**CRIS Out-Back Fellowship Programme Ethical Self-Assessment Report**

This document is intended to ensure that the applicant meets all the ethical specifications of the initiatives under the Horizon Europe 2021-2027 funding. This document will be evaluated along with the rest of the application. It is important that the candidate provides as much documentation as possible regarding the fulfilment of the ethical issues.

Please complete this form, following the guidelines provided in each section. Please attach all relevant documentation to this form and submit it as a single pdf document.

1. **Research with human embryos and foetuses:**

Does your research involve Human Embryonary STEM Cells?

*If so,*

* *Will they be directly delivered from embryos within this project? (In this case the Project is not eligible for funding)*
* *If not, do they come from pre-established cell lines?*
	+ *In that case, please detail the origin and name of the cell line.*
	+ *Provide details on the licensing and control measures by the competent authorities of the Member States Involvement.*
	+ *Provide documentation on: Ethics approval, Guarantees Commission for the Donation and Use of Human Cells and Tissues approval, and relevant declarations.*

Does your research involve the use of human embryos?

*If so, the Project is not eligible for funding.*

Does your research involve human foetal tissues or cells?

*If so,*

* *Please, explain their origin and details on how the informed consent documents were obtained.*
* *Provide a template of the informed consent and copies of the information provided. Also, provide a copy of the ethics approval.*
1. **Research involving human beings**

Does your research involve Human Participants?

*If so,*

* *Provide details on the informed consent forms and how they were obtained.*

Are the participants volunteers for research?

*If so, explain the details of the recruitment, provided information, inclusion criteria and provide copies of the informed consent and ethics approval (in case they are required).*

*In relation to this last requirement, if the ethic Committee approval is not required, explain the scientific reason about why it would not be possible to carry out the project/study with adults, exclusively*

Are the participants persons unable to give an informed consent (including children/minors)?

*If so,*

* *Explain from scientific point of view, why it would not be possible to carry out the project/study without unable volunteers*
* *Explain the procedure by which the approval of the legal representative was obtained*
* *Explain the type of vulnerability of the participants.*
* *Explain the measures taken to ensure that the participants were not subjected to any form of coercion. Also detail the measures to inform and provide full understanding of the implications of this participation.*
* *Explain the details of the recruitment, provided information, inclusion criterion.*
* *Provide copies of the informed consent and ethics approval.*

Are the participants children or minors?

*If so,*

* *Provide details on the age range and the inclusion criteria.*
* *Justification of the involvement of minors and not to carry out the project/study with adults exclusively.*
* *Explain the procedure by which the approval of the parents or legal representatives was obtained.*
* *Explain the measures taken to ensure the welfare of the minor and the risk/benefit balance.*
* *Provide copies of the ethics approval and informed consents.*

Are the participants patients?

*If so,*

* *Provide details on the disease or condition of the patients.*
* *Provide details on the inclusion criterion and the informed consent procedure.*
* *Which is your policy on incidental findings?*
* *Provide copies of the ethics approval and informed consents.*

Are the participants healthy volunteers?

*If so, provide copies of the ethics approval and informed consent.*

Does your research involve physical intervention on the study participants?

*If so,*

* *Does it involve invasive techniques (including collection of human cells or tissues, medical interventions, invasive studies etc.)?*
	+ *If so, provide copies of the ethics approvals and informed consent.*
	+ *Detail risk assessments overall and on each individual techniquProvide details about the insurance policy contracted to cover any damage or injury suffered by the participants (Name of the Insurance company and policy reference number. Provide a copy or a policy certificate). If not, provide the reason about no to have been contracted an insurance policy.*
* *Does it involve collection of biological samples?*
	+ *If so, detail which samples are being collected and by which procedure.*
	+ *Provide copies of the ethics approvals and informed consent.*
1. **Research involving human cells or tissues**

Does your research involve human cells or tissue (different from human embryos or foetuses)?

*If so, provide details of the cells, tissue types, origin and copies of the relevant ethics approval and accreditation for use, processing and collection of human cells.*

Are these cell or tissues available commercially?

*If so,*

* *Provide details of the provider company or laboratory.*
* *Provide copies of the relevant licences.*

Are the cells or tissues obtained within this project?

*If so,*

* *Provide details of the source and origin of the material, and the procedure to obtain it.*
* *Explain the storage process, the duration of the storage and final destination of the material.*
* *Provide details of the informed consent.*
* *Provide copies of the informed consent, information sheets and relevant ethics approval (if applicable).*

Are the cell or tissues obtained from another project, laboratory or institution?

