MSCA4Ukraine Fellowship Programme: 2024 Call for Applications

Ethics Self-Assessment Form

This ethics self-assessment form contains the questions posed during the ethics self-assessment process for EU grant applications. For detailed guidance on completing this form, applicants to MSCA4Ukraine should refer to 'How to Complete your Ethics Self-Assessment'. This form must be filled by the candidate, supported by the academic mentor and the contact person for ethics (if applicable) and submitted as a separate pdf-document through the online application portal.

If you have answered 'yes' to one or more ethics categories, we kindly ask you to provide a more detailed explanation of the issues. Please refer to the table column "Information to be provided in the proposal" in the form below for information required. Please upload this information as a separate pdf-document in the online portal using the upload option "Additional ethics-related information."

Please note that the host organisation of a candidate whose project contains ethically relevant issues is required to identify a contact person for ethics, who will be responsible for ensuring that all necessary formal ethics approvals are obtained as required by relevant national and EU regulations and in due time. This contact person for ethics should be consulted/ assist the candidate in filling out this form and providing any additional information required.

Funded by the European Union

1. Ethics: Human embryonic stem cells and human embryos

1.1 Ethics issues checklist

1 HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS		YES	NO	Information to be provided in the proposal	Documents be provided/kept on file
Does your activity involve Human Embryonic Stem Cells (hESCs)?		☐	☐		
If **YES:**	Will they be directly derived from embryos within this project?	☐	☐	*Activity not eligible for funding*	*Activity not eligible for funding*
	Are they previously established cells lines? Are the cell lines registered in the European registry for human embryonic stem cell lines?	☐	☐	1) Origin and line of cells. 2) Details on licensing and control measures by the competent authorities of the Member States involved 3)Declaration confirming that the 6 specific conditions *(see below)* for activities involving human embryonic stem cells are met.	1) Copies of ethics approval. 2) Declaration that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hpscreg.eu).
Does your activity involve the use of human embryos?		☐	☐	1) Origin of embryos. 2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) Confirmation that informed consent has been obtained.	1) Copies of ethics approval. 2) Informed consent forms and information sheets.
If **YES:**	Will the activity lead to their destruction?	☐	☐	*Activity not eligible for funding*	*Activity not eligible for funding*
Does your activity involve the use of other human embryonic or foetal tissues / cells?		☐	☐	*See section 3 below*	

2. Humans

2.1 Ethics issues checklist

2 HUMANS		YES/ NO		Information to be provided in the proposal	Documents to be kept on file and provided on request
Does your activity involve human participants?		☐	☐	Please provide information in one of the subcategories below	
If **YES:**	Are they volunteers?	☐	☐	1) Details on recruitment, inclusion and exclusion criteria and informed consent procedures. 2) Details on unexpected findings policy.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.
	Are they healthy volunteers for medical studies?	☐	☐	1) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 2) Details on incidental findings policy.	1) Copies of ethics approvals. 2) Informed consent forms and information sheets.
	Are they patients for medical studies?	☒	☐	1) Details on the disease/condition /disability 2) Details on the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) Details on incidental findings policy	1) Copies of ethics approvals. 2) Informed consent forms and information sheets.
	Are they potentially vulnerable individuals or groups?	☐	☐	1) Details on the type of vulnerability. 2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.

2 HUMANS		YES/ NO		Information to be provided in the proposal	Documents to be kept on file and provided on request
				3) Procedures to ensure participants are not subject to any form of coercion and undue inducement.	
	Are they children/minors?	☐	☐	1) Details on the age range. 2) Details on assent procedures and parental consent for children and other minors. 3) Procedures to ensure the welfare of the child or other minors. 4) Justification for involving children/minors.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.
	Are there other persons unable to give informed consent?	☐	☐	1) Details on the procedures for obtaining consent from the guardian/legal representative. 2) Procedures to ensure participants are not subject to any form of coercion and undue inducement.	1) Copies of ethics approvals. 2) Informed consent forms and information sheets.
Does your activity involve interventions (physical also including imaging technology, behavioural treatments, tracking and tracing, etc.) on the study participants?		☐	☐		
If **YES:**	Does it involve invasive techniques *(e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)*?	☐	☐	1) Risk assessment for each technique and overall.	1) Copies of ethics approvals.

