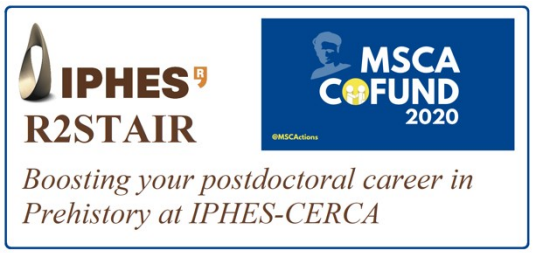
Ethics Appraisal Procedure



The Grant Agreement No 101034349 of the R2STAIR Fellowship Programme, signed between IPHES and the Research Executive Agency (REA), include obligations for the following **ethics aspects:**

Personal Data: During the selection process, personal data will be collected and digitally sealed from all the applicants. The details provided will be included in a file managed by IPHES for the purpose of managing the grant application and award process. Therefore, in accordance with the provisions of General Data Protection Regulation (EU) 2016/679 ("GDPR") on data protection:

- Applicants will be informed that their data will be stored for the purpose of the selection process.
- The database will be registered on the Catalan Registry.
- Applicants who wish to access, rectify or cancel their details will be able to exercise their right using the contact details provided at the time they submit the information.

Ethics: ethical issues will be taken in consideration and monitored at all stages of the development of the research activities:

- Applicants - Applicants will receive at the application phase the H2020 ethics checklist and instruction ('How to complete your ethics self-assessment'). All applicants will be requested to declare if their research will be affected by ethical issues and how will they address them.

- Evaluation – the selection panels will flag if they identify any ethical issues in the project proposals during the evaluation stage.

- Project proposals – All selected Fellows' research projects which have been flagged as potential projects with ethical issues, both on the main list as well as on the reserve list, will be submitted to an ethical evaluation, which will be conducted by IPHES RRI Committee, responsible for ensuring that all research at IPHES is in compliance with ethical principles and rules, according to the legislation. The projects will have an explicit ethics approval from IPHES RRI committee and/or from committees that provide legally mandatory ethics advice before research activities that raise ethics issues can begin.

Project follow-up – The responsibility of the implementation of ethics requirements and for the ethics reporting described in WP5 will be from the supervisors of individual fellows, with the advice of IPHES RRI committee and the support of the PM of the programme. There are partners from the UK, Switzerland and Israel. In case activities undertaken in non-EU countries raise ethics issues, the beneficiary will ensure that the research conducted outside the EU is legal in at least one EU Member State.

"Beneficiary's obligations regarding selected research proposals involving the use of human embryonic stem cells (hESC) or human embryos (hE): "Notwithstanding the stipulations under Article 34.3 of the Grant Agreement, the beneficiary shall inform the Research Executive Agency

(REA) in writing of any research project selected for funding that may involve the use of human embryonic stem cells (hESC) or human embryos (hE). Such research may not start without the approvals of the EC ethics review and of the relevant Programme Committee completed by the communication of the explicit approval in writing from the REA to the beneficiary. If the beneficiary breaches any of its obligations regarding selected research proposals involving the use of human embryonic stem cells (hESC) or human embryos(hE), the grant may be reduced (see Article 43 of the Grant Agreement) and the Grant Agreement may be terminated (see Article 50 of the Grant Agreement) without prejudice to any of the other measures described in Chapter 6 of the Grant Agreement."

In this sense, all applicants are requested to complete an Ethics Appraisal Procedure. It is composed of three different parts. It starts with the Ethics Issues Table (EIT). Furthermore, only if any ethics issues apply and has been pointed out in the EIT, the applicants must complete an Ethics self-assessment and explain how they will address the ethics concerns in an additional Ethics Statement. **Applications which do not include completed this ethics section will not be accepted for review**, deeming as ineligible.

The Ethics Issues Table included in the section 10 of this guide is identical to other Horizon 2020 proposals. Applicants will be asked whether her/his application deals with any ethics issues, pointing out the page number in the proposal in which these concerns appear.

Therefore, only when ethics issues have been affirmatively identified in the Ethics Issues Table, the applicants must complete the Ethics Self-Assessment, writing also an Ethics Statement of not more than 2 pages, including a description of the nature of these issues and how they plan to deal with them, annexing the Ethics Statement to the Research Proposal (see section 10).