*If so,*

* *Provide details on the institution and country where the source material is stored.*
* *Detail the legislation under which the material is stored.*
* *Explain how long the material will be stored and the final destination of the material.*
* *Confirm that the material is anonymised or that it was obtained after an informed consent.*
* *Provide details of import licences and relevant MTAs.*
* *Provide a statement of the source laboratory/institution that the material was obtained under an informed consent.*

Are the cell or tissues obtained from a biobank?

*If so,*

* *Detail the name of the biobank and provide information on the country where it is located, legislation applicable and confirm that the material is anonymised and obtained after informed consent.*
* *Provide copies of relevant licences or MTAs, and a statement of the biobank that the material was obtained after informed consent or, if not, the legal justification to obtain biological material without previous informed consent.*
1. **Research involving personal data:**

Does your project involve use or processing of personal data?

*If so,*

* *Provide details on how you are going to safeguard the rights of the research participants. If your organisation has a Data Protection Officer, explain his role. Provide details of the data protection policy in this project and provide details in which country/area the data will be hosted.*
* *Provide details of the informed consent and the security measures to prevent unauthorised access to the personal data.*
* *Explain how the use of data is going to be limited to the purposes of the project.*
* *Provide details on the anonymisation procedures. In case some dates are not going to be anonymised, provide a fitting justification.*
* *In case data are going to be transferred, provide details of the time of data and transference destiny details. If so, provide details about the Non-Disclosure Agreement.*
* *Provide a copy of the informed consent and the information sheets.*

Does the project involve the processing of special categories of personal data (genetic, health, sexual lifestyle, ethnicity, political, religious or philosophical groups)?

*If so,*

* *Provide a justification of the use of these special categories.*
* *Justify why the research objectives cannot be reached by use of anonymised data.*
* *Provide confirmation if a Data Protection Impact Assessment was carried out.*

Does the project involve the processing of genetic, biometric or health data?

*If so, provide a declaration confirming compliance with the laws of the country where data were collected.*

*Provide confirmation if a Data Protection Impact Assessment was carried out.*

Does the project involve profiling / systematic monitoring of individuals, processing large scale special categories of data, intrusive methods of data processing (including tracking, audio/video recording etc.) or any operation that may compromise rights and freedoms of the participants?

*If so,*

* *Detail the methods of special data obtention, including tracking, surveillance or observation.*
* *Detail the methods used for profiling.*
* *Provide a risk assessment for the data processing activities.*
* *Explain how the activity could compromise the rights and freedoms of the participants, and how you will prevent this situation.*
* *Explain the information provided to the participants.*
* *Provide an Opinion of the data controller on the need for a data protection impact assessment ~~(if relevant).~~*

Does the project involve further processing of previously collected data?

*If so,*

* *Provide details of the database or source of the information.*
* *Detail the data processing operations.*
* *Explain how the rights of the research participants will be safeguarded.*
* *Justify the use of the previous analysed data.*
* *In the event that data are not anonymised, please provide a suitable justification.*
* *Provide a declaration confirming that the use of the data is legal.*
* *Provide a permission of the owner/manager of the dataset.*
* *Provide all informed consents, information sheets or relevant documentation.*
* *Provide information about any agreement with responsible or owner of the database to use it content.*

Does your project involve publicly available data?

*If so, provide information that confirms that the data is publicly available to use for your project. Also, provide a document with the permission of the owner/manager of the data sets.*

Do you plan to export personal data from the EU to other non-EU countries?

*If so,*

* *Provide details of the personal data that will be exported.*
* *Explain how you are going to safeguard the rights of the participants and provide all relevant documentation that supports this export.*
* *Provide scientific justification to carry out this international transfer of personal data*

Do you plan to import personal data from non-EU countries into the EU?

*If so,*

* *Provide details of the personal data that will be imported.*
* *Provide a declaration confirming that the data were collected complying with the legislation of the origin country.*
1. **Research involving animals:**

*If your research involves animals,*

* *Provide details of the species, number of animals and their origin.*
* *Provide appropriate accreditation to work with these species.*
* *Explain the rationale behind the numbers, nature of the experiments and which procedures are going to be performed.*
* *Provide a justification of animal use, why are you using this specific species and why other alternatives cannot be used.*

Does your research involve non-human primates?

*If so,*

* *Justify the use of Non-Human Primates (NHPs) and explain why the results are not achievable by use of any other animal model.*
* *Detail the purpose and objective of the animal testing.*
* *Provide details of the animal origin.*
* *Provide a personal history file of Non-Human Primates.*

Does your research involve Genetically Modified Organisms (GMOs)?