2 HUMANS		YES/ NO		Information to be provided in the proposal	Documents to be kept on file and provided on request
	Does it involve collection of biological samples?	☐	☐	1) Details on the type of samples to be collected. 2) Procedure for the collection of biological samples.	1) Copies of ethics approvals.
Does your activity involve conducting a clinical study as defined by the Clinical Trial Regulation 536/2014 (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)? *(n/a for DEP)*		☐	☐		
If **YES:**	Is it a clinical trial?	☐	☐	1) Details on the medical products that are being used and risk assessment. 2) Details on the disease/condition /disability of the participants 3) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 4) Details on the incidental findings policy	1) Registration in the EU database (when applicable). 2) Copy of authorisation/ethics approval to conduct clinical trial. 3) Copy of the insurance and liability details.
	Is it a low-intervention clinical trial?	☐	☐	1) Details on the medical products that are being used and risk assessment. 2) Details on the disease/condition /disability of the participants 3) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.	1) Registration in the EU database (when applicable). 2) Copy of authorisation/ethics approval to conduct clinical trial. 3) Copy of the insurance and liability details.

2 HUMANS		YES/ NO		Information to be provided in the proposal	Documents to be kept on file and provided on request
				4) Details on the incidental findings policy.	

Funded by the European Union

3. Human cells or tissues

3.1 Ethics issues checklist

3 HUMAN CELLS / TISSUES		YES/ NO		Information to be provided in the proposal	Documents to be provided on request
Does your activity involve the use of human cells or tissues (other than those covered by *section 1*)**?**		☐	☐	Please provide information in one of the subcategories below.	
If **YES:**	Are they human embryonic or foetal cells or tissues?	☐	☐	1) Origin of human foetal tissues/cells. 2) Details on informed consent procedures. 3) Confirmation that the informed consent has been obtained. 4) If applicable, details on the induced human pluripotent cell lines.	1) Copies of ethics approvals. 2) Informed consent forms and information Sheets. 3) If applicable, registration certificates of the cell lines and project from the hPSCreg.
	Are they available commercially?	☐	☐	1) Details on cell types and provider (company or other).	1) Copies of import licences (if relevant).
	Are they obtained within this project?	☐	☐	1) Details on cell types including the source of the material, the amount to be collected and the procedure for collection. 2) Details on the duration of storage and what will be done with the material at the end of the activity. 3) Confirmation that informed consent has been obtained.	1) Copies of ethics approvals (if relevant). 2) Informed consent forms and information sheets.

3 HUMAN CELLS / TISSUES		YES/ NO		Information to be provided in the proposal	Documents to be provided on request
	Are they obtained from another project, laboratory or institution?	☐	☐	1) Details on cell types. 2) Country where the material is stored. 3) Details of the legislation under which material is stored. 4) Details on the duration of storage and what will you do with it at the end of the project? 5) Name of the laboratory/institution. 6) Country where the laboratory/institution is located. 7) Confirm that material is fully anonymised or that consent for secondary use has been obtained.	1) Authorisation by primary owner of cells/tissues (including references to ethics approvals) 2) Copies of import licences (if relevant). 3) Statement from the primary laboratory/institution that informed consent has been obtained.
	Are they obtained from a biobank?	☐	☐	1) Details on cell types 2) Details on the biobank (name and country where it is located) 3) Details of the legislation under which material is stored. 4) Confirmation that material is fully anonymised or that consent for secondary use has been obtained.	1) Copies of import licences (if relevant). 2) Statement of biobank that informed consent has been obtained.

