**COFUND-R2STAIR Ethics Appraissal Procedure**

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 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.

**The Ethics Issues Table (EIT)**

|  |  |  |
| --- | --- | --- |
| **1. HUMAN EMBRYOS/FOETUSES** |  | **Page** |
| Does your research involve [Human Embryonic Stem Cells (hESCs)](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF)? | **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](https://datahelpdesk.worldbank.org/knowledgebase/articles/906519), 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** **[ ]**  |  |

**The Ethics Self-Assessment Table**

*(only if any ethics issues apply, and has been pointed out in the EIT)*

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| **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** **[ ]**  |

**The Ethics Statement**

*(only if any ethics issues apply, and has been pointed out in the EIT)*

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]](#footnote-2) please see Article 34 of the [Annotated Model Grant Agreement](http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/amga/h2020-amga_en.pdf), as well as the [rules for the protection of personal data inside and outside the EU](http://ec.europa.eu/justice/data-protection/international-transfers/adequacy/index_en.htm.).

**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.

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.

1. In the context of ethics review, non-EU countries are all Non-member States, i.e. also Associated Countries. [↑](#footnote-ref-2)