MSCA-IF ETHICS REVIEW
STEP BY STEP
GUIDE FOR EXPERTS 2017
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1 GENERAL ASPECTS

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Why this Guide

Ethics Experts for the Horizon 2020 Marie Skłodowska-Curie Actions Individual Fellowships programme (H2020-MSCA-IF) have the important task of screening applications likely to be funded from among Europe’s best and most promising researchers.

Please note that as ethics experts you are not asked to perform a scientific evaluation. Your role is to ensure that the researchers will carry out the research with probity and with ethical engagement.

This guide will help you to review proposals and draft your screening reports.

If you have been involved as an expert in other EU ethics review exercises, please remember that each call has its specificities and practices.

The aim of this guide is to walk you through the 2017 MSCA Individual Fellowships ethics review.
Working as an Expert

H2020-MSCA-IF is one of the EU's most competitive research funding programmes. It is based on applications made jointly by the researcher and the beneficiary in academic or non-academic sectors in response to an annual call for proposals. About 10,000 proposals are submitted each year, with a success rate of approximately 14%.

The Research Executive Agency (REA) uses independent experts to assist with the evaluation and the ethics review of the IF proposals. These experts have different roles, namely:

- Expert Evaluators
- Ethics Experts
- Independent Observer

When working as an expert, you should consider:

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

**Conflict of Interest (CoI):** the REA will not appoint you as an expert to screen proposals if you have a vested interest that could influence your review. For more details, please see section 3.1.6 of this guide and/or your contract.

**Remuneration:** as an expert, you are entitled to a fee per task, with a maximum stipulated in your contract. In April 2017, the European Commission introduced a new version of the model contract, introducing a new methodology for calculating expert fees for remote work. For further details, please refer to your contract.

**Volume of work:** participation in the H2020-MSCA-IF ethics review exercise does not imply consecutive or 9-to-5 working days, but flexible working hours according to the deadlines which will be set in due time. The number of proposals you will be asked to screen largely depends on the number of proposals received in your area of expertise.

Please follow the instructions from your REA Correspondent on how to prioritise your tasks.
Guide for Applicants

The goal of the MSCA Individual Fellowships (IF) is to enhance the creative and innovative potential of experienced researchers who are seeking to diversify their individual competences in terms of skill acquisition through advanced training, international and inter-sectoral mobility.

Individual Fellowships (IF) provide opportunities to acquire and transfer new knowledge and to work on research and innovation either in a European context (EU Member States and Associated Countries) or outside Europe.

As an ethics expert, you will screen the different Individual Fellowships:

1. European Fellowships (EF)

European Fellowships are hosted from 12 to 24 months in EU Member States or Associated countries and are open to experienced researchers of any nationality either coming to Europe from any country in the world or moving within Europe.

2. Global Fellowships (GF)

Global Fellowships 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.
2 THE ETHICS REVIEW PROCESS IN PRACTICE

2.1 Who is Who
2.2 Overview of the Workflow
2.3 The ethics review phases in detail
The ethics review of the Marie Skłodowska–Curie Actions Individual Fellowships

Who is Who

Individual Fellowships are awarded through an open competition and a transparent, independent evaluation. Each proposal is evaluated on the basis of a pre-defined list of criteria by at least three expert Evaluators.

After the scientific evaluation, proposals likely to be funded are subject to an ethics review.

The ethics expert is responsible for drafting the Ethics Individual Report (EthIR).

The Independent Observer is an independent expert appointed by the REA who follows, observes and checks the entire evaluation process and related procedures. He/she checks compliance with the procedures stipulated in the Work Programme 2016-2017 and the Guide for Proposals Submission and Evaluation.

He/she reports on the correct and fair implementation of the evaluation and the ethics review, findings and gives his/her suggestions for improvements, as necessary, in a report to the REA.

However, the observer does not express views on the specific proposals or on other experts' opinions.