All the proposals with ethical considerations selected for funding at **"Stage 2: Eligibility check"** of the evaluation process will be submitted to an ethical evaluation conducted by IPHES-CERCA RRI Committee, which is responsible for ensuring that all research at IPHES-CERCA is in compliance with ethical principles and rules, according to the legislation. These proposals with ethical concerns must have an explicit ethics approval from IPHES-CERCA RRI Committee, that may require, if appropriate, the evaluation and approval from other external committees that provide legally mandatory ethics advice, before the research activities of the project raising ethics issues can begin.

Section 10.5. Ethical Issues

Compliance with the relevant ethics provisions is essential from the beginning to the end of the action and is an integral part of research funded by the European Union within Horizon 2020.

Applicants submitting research proposals for funding for the Horizon 2020 R2STAIR COFUND Marie Skłodowska-Curie Action should demonstrate proactively in their proposal that they are aware of, and will comply with, ethical principles and applicable International, European and national law. Key sources of EU and international law are the European code of conduct for research integrity, the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Another important source is the UN Convention on the Rights of Persons with Disabilities (UN CRPD).

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring Replacement, Reduction and Refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations

Please be aware that it is the applicants' responsibility to identify any potential ethical issues, to handle the ethical aspects of the proposal and to detail how these aspects will be addressed. The appropriateness of the measures proposed will be assessed by ethics experts during the ethics review, which is a part of the overall evaluation procedure, and if necessary, during the implementation of the action and up to two years afterwards (ethics checks, reviews and audits).

1.- The Ethics Issues Table (EIT)

1. HUMAN EMBRYOS/FOETUSES		Page
Does your research involve Human Embryonic Stem Cells (hESCs)?	YES ☐ NO ☐	
Does your research involve the use of human embryos?	YES ☐ NO ☐	
Does your research involve the use of human foetal tissues / cells?	YES ☐ NO ☐	
2. HUMANS		**Page**
Does your research involve human participants?	YES ☐ NO ☐	
Does your research involve physical interventions on the study participants?	YES ☐ NO ☐	
3. HUMAN CELLS / TISSUES		**Page**
Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses, i.e. section 1)?	YES ☐ NO ☐	
4. PERSONAL DATA		**Page**
Does your research involve personal data collection and/or processing?	YES ☐ NO ☐	
Does your research involve further processing of previously collected personal data (secondary use)?	YES ☐ NO ☐	
5. ANIMALS		**Page**
Does your research involve animals?	YES ☐ NO ☐	
6. THIRD COUNTRIES		**Page**
In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?	YES ☐ NO ☐	
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.)?	YES ☐ NO ☐	
Do you plan to import any material - including personal data - from non-EU countries into the EU?	YES ☐ NO ☐	
Do you plan to export any material - including personal data - from the EU to non-EU countries?	YES ☐ NO ☐	
In case your research involves low and/or lower middle income countries, are any benefits-sharing actions planned?	YES ☐ NO ☐	
Could the situation in the country put the individuals taking part in the research at risk?	YES ☐ NO ☐	
7. ENVIRONMENT & HEALTH and SAFETY		**Page**
Does your research involve the use of elements that may cause harm to the environment, to animals or plants?	YES ☐ NO ☐	
Does your research deal with endangered fauna and/or flora and/or protected areas?	YES ☐ NO ☐	
Does your research involve the use of elements that may cause harm to humans, including research staff?	YES ☐ NO ☐	
8. DUAL USE		**Page**
Does your research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?	YES ☐ NO ☐	
9. EXCLUSIVE FOCUS ON CIVIL APPLICATIONS		**Page**
Could your research raise concerns regarding the exclusive focus on civil applications?	YES ☐ NO ☐	
10. MISUSE		**Page**
Does your research have the potential for misuse of research results?	YES ☐ NO ☐	
11. OTHER ETHICS ISSUES		**Page**
Are there any other ethics issues that should be taken into consideration? Please specify	YES ☐ NO ☐	

Taking into account all the ethics issues above and that, if any ethics issues apply, the applicant must complete the ethics self-assessment as described in the H2020 guidelines How to Complete your Ethics Self-Assessment.

2.- The Ethics Self-Assessment

In order to facilitate the ethics review of the proposal, only if any ethics issues apply and has been pointed out in the EIT, the applicants must complete a second table of the Ethics self-assessment and explain further in an additional Ethics Statement of a maximum of two pages, how will they address the ethics concerns, including the statements or documentation that are relevant and/or applicable.

The table below is not about declaring whether the applicants identified ethics issues or not as is done in Ethics Issues Table (EIT). **Please fill in the table below only if you flagged the corresponding ethics issue in the EIT of the proposal**. **Do not answer yes if opinions/approvals/licenses/authorisations/etc still have to be obtained**. If applicable, please provide the licence/authorisation/etc. number and issue date in the additional Ethics Statement.