4. Personal data

4.1 Ethics issues checklist

4 PROTECTION OF PERSONAL DATA	YES/NO		Information to be provided in the proposal	Documents to be provided on request
Does your activity involve processing of personal data?	☐	☐	1) Details of the technical and organisational measures to safeguard the rights and freedoms of the participants/data subjects. These may include: - Project specific data protection policy and/or the contact details of the data protection officer (these must be provided to the participants) The security measures to prevent unauthorised access to personal data - Anonymisation /pseudonymisation techniques. 2) Details of the informed consent procedures with regard to the data processing (if relevant). 3) Explanation as to how all of the processed data is relevant and limited to the purposes of the project ('data minimisation' principle) 4) Justification of why personal data will not be anonymised/ pseudonymised (if relevant).	1) Informed consent forms and information Sheets (if relevant). 2) Data management plan (if relevant). 3) Data protection impact assessment (if relevant)

4 PROTECTION OF PERSONAL DATA			YES/NO		Information to be provided in the proposal	Documents to be provided on request
					5)Details of the data transfers (type of data transferred and country to which data are transferred).	
If **YES:**	Does it involve the processing of special categories of personal data *(e.g. sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)*?		☐	☐	1) Justification for the processing of special categories of personal data (if relevant). 2) Justification to why the project objectives cannot be reached by processing anonymised/ pseudonymised data (if applicable).	
	If **YES:**	Does it involve processing of genetic, biometric or health data?	☐	☐		1) Declaration confirming compliance with the laws of the country where the data were collected.
	Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing *(such as surveillance, geolocation tracking etc.)*?		☐	☐	1) Details of the methods used for tracking, surveillance or observation of participants. 2) Details of the methods used for profiling. 3) Assessment of the ethics risks related to the data processing operations. 4) Explanation as to how the rights and freedoms of the participants/data subjects will be safeguarded and harm	1) Opinion of the data controller on the need for conducting data protection impact assessment under art 35 GDPR. (if relevant).

4 PROTECTION OF PERSONAL DATA	YES/NO		Information to be provided in the proposal	Documents to be provided on request
			will be prevented. 5)Explanation as to how the data subjects will be informed of the existence of the profiling, its possible consequences and how their fundamental rights will be safeguarded.	
Does your activity involve further processing of previously collected personal data *(including use of pre-existing data sets or sources, merging existing data sets)***?**	☐	☐	1) Details of the database used or of the source of the data. 2) Details of the data processing operations. 3) Explanation as to how the rights of the participants/data subjects will be safeguarded. 4) Explanation as to how all of the processed data is relevant and limited to the purposes of the project ('data minimisation' principle) 5) Justification of why the data will not be anonymised/ pseudonymised (if relevant).	1) Confirmation that the data controller has a 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 2) Permission by the owner/manager of the data sets *(e.g. social media databases)* (if applicable). 3) Informed Consent Forms + Information Sheets + other consent documents (if applicable).
Is it planned to export personal data (data transfer) from the EU to non- EU countries? *Specify the type of personal data and countries involved*	☐	☐	1) Details of the types of personal data and countries involved. 2) Explanation as to how the rights and freedoms of the participants/data subjects will be safeguarded	1) Confirmation that data transfers will be made in accordance with Chapter V of the General Data Protection Regulation 2016/679

4 PROTECTION OF PERSONAL DATA	YES/NO		Information to be provided in the proposal	Documents to be provided on request
Is it planned to import personal data (data transfer) 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*	☐	☐	1) Details of the types of personal data and countries involved.	1) Confirmation of compliance with the laws of the country in which the data was collected.
Does your activity involve the processing of personal data related to criminal convictions or offences?	☐	☐	1) Details on the personal data to be processed and the legal basis for the processing; 2) Risk assessment for the data processing operations. 3) Explanation as to how harm will be prevented and the rights of the participants/data subjects will be safeguarded.	1) Opinion of the data controller on the need for conducting data protection impact assessment under art 35 GDPR (if relevant).