REA staff members, are responsible for managing the ethics review process and monitoring its progress. They ensure that the appraisal rules are respected and give the experts advice for a quality and timely completion of the process.
The ethics review of the Marie Skłodowska-Curie Actions Individual Fellowships

OVERVIEW OF THE WORKFLOW

Ethics appraisal process

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 participate in the process at the stage of the Ethics Review, by implementing Ethics Pre-Screenings and Screenings of proposals that are likely to be funded.
The ethics review of the Marie Skłodowska-Curie Actions Individual Fellowships

- Proposal passes the scientific evaluation
  - Pre-screening
    - NO ethical issues
      - Proposal receives ethics clearance
  - Ethical issues
    - Ethical issues well addressed and documents provided
      - Proposal receives ethics clearance
    - Ethical issues
      - Critical ethical issues (additional information might be necessary)
        - Assessment
          - Requirements to be implemented
          - Proposal receives conditional ethics clearance
      - Ethical issues partially addressed
        - Proposal rejected on ethical grounds
          - negative ethics opinion
            - Proposal receives ethics clearance
              - Proposal receives ethical clearance
The ethics review phases in detail

Remote Phase
6 November – 3 December 2017

Expert should accept the tasks for the allocated proposals. Tasks will be assigned "on the fly".

Pre-Screening (EthPR)
During ethics screening, proposals that raise no immediate ethics issues are pre-screened to identify any potential issues of this nature. The pre-screening is active only for the following scientific panels: Chemistry, Information Science and Engineering, Economic Sciences, Physics and Mathematics.

The expert (one for each proposal) has to list the (potential) ethical issues but not to assess them. If there is at least one, the proposal is subject to a full Ethics Screening to check whether applicants are giving due consideration to these potential problems.

Deadline to complete the task: 3 days after receiving the task.

Ethics Individual Reports (EthIRs)
Projects are assessed to see whether they raise ethics issues and, if so, whether these are adequately addressed. During this phase two experts for each proposal draft and submit the EthIRs.

Deadline to complete the task: 5 days after receiving the task.

Ethics Consensus Report (EthCR)
Following a remote discussion, the two experts reach consensus and submit the EthCRs. This phase starts as soon as the two experts submitted the EthIR.

Central Phase
11–15 December 2017

Ethics Summary Report (EthSR) Phase

A selected number of ethics experts meet in Brussels to perform quality check of the reports and to participate in panel meetings. EthCRs are converted in EthSRs that are sent to the applicants as official communication.
The ethics review of the Marie Skłodowska-Curie Actions Individual Fellowships

1. REA allocates proposals to ethics experts
2. Ethics experts accept their screening tasks in SEP
3. Ethical screening of proposals:
   - 1 expert (only if no ethics issues self-declared)
   - 2 experts
4. Each expert submits her/his EthIR in SEP
5. The rapporteur drafts and submits the EthIR in SEP
6. The two experts (rapporteur + fellow expert) participate in the remote discussion via SEP and reach consensus
7. The rapporteur incorporates possible changes in the EthIR and submits it. The fellow expert approves in SEP.
8. A quality check is performed during the central week.

* Proposals submitted in the scientific panels: Environment & Geosciences, Life Sciences and Social Sciences & Humanities will be subject to a full ethics screening, regardless of the applicants’ self-assessment.
The ethics review of the Marie Skłodowska-Curie Actions Individual Fellowships

EthIR PHASE
FOR ALL EXPERTS

WRITE EthIR
SUBMIT

WRITE EthIR
SUBMIT

EthCR PHASE
FOR ALL EXPERTS

WRITE EthCR
SUBMIT

APPROVE EthCR
SUBMIT

DISAPPROVE

EthSR PHASE
SELECTED EXPERTS

QUALITY CONTROL
SUBMIT

FINALISE EthSR

DISAPPROVE
3 THE PROPOSAL SCREENING

3.1 Guiding principles
3.2 Ethics legal basis
3.3 Where to...?
3.4 Ethics issues
While performing the screening work, you are expected to comply with the following principles, as stated in Annex 1 of the Code of Conduct of the expert contract:

1. Independence
You are appointed in your personal capacity and act independently and in the public interest, not in your country or employer's interest.