Humans	
I confirm that templates of the informed consent forms and information sheets (in language and terms intelligible to the participants) will be kept on file.	**YES** ☐ **NO** ☐
I confirm that opinions/approvals by ethics committees and/or competent authorities for the research with humans have been obtained, and are kept on file	**YES** ☐ **NO** ☐
Human Cells	
I confirm that confirm that authorisation has been obtained from the primary owner of cells/tissues (including references to ethics approval) and is kept on file.	**YES** ☐ **NO** ☐
Data protection	
I confirm that a Data Protection Officer (DPO) has been appointed and the contact details of the DPO are made available to all data subjects involved in the research.	**YES** ☐ **NO** ☐
I confirm that data intended to be processed is relevant and limited to the purposes of the research project (in accordance with the 'data minimisation' principle).	**YES** ☐ **NO** ☐
In case of further processing of previously collected personal data, I confirm to have lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects.	**YES** ☐ **NO** ☐
I confirm that the data used are publicly available and can be freely used for the purpose of the project.	**YES** ☐ **NO** ☐
I confirm that the transfer(s) of personal data from the EU to a non-EU country or international organisation, is(are) in accordance with Chapter V of the General Data Protection Regulation 2016/679.	**YES** ☐ **NO** ☐
I confirm that the transfer(s) of personal data from a non-EU country to the EU (or another third state) comply(ies) with the laws of the country in which the data was collected.	**YES** ☐ **NO** ☐
I confirm that confirm that templates of the informed consent forms and information sheets (in language and terms intelligible to the participants) are kept on file.	**YES** ☐ **NO** ☐
Animal	
I confirm that training certificates/personal licenses of the staff involved in animal experiments have been obtained and will be kept on file.	**YES** ☐ **NO** ☐
I confirm that relevant authorisations for animal experiments (covering also the work with genetically modified animals, if applicable) have been obtained, and will be kept on file.	**YES** ☐ **NO** ☐

Third country	
I 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.	YES ☐ NO ☐
I confirm that fair benefit-sharing arrangements with stakeholders from low and/or lower-middle income countries are ensured during the project.	YES ☐ NO ☐
Environmental protection and safety	
I confirm that appropriate health and safety procedures conforming to relevant local/national guidelines/legislation are followed for staff involved in this project.	YES ☐ NO ☐
I confirm that authorisations for relevant facilities (e.g. security classification of laboratory, GMO authorisation) have been obtained and will be kept on file.	YES ☐ NO ☐

3.- The additional Ethics Statement of a maximum of two pages must cover 3 points:

Point 1.- Explain briefly the ethical dimension of the objectives, methodology and likely impact in particular with regard to:

- the research **objectives** (e.g. study of vulnerable populations, cooperation with a Third Country, etc.);
- the research **methodology** (e.g. clinical trials, involvement of children and related information and consent/assent procedures, data protection and privacy issues related to data collected, etc.);
- processing of sensitive **personal data;**
- safeguard of the **rights** and **freedoms** of the data subjects/research participants;
- the potential **impact** of the research (e.g. dual use issues, environmental damage, malevolent use, etc.);
- appropriate **health and safety** procedures - conforming to relevant local/national guidelines/legislation - for the staff involved;
- possible **harm to the environment** the research might cause (e.g. environmental risks of nanomaterials), and measures that will be taken to mitigate the risks.

Point 2.- Explain how the proposal complies with ethical principles and the applicable international, EU and national law in the country/countries where the activity raising ethical issues is to be carried out.

- Please note that activities carried out in a non-EU country must comply with the laws of that country AND be allowed in at least one EU Member State. Applicants must confirm in this section that this condition is met.

- For more information on how to deal with non-EU countries[1] please see Article 34 of the Annotated Model Grant Agreement, as well as the rules for the protection of personal data inside and outside the EU.

Point 3.- Explain if the applicant has already or not yet applied for an official ethics committee, received its ethics approval, or have or not the required ethics documents when submitting the proposal.

1 In the context of ethics review, non-EU countries are all Non-member States, i.e. also Associated Countries.

If they are already available, it is possible to add the relevant ethics documents as annexes. If they are not in English, they must be submitted together with an English summary. Please list the documents provided with their expiry date.

If they are not yet these relevant ethics documents, please indicate the approximate date by which they will be obtained the relevant approvals and/or authorisations and any other ethics documents.

In that case, the applicant must state explicitly that she/he will not proceed with any research with ethical implications before obtaining the necessary authorisations and/or opinions of IPHES-CERCA RRI Committee.