*If so,*

* *Detail of the genotype/phenotype and explain if there is any inherent suffering expected.*
* *Justify the production and use of such animals.*
* *Explain the measures that you will take to minimise suffering in breeding, maintenance and use the GMOs.*
* *Provide copies of all relevant documentation and authorisations.*

Does your research involve cloned farm animals?

*If so,*

* *Detail of the genotype/phenotype and explain if there is any inherent suffering expected.*
* *Justify the production and use of such animals.*
* *Explain the measures that you will take to minimise suffering in breeding, maintenance and use the cloned farm animals.*
* *Provide copies of all relevant documentation and authorisations.*

Does your research involve any endangered species?

*If so,*

* *Justify the use of these specific species and explain why the results are not achievable by use of any other animal model.*
* *Detail the purpose and objective of the animal testing.*
* *Provide copies of all authorisations relevant for the supply and use of endangered animal species.*
1. **Research involving Non-EU countries:**

Does the implication of non-EU countries in the project raise potential ethics issues?

* *Perform a Risk-benefit analysis.*
* *Specify which activities are carried in non-EU countries.*
* *Provide all relevant ethics approvals and other authorisations.*
* *Confirm that the activity could have been performed legally in the EU.*

Do you plan to use local resources of these countries (such as tissue samples, genetic material, animals, materials of historical value, endangered species, etc.)?

*If so,*

* *Specify which local resources will be used and exactly how are they going to be used.*
* *Provide all relevant authorisation and approvals.*
* *If human samples or tissues are going to be used, provide all relevant authorisations, ethics approvals and informed consents.*
* *If other organisms are going to be used, provide relevant information, authorisations and documentation that proves compliance with the UN Convention on Biological Diversity.*

Do you plan to import any material from non-EU countries into the EU?

*If so,*

* *Specify the materials and countries involved.*
* *Detail the type of materials that you will import.*
* *Provide copies of import licences.*

Does your research involve low or lower-middle income countries?

*If so,*

* *Is any benefit sharing actions planned?*
* *Provide responsiveness to local research needs and explain the benefit of the sharing measures.*
* *Detail the procedure to facilitate effective capacity building.*

Does the situation of the non-EU country put the individuals taking part in the research at risk?

* *Provide details of the safety measures you intend to take. Include training for staff and insurance cover documents.*
1. **Environmental issues:**

Does your project involve the use of elements that might cause harm to the environment, animals or plants?

* *Perform a risk-benefit analysis.*
* *Explain how you will apply the precautionary principle.*
* *Detail the safety measures that you will take.*
* *Provide the safety classification of the laboratories.*
* *Provide all authorisations required to work with any species used.*

Does your project deal with endangered fauna/flora/protected areas?

*If so, provide all the specific authorisations required to perform your research.*

Does your research involve the use of elements that may cause harm to humans, including research staff?

*If so,*

* *Detail the health and safety procedures that will be applied.*
* *Provide documentation on the safety classification of the laboratory.*
1. **Research involving dual-use items:**

*Dual-use items are goods, software and technologies covered by the EU Export Control Regulation No 428/2009. Although they are normally used for civilian purposes, they might have military applications or contribute to proliferation of weapons of mass-destruction.*

Does your project involve dual-use items in the sense of Regulation 428/2009 or similar items that require authorisation?

*If so,*

* *Explain which goods and information used and produced by your research will need export licences.*
* *Explain how you will ensure compliance.*
* *Explain how exactly you will avoid negative implications.*
* *Provide copies of export licences.*
1. **Ensuring focus on civil applications:**

Could your project raise concerns regarding the exclusive focus on civil applications?

*If so,*

* *Explain why your research has an exclusive civilian focus.*
* *In case military partners or technologies are included, justify their participation and how this will contribute exclusively to civilian applications.*
1. **Potential misuse of research results:**

Does your research have a potential for misuse of research results?

* *Perform a risk assessment of your research project.*
* *Provide details of the applicable legal requirements.*
* *Explain the measures that will be taken to prevent misuse of results.*
* *Provide copies of any required authorizations.*
* *Provide copies of security clearances, if they are applicable.*
* *Provide copies of all relevant ethics approvals.*
1. **Other ethics issues:**

Does your research involve any other ethics issues that should be taken into consideration?

*If so, provide a justification for using that issue, all relevant information and documentation.*