2. Impartiality
You treat all proposals equally and screen them impartially, irrespective of their origin or the identity of the applicants.

3. Objectivity
You screen each proposal as submitted and not based on its potential if certain changes were to be made.

4. Consistency
You apply the same standard of judgment to all proposals.

5. Confidentiality
You discuss review matters—such as the content of proposals, ethics review results or opinions of fellow experts—only with your fellow experts involved in screening the same proposal.
- You do not contact applicants or any third parties.
- You do not disclose the names of your fellow experts (each year, the Commission publishes the experts’ names—as a group—but no link is made between an expert and a proposal).
- You maintain the confidentiality of documents, paper or electronic, at all times and wherever you do your work (on-site or remotely), and you must return, destroy or delete all confidential documents, paper or electronic, upon completing your work.

6. Conflict of interest rules (CoI)
You have a CoI and are excluded from the screening session if you:
- benefit directly or indirectly if a proposal is accepted or rejected;
- have a close family or personal relationship with any person involved in the preparation of any proposal submitted to this call;
- are a director, trustee or partner or are in any way involved in the management of an organisation involved in the preparation of any proposal submitted to this call;
- are employed or contracted by one of the applicants or any named subcontractors;
- are a member of an advisory group set up by the Commission to advise on the preparation of Euratom or EU Horizon 2020 work programmes or work plans in an area related to the call;
- are a National Contact Point (NCP) or a person working directly for the Enterprise Europe Network (EEN);
- are a member of a Programme Committee.

However, the REA may decide to invite an expert with a declared CoI.
to take part in the ethics review session, while being excluded from the screening of the proposal(s) concerned, if all of the following apply:
• the expert works in a different team/department/laboratory/institute from where the action is to be carried out;
• the bodies operate with a high degree of autonomy.

In addition, the REA will decide whether a CoI exists — taking into account the objective circumstances, available information and related risks — if an expert:
• was employed by one of the applicants in the previous three years;
• is involved in a contract or grant agreement, grant decision, membership of management structures (e.g. member of management or advisory board etc.) or research collaboration with an applicant or fellow (or had been in the last three years);
• is in any other situation that could cast doubt on their ability to participate impartially in the screening of the proposal (or that could reasonably appear to do so in the eyes of an external third party).

You must inform the REA as soon as you become aware of a CoI:
• before signature of the expert contract;
• upon receipt of proposals; or
• during the course of your work.

The REA will determine if there is a CoI on a case-by-case basis and decide the course of action to follow. If a CoI is limited to a certain proposal, then you will not be allowed to screen it.
The ethics review of the Marie Skłodowska-Curie Actions Individual Fellowships

ETHICS LEGAL BASIS

**Rules for Participation of Horizon 2020**

**Article 13 – Proposals**

A proposal which contravenes ethical principles ... may be excluded from the evaluation, selection and award procedures at any time.

**Article 14 – Ethics Review**

**Article 18 – Grant Agreement**

**Article 23 – Implementation of Actions**

Participants shall comply with national legislation, regulations and ethical rules in the countries where the action will be carried out.

**Horizon 2020 Grant Agreement**

**Article 34 – Ethics**

**34.1 – Obligation to comply with ethical principles**

The beneficiaries must carry out the action in compliance with:

(a) **ethical principles**

and

(b) **applicable international, EU and national law.**

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States. The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

**34.2 – Activities raising ethical issues**

Activities raising ethical issues must comply with the ethics requirements set out in Annex 1. Before the beginning of an activity raising an ethical issue, the beneficiary must have obtained:

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

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law needed for implementing the action tasks in question. The documents must be kept on file and be submitted upon request by the beneficiary to the REA.

**34.3 – Activities involving human embryos or hESC**

**Article 39 – Processing of Personal Data**

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).
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.