5. Animals

5.1 Ethics issues checklist

5 ANIMALS		YES/NO		Information to be provided in the proposal	Documents to be provided on request
Does your activity involve animals?		☐	☐	1) Details on the numbers of animals to be used, nature of the experiments, procedures and techniques to be used. 2) Details on species and rationale for their use. 3) Details on procedures to ensure animal welfare. 4) Details on implementation of the 3Rs Principle.	1) Copies of all appropriate authorisations for the supply of animals and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments.
If **YES:**	Are they vertebrates? *(n/a for DEP)*	☐	☐	Same information as above.	Same documents as above.
	Are they non-human primates (NHP) *(e.g. monkeys, chimpanzees, gorillas, etc.)*? *(n/a for DEP)*	☐	☐	Same information as above plus: 1) Justification on why NHPs are the only subjects suitable for achieving your scientific objectives. 2) Details on the purpose of the animal testing. 3) Details on the origin of the animals.	Same documents as above plus: 1) Personal history file of NHP *(See art 31 of Directive 2010/63)*.
	Are they genetically modified? *(n/a for DEP)*	☐	☐	1) Number of animals to be used, nature of the experiments, procedures, anticipated impact and how this will be minimised. 2) Details on species and rationale for their use.	1) Copies of all appropriate authorisations for the supply of animals and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments.

5 ANIMALS		YES/NO		Information to be provided in the proposal	Documents to be provided on request
				3) Details on procedures to ensure animal welfare. 4) Details on implementation of the 3Rs Principle.	
	Are they cloned farm animals? *(n/a for DEP)*	☐	☐	*Same information as above.*	1) Copies of all appropriate authorisations for the supply of animals and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments. 3) Copies of authorisations for cloning (if required).
	Are they an endangered species? *(n/a for DEP)*	☐	☐	1) Justification on why there is no alternative to using this species. 2) Details on the purpose of the activity.	1) Copies of authorisations for supply of endangered animal species (including CITES) and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments.

6. Non-EU countries

6.1 Ethics issues checklist

6 THIRD COUNTRIES	YES/ NO		Information to be provided in the proposal	Documents to be provided on request
Will some of the activities be carried out in non-EU countries? *Specify the countries*	☐	☐	1) Countries involved. 2) Risk-benefit analysis. 3) Details on activities are carried out in non-EU countries.	
In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues? *Specify the countries*	☐	☐	1) Details on the materials and the countries involved.	1) Copies of ethics approvals and other authorisations or notifications (if required). 2) Confirmation that the activity could have been legally carried out in an EU country (for instance, an opinion from an appropriate ethics structure in an EU country).
Is it planned to use local resources *(e.g. animal and/or human tissue samples, genetic material, live animals, human remain* *s, materials of historical value, endangered fauna or flora samples, etc.)***?**	☐	☐	1) Details on the type of local resources to be used and modalities for their use.	1) For human resources: copies of ethics approvals. 2) For animals, plants, micro-organisms and associated traditional knowledge: documentation showing compliance with the *UN Convention on Biological Diversity (e.g. access permit and benefit sharing agreement)*.
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? *(n/a for EDF)* *For data imports, see section 4.* *For imports of human cells or tissues, see section 3.*	☐	☐	1) Countries involved. 2) Details on the type of materials to be imported.	1) Copies of import licences/ Material Transfer Agreement (MTA).

6 THIRD COUNTRIES	YES/ NO		Information to be provided in the proposal	Documents to be provided on request
Specify the material and countries involved				
Is it planned to export any material (other than data) from the EU to non-EU countries? *(n/a for EDF)* *For data exports, see section 4.* *Specify the material and countries involved*	☐	☐	1) Countries involved. 2) Details of the type of materials to be exported.	1) Copies of export licences/ Material Transfