers. These sensory tests will be performed with the involvement of human participants (adult healthy volunteers).

Data will be collected from these participants. Associated ethics issues (e.g., informed consent procedures and protection of personal data collected from the study participants) are addressed in the proposal.

- d) A project collects samples, which are analysed at an open ocean site that is located in a protected area. The collected marine samples could contain bacteria (e.g., e-coli), and therefore could pose some risk to the research staff involved during laboratory analyses. The applicant has ensured all relevant labour safety standards are met and adhere to all national and EU legislation dealing with environmental safety and protected areas.

7. ETHICS ASSESSMENT

As a general reminder, ONLY a limited number of proposals **with serious or complex ethics issues** (and all proposals involving the use of hESCs or hE) will go to assessment.

The ethics assessment **takes place after the end of the ethics screening**, and it:

- is performed by at least four external experts (with one of them acting as chairperson).
- uses the full Ethics Issues Table (same as in the proposal) and verifies the applicable ethics issues.
- defines ethics requirements for ethics issues not satisfactorily addressed in the proposal.
- decides if the project should be subject to an ethics check or ethics review during its implementation.

- decides if there is the need to appoint an independent ethics advisor, ethics board or ethics mentor.

Possible outcome of the ethics assessment:

Ethics clearance — proposals without serious or complex ethics issues, no requirements.

Conditional ethics clearance — at least 1 requirement should be entered.

Additional information requested — only if the elements can easily be gathered and quickly transmitted.

Second ethics assessment — only in exceptional cases when it is not possible to formulate a list of suitable requirements. A second assessment would be required to declare a proposal NOT ethically acceptable.

8. TIMETABLE

Ethics individual Report (EthIR)	
WHEN	➤ Start: - Tuesday 7 January 2025
DEADLINE	➤ By Friday 17 January 2025 : all EthIR should be submitted, if you have pre-screening tasks, treat them as a priority
WHO?	➤ Ethics experts, guided by Vice-chairs
Ethics Consensus Report (EthCR)	
WHEN	➤ As soon as the two EthIRs are submitted
DEADLINES	<ul style="list-style-type: none"> ➤ By Monday 20 January 2025: 50 % of EthCRs submitted ➤ By Thursday 23 January 2025: 75 % of EthCRs submitted ➤ By Sunday 26 January 2025: 100 % of EthCRs submitted
WHO?	➤ Appointed Rapporteur supervised by their Vice-Chair and second expert
HOW?	➤ The Rapporteur synthesises the two EthIRs into a draft EthCR. The second expert approves the EthCR.
Ethics Summary Report (EthSR)	
WHEN	➤ As soon as the EthCRs are submitted
DEADLINES	<ul style="list-style-type: none"> ➤ By Tuesday 28 January 2025: 50 % of EthSRs submitted ➤ By Friday 31 January 2025: 100 % of EthSRs submitted
WHO?	➤ Vice-Chairs

Please remain available until the closure date indicated in your contract.

REFERENCE DOCUMENTS

REGULATION (EU) 2021/695 establishing Horizon Europe

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0695&from=EN>

Eligible actions and ethical principles (Article 18) and Ethics (Article 19). All granted actions shall comply with ethical principles and relevant EU, national and/or international legislation.

Horizon Europe Work Programme 2024-2025, Marie Skłodowska-Curie Actions:

https://research-and-innovation.ec.europa.eu/document/download/338af967-94ba-4b5f-90ca-2c0c5b92fe73_en

Horizon Europe Programme Guide:

[https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf)

[2027/horizon/guidance/programme-guide_horizon_en.pdf](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf)

Horizon Europe (HORIZON) Model Grant Agreement Unit Grants:

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/agr-contr/unit-mga_he_en.pdf

Ethics issues are addressed in Article 14 and Annex 5.

Guide on “How to complete your ethics self-assessment”:

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

Guidelines on “Identifying serious and complex ethics issues in EU-funded research”:

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/guidelines-on-serious-and-complex-cases_he_en.pdf

THE ALLEA EUROPEAN CODE OF CONDUCT FOR RESEARCH INTEGRITY

<https://allea.org/code-of-conduct/?cn-reloaded=1&cn-reloaded=1>

All legal entities involved in a project must comply with the ALLEA European Code Of Conduct For Research Integrity.

SEP User Manual

https://ec.europa.eu/research/participants/data/support/expert/evaluation_user_manual.pdf

SEP Online Guide

<https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/Evaluate+a+proposal>

BEST PRACTICES

Compliance with deadlines

Any delays on the expert side in delivering the work may affect other experts' work and block the whole process. Therefore, experts should:

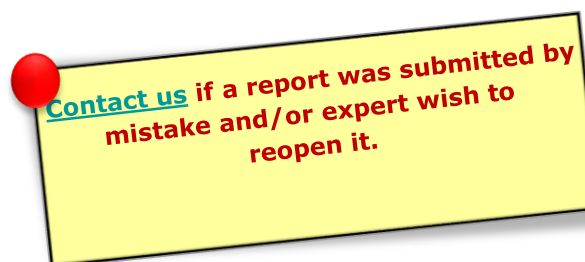
- ✓ **Check** their 'Active Tasks' in **SEP regularly** throughout the whole remote screening phase;
- ✓ **Be reachable**: in case of unavailability on a certain day(s), experts should let their fellow experts and their Vice-Chair know;
- ✓ **Be proactive**: the Rapporteur must monitor the progress of the EthCR and contact the other expert via the comments box in SEP should delays occur.

How to move forward with the reports

The first time experts *Edit* the report, the task status changes from *Assigned* to *Open*.

Experts are not obliged to *Submit* the report at once: they may save it and return to the report at a later time. They will be able to re-open the report by clicking on the *Edit* button in the Active Tasks tab. It is a good practice to inform the VC before submitting reports where an ethics advisor / ethics check / ethics assessment is recommended.

Once submitted, the task status changes to *Finished*. The report is no longer editable, but is still accessible from the *All Tasks* tab (as read-only), by clicking the *View* button.



Contact

For any questions, please contact us via the functional mailbox:

REA-MSCA-HE-PF-ETHICS@ec.europa.eu

GLOSSARY

AC: Associated country. A country associated to Horizon Europe. Click [here](#) for the list.

Associated Partner: Entities that contribute to the implementation of the action, but do not sign the Grant Agreement:

- In EF, organisations in MS or AC that host the researcher during optional secondments/placements and provide additional training.
- In GF, organisations in TC that host the researcher during the compulsory initial outgoing period and provide additional training.

Duration of fellowships: The duration for European Fellowships is between 12 and 24 months. For the Global Fellowships there is an initial outgoing phase of between 12 and 24 months, and an additional mandatory 12 months return phase.

EC: European Commission

EF: European Fellowship

EthCR: Ethics Consensus Report

EthIR: Ethics Individual Report

EthPR: Ethics Pre-screening Report

EthSR: Ethics Summary Report

Experienced Researcher (or Researcher or ER): the researcher must be in possession of a doctoral degree at the date of the call deadline.

GF: Global Fellowship

hESC: Human embryonic stems cells

hE: Human embryos

HE: Horizon Europe, EU's key funding programme for research and innovation

Host institution (beneficiary): Legal entity that signs the Grant Agreement and has the complete responsibility for the proper implementation of the action.

MS: EU Member States

MSCA: Marie Skłodowska-Curie Actions, EU's reference programme for doctoral education and post-doctoral training.

PF: Postdoctoral Fellowship

REA: European Research Executive Agency

SEP: Web-based electronic evaluation tool

Supervisor: Scientist appointed at the host institution to supervise the researcher throughout the whole duration of the project.

TC: Non-associated third countries. Countries which are neither EU Member States (MS), nor associated to Horizon Europe (AC).

WP: Horizon Europe [Work Programme 2023-2025 MSCA](#)