Which part of the proposal must be checked by the ethics screener?

Part A – questionnaire

Part B – ethics self-assessment where the applicant provided a description of the ethics issues and related arrangements.

Scan through the proposal – information can be anywhere!

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 Ethics Self-Assessment Guidance is available in the participant portal, under the reference documents (Grant Manuals/Horizontal Issues/Ethics): Please get yourself familiar with the Guidance How to complete your ethics self-assessment

Key document for Ethics Experts and applicants

3. Human cells or tissues

This section refers to research using, producing or collecting human cells or tissues. You may obtain cells or tissues:

- from commercial sources
- as part of this research project
- from another research project, laboratory or institution
- from a biobank.

3.1 Ethics issues checklist

<table>
<thead>
<tr>
<th>Section: 3. Human cells or tissues</th>
<th>Yes/No</th>
<th>Information to be provided</th>
<th>Documents to be provided/approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of the cells or tissue type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethical committee/approval</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suspension of research approval</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suspension of research registration/authorisation/</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>licensing for using, processing or collecting human cells or tissues (if required)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
The ethics review of the Marie Skłodowska-Curie Actions Individual Fellowships

### Ethics Issues Table

<table>
<thead>
<tr>
<th>1. HUMAN EMBRYOS/FETUSES</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your research involve Human Embryonic Stem Cells (hESCs)?</td>
<td>Yes</td>
</tr>
<tr>
<td>Does your research involve the use of human embryos?</td>
<td>Yes</td>
</tr>
<tr>
<td>Does your research involve the use of human foetal tissues / cells?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>2. HUMANS</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your research involve human participants?</td>
<td>Yes</td>
</tr>
<tr>
<td>Does your research involve physical interventions on the study participants?</td>
<td>Yes</td>
</tr>
<tr>
<td>Does it involve invasive techniques?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. HUMAN CELLS / TISSUES</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your research involve human cells or tissues?</td>
<td>Yes</td>
</tr>
<tr>
<td>If your research involves human embryos/fetuses, please also complete the section “Human Embryos/Fetuses” [Box 1].</td>
<td></td>
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</tbody>
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<tr>
<th>4. PROTECTION OF PERSONAL DATA</th>
<th>Page</th>
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<tbody>
<tr>
<td>Does your research involve personal data collection and/or processing?</td>
<td>Yes</td>
</tr>
<tr>
<td>Does your research involve further processing of previously collected personal data (secondary use)?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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<tr>
<th>5. ANIMALS</th>
<th>Page</th>
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<tbody>
<tr>
<td>Does your research involve animals?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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<tr>
<th>6. NON-EU COUNTRIES</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your research involve non-EU countries?</td>
<td>Yes</td>
</tr>
<tr>
<td>Do you plan 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.)?</td>
<td>Yes</td>
</tr>
<tr>
<td>Do you plan to transport any material - including personal data - from non-EU countries into the EU? If you consider importing data, please also complete the section “Protection of Personal Data” [Box 4].</td>
<td>Yes</td>
</tr>
<tr>
<td>Do you plan to export any material - including personal data - from the EU to non-EU countries? If you consider exporting data, please also complete the section “Protection of Personal Data” [Box 4].</td>
<td>Yes</td>
</tr>
<tr>
<td>If your research involves low and/or lower income countries, are benefits-sharing measures foreseen?</td>
<td>Yes</td>
</tr>
<tr>
<td>Could the situation in the country put the individuals taking part in the research at risk?</td>
<td>Yes</td>
</tr>
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<tr>
<th>7. ENVIRONMENT PROTECTION</th>
<th>Page</th>
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<tbody>
<tr>
<td>Does your research involve the use of elements that may cause harm to the environment, to animals or plants?</td>
<td>Yes</td>
</tr>
<tr>
<td>Does your research deal with endangered fauna and/or flora and/or protected areas?</td>
<td>Yes</td>
</tr>
<tr>
<td>Does your research involve the use of elements that may cause harm to humans, including research staff?</td>
<td>Yes</td>
</tr>
</tbody>
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<tr>
<th>8. DUAL USE</th>
<th>Page</th>
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<tbody>
<tr>
<td>Does your research have the potential for military applications?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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<tr>
<th>9. MISUSE</th>
<th>Page</th>
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<tbody>
<tr>
<td>Does your research have the potential for malicious/criminal/terrorist abuse?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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<tr>
<th>10. OTHER ETHICS ISSUES</th>
<th>Page</th>
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</thead>
<tbody>
<tr>
<td>Are there any other ethics issues that should be taken into consideration? Please specify.</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Indicates pages in Part B1 of the proposal
ETHICS ISSUES

In H2020, different ethics categories have been identified and room was left for other issues not listed.

1. Human Embryos and Foetuses
2. Human beings
3. Human cells/tissues
4. Personal Data
5. Animals
6. Non-EU Countries
7. Environment & Health safety
8. Dual use & exclusive focus on civil applications
9. Exclusive Use on Civil Applications
10. Misuse of research results
11. Other issues

Research on human stem cells (both adult & embryonic) might be financed depending on the contents of the proposal & the legal framework of the MS where the action will take place.

Human cloning and research that leads to destruction of human embryos are excluded from funding.

In the context of ethics appraisal, Third Country refers to non-EU country. US, Australia, Japan and even Associated Countries, for what concerns ethics, are considered as Third Countries.

Under Horizon 2020, only research that has an exclusive focus on civil application can be funded:

Specificities to be considered in the Ethics Screening Report:

✓ Humans

This ethics issue refers to the individuals participating in the research (i.e., patients, healthy volunteers)

Do not confuse "volunteers for social or human sciences research" (question 1.1) 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, bio bank, etc.) use the different requirement options (do not make assumptions)

✓ Human Embryonic Stem Cells (hESC)

If the project involves hESC, check the applicable ethical issues and select Ethics Assessment recommended in the Ethics Opinion.

✓ Animals

The research proposed must respect the Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on
The ethics review of the Marie Skłodowska-Curie Actions Individual Fellowships

The protection of animals used for scientific purposes

The concept of the principle of the Three Rs (Replacement, Reduction and Refinement of animal use) is used to help to ensure humane, robust and responsible science and is a major consideration in animal research.

✓ **Data Protection**

‘Personal data’ means any information, private or professional, which relates to an identified or identifiable natural person.

**Workshops** organised in the framework of the project with researchers do **NOT** raise data protection issues.

The new General Data Protection Regulation No **2016/679** will apply from 25 May 2018

✓ **Third Countries = Non-EU Countries**

In the context of the ethics appraisal, Third country refers to **non-EU country**. Associated countries (like Switzerland, Norway, etc) are also considered as **Third Countries**.

*Activities undertaken in non-EU countries do not necessarily imply potential ethics issues*

When not declared in the proposal, the following requirement must be added:

*The beneficiary must confirm that the research performed outside the EU is compatible with the Union, National and International legislation and could have been legally conducted in one of the EU Member States.*

**Remark:**

In **Global Fellowship** the **Outgoing phase** takes place in a Third Country: this does not automatically imply Ethics Issues **Third Countries**.

✓ **Environment & Health & Safety**

- harm to researchers or to the environment can occur as part of the experiment of the research and as the result of undesirable side-effects of the technologies.

✓ **Dual Use and misuse**

**EC Explanatory notes:**

✓ **Dual Use**
✓ **Misuse of research**
✓ **Exclusive focus on Civil applications.**
4 PERFORMING THE WORK

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Please make sure you work on the screening of proposals in the order you receive the tasks without leaving significant time gaps since different actors work on the proposals simultaneously and delays by some experts can put the ethics review process at risk.
As soon as a task is allocated to you, you will be given access to SEP where you will see the proposal abstract and the name of the beneficiary, so that you can declare (if any) a conflict of interest.

You must confirm the screening of each proposal assigned to you in SEP within two days of receiving access. It is important that you accept the tasks without unnecessary delay, unless you detect a ‘CoI’ (see above Section 3.1.6 of this guide).

How to access SEP?

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

Use your EU-Login (formerly ECAS) credentials
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 Pre-Screening REPORT (EthPR) PHASE

This phase concerns proposals that are likely to be funded and for which no ethics issues were flagged by the applicants. It applies to proposals submitted in the following scientific panels: Chemistry, Information Science and Engineering, Economic Sciences, Physics and Mathematics.

This phase involves one expert per proposal.

Confirmation of no ethics issues = "ethics clearance". The process is then finished.

The role of the expert is to list the (potential) ethical issues but not to assess them.

Please note that a proposal in which the ethics issues are well addressed (that is: no requirements needed), can be safely declared ethics ready and therefore cleared.

When there is at least one confirmed ethical issue, the proposal is subject to a complete Ethics Screening.

Note: in SEP you need to confirm twice the clearance of the same proposal. That is, when you submit the EthPR of a proposal with no ethics issues, you will receive another task to confirm your review.

The system was originally designed to have two experts confirming ethics clearance. For MSCA-IF proposals, we limited the number to one. However, the two clicks remain.
The ethics review of the Marie Skłodowska-Curie Actions Individual Fellowships

Pre-screening Report in SEP

1. The type of report is indicated on top of the screen.
2. The Evaluation progress is indicated on the right side.
3. Click the + to expand each section.
4. For each section indicate if there are ethics issues (the default option is No).
5. Complete the boxes if applicable.
6. Indicate the page of the proposal where the ethics issue is identified.
The Individual Screening REPORT (EthIR) PHASE

During screening, proposals are examined by two ethics experts for ethics issues and the way they are addressed.

Each expert must first examine each proposal individually. Then the expert drafts and submits his/her ethics screening individual report (EthIR) (in SEP).

Exception:

All proposals involving the use of human embryonic stems cells (hESCs) will undergo an ethics assessment.
The Consensus REPORT (EthCR) PHASE

As soon as both experts submit their EthIR, the EthCR phase opens. The two experts must look at each proposal together and come to a common view on:

- the ethics issues
- the 'ethics opinion'
- the need for ethics checks during grant implementation (and their timing)
- other ethics recommendations (i.e. non-binding suggestions and advice, if any).

The rapporteur prepares — for each proposal — an ethics screening consensus report (EthCR) (in SEP) and leads the remote consensus report finalisation.

Please note that it is possible to merge the two EthIR reports.

When the experts have reached a consensus view, they must approve the report (in SEP) — within a certain deadline.

Each expert acts as Rapporteurs for a half of their proposals and approves the EthCR for the remaining ones.

Fellow expert needs to approve EthCR. Please note that inaction (i.e. no approval by the deadline) will be considered as tacit approval!

A Video-demonstration of the creation of a Consensus Report is accessible here (it requires EU Login authentication)².

² Please note that the video is about consensus reached during the scientific evaluation. However, the two processes are very similar.
CONSENSUS REPORT in SEP

Screening - Ethics Consensus Report

1. Does this research involve human participants? *
   - No
   - Yes

Page

1. Click the + to expand each section
2. Indicate if the respective issue applies (default if No), indicate the page and complete the comment box, if relevant.
ETHICS OPINION:

You must select one of the “Ethics Opinion” options, according to the situation of the proposal.

1. Choose the appropriate option amongst the 4 available.

2. In the box “Ethics opinion Reason”, you can explain why the particular opinion was selected.
ETHICS CLEARANCE

Proposals are fully compatible with Article 34 of H2020 Grant Agreement.

Only proposals that are 'ethics-ready' receive ethics clearance (i.e. respect ethical principles and applicable laws, provision of the needed copies of Ethics Approvals, clear information on the ethics issues are provided...).

ADDITIONAL INFORMATION NEEDED

A reason must be stated/to be used exceptionally.

IMPORTANT: Please note that asking for “Additional Info” in many cases might be easily translated into requirements to be fulfilled by the applicants.
CONDITIONAL ETHICS CLEARANCE

The clearance is subject to conditions that must be included as ethics requirements.

Ethics requirements should be fulfilled during grant implementation (instead of before GA signature), in particular when certificates are requested.

Ethics requirements that must be fulfilled during grant implementation become contractual obligations and are consequently deliverables in Annex 1 to the Grant Agreement.

Only requirements that have not been full filled in the application need to be included in the report.

Authorisations from national competent bodies must be obtained before the start of the relevant research.

Ethics requirements may include:
- regular reporting to the REA;
- the appointment of an ethics mentor who may be asked to report to the REA on the compliance with the ethics requirements;
- submission of further information, documents or confirmation that necessary authorisation / licence / certificate have been obtained from National/local Authorities.

How to translate ethics requirements in the Screening Reports:
- You should select the type of the ethics issues in the Ethics Issues Table.
- The requirements should be concise and project specific.
- Split requirements: do NOT group all conditions in one single requirement. Rather you may group together requirements (belonging to the same category) that can be fulfilled at the same time.
- When a requirement is linked to a confirmation or to the delivery of a document (ethics approval, informed consent, authorisation, etc.) you must indicate a month X of the project. Month X is the first month of the Work Package that raises the respective ethics issue. To define month X please check the WP Start Month in the Work Package List table of Part B.

Requirement = Deliverable = Action from the beneficiary!
HOW TO ADD REQUIREMENTS in SEP

1- Click Add requirement.
2- Select the Ethics issue from those that you have identified. Note that at the end of the list, there is a section "General", for requirements that are not linked to a particular ethics issue (for example, appointment of an ethics mentor).
3- Complete the requirement text.
4- To tailor the ethics requirements to the MSCA Individual Fellowships, a separate document with pre-defined requirements is at your disposal. We strongly recommend using them and not the pre-defined text in SEP. You can still edit the suggested text whenever it is appropriate to do so.
5- Select "After the Grant Signature". Usually a MSCA Individual Fellowship starts several months after the Grant signature.
6- For requirements after the signature: indicate the month of the project by which it must be fulfilled (Check relevant activity in the proposal). Please, do not put zero!
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 experts (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.

*In practice:*

The role of the experts during the current exercise is to recommend in the Consensus Report when an Assessment is needed: **NO requirements.**

Assessments must be recommended for very limited cases only:

- for proposals involving the use of hESC of human embryonic stems cells (automatically sent to Assessment).

Inform the REA if you think a proposal should be 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.
ETHICS ASSESSMENT in SEP

1. In the box "Ethics opinion Reason", explain why the assessment is recommended.
2. List the additional information that must be provided for the ethics assessment. You should also formulate suggestions for the experts that will carry out the ethics assessment.

Recommendations for the experts that will carry out the ethics assessment, e.g. concerning missing information or documents.
ETHICS CHECK

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

When a check is requested, you 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.

When to request:

- In case of complex and difficult ethics issues;
- When compliance with Ethics requirements needs to be checked during the implementation;
- Ethics checks can be recommended independently of the ethics opinion (i.e. even in case of 'ethics clearance');
- Timing for the check must also be mentioned (Month number X of the project).
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**ETHICS CHECK in SEP**

- Ethics Checks
  Current status: Yes

  In your opinion, would an ethics check during the project implementation be necessary (see Article 22 H2020 General MGA)? *

  - [ ] No
  - [x] Yes

  **Reasons** *

  1. Indicate that you recommend an Ethics Check.

  2. **Explain why** an ethics check is recommended during the project implementation.

  3. In case an Ethics Check is recommended, **indicate the month of the project when it should take place.**
ETHICS RECOMMENDATIONS in SEP

Recommendations can be made to the applicant. These are **not** requirements to be fulfilled by the applicant.
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BEST PRACTICES

How to finalise the reports:

- The first time you Edit the report the task status changes from Assigned to Opened.
- You are not forced to Submit your report at once: you may save it and return to the report at a later time. You will be able to re-open the report by clicking on the Edit button in the Active Tasks tab.
- When you are satisfied with your comments, click the Submit button.
- 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), with the View button.

Ethics Individual Report:

- Select the appropriate Ethics issue, if applicable.
- Add the relevant requirements.
- Select one of the 4 Ethics opinions.

Ethics Consensus Report:

- Edit different opinions in order to achieve a more coherent report for the applicant.
- Eliminate contradictions.
- Don't delete relevant comments and keep ethics issues even if clearance given.

Requirements:

- Pre-defined standard sentences in document Ethics requirements MSCA-IF-2017 (preferred).
- Project specific requirements (if appropriate).
- Ensure requirements are aligned with the ethical issues identified.
- Requirement = clear instructions to the applicants!
- Ethics reports must be clear, concise and project specific.
- All ethical issues identified in the proposal must be addressed in the report.

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

Keep in mind that:

- 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 in the Ethics Consensus Report.
- This document will be sent to applicants.
- If you come across sensitive proposals according to your experience, let us know for reinforced monitoring.

If you have submitted your Ethics Report by mistake and/or wish to reopen it, please contact us.
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CONTACT
For any question please contact us via the functional mailbox.

USEFUL LINKS
Participant Portal H2020 Ethics section

SEP
SEP Evaluation Expert Quick Guide

Horizon 2020 Legislation
- Legal basis - Horizon 2020 Rules for Participation: Ethics Reviews (Article 14)
- Horizon 2020 - Regulation of Establishment: Ethical principles (Article 19)
- Model Grant Agreement: Ethics (Article 34)
- Statements by the Commission on human embryonic stem cell research
- Guide for proposal submission and evaluation
- Charter of Fundamental Rights of the European Union
- European Code of Conduct for Research Integrity

General guidance documents
- Ethics Issues Table
- Guideline: HOW TO COMPLETE YOUR ETHICS SELF-ASSESSMENT

- Ethics for Researchers
- Ethics in "Science with and for society"
- European Textbook on Ethics in Research (2010)

Domain-specific guidance notes
- Guidance note — Research involving dual use items
- Guidance note — Potential misuse of research results
- Guidance note — Research focusing exclusively on civil applications
- Guidance note — Research on refugees, asylum seekers & migrants
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GLOSSARY

AC: Associated country. A Country associated to Horizon 2020. Click here for the list

CAR: Career Restart Panel of the European Fellowships

CR: Consensus Report

Duration of fellowships: The duration for European Fellowships (ST, CAR, RI, and SE) 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 month return phase, making the total duration of this type of fellowship between 24 and 36 months.

EC: European Commission

EF: European Fellowship

EthCR: Ethics Consensus Report

EthIR: Ethics Individual Report

EthPR: Ethics Prescreening Report

EthSR: Ethics Summary Report

Experienced Researcher (or Researcher or ER): the researcher must be in possession of a doctoral degree or has at least four years of full-time equivalent research experience at the date of the call deadline.

GF: Global Fellowship

GfA: Guide for Applicants

hESC: Human embryonic stem cells

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

IF: Individual Fellowship

MS: EU Member States

MSCA: Marie Skłodowska-Curie Actions

Partner organisations: 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 and provide additional training.
- In GF, organisations in TC that host the researcher during the compulsory initial outgoing period and provide additional training.

REA: Research Executive Agency

RI: Reintegration Panel of the European Fellowships

SE: Society & Enterprise Panel of
the European Fellowships

**SEP:** Web-based electronic evaluation tool

**ST:** Standard European Fellowship

**Supervisor:** Scientist appointed at the beneficiary to supervise the researcher throughout the whole duration of the action.

**TC:** Non-associated third countries. Countries which are neither EU Member States (MS), nor associated to Horizon 2020 (AC).

**WP:** Work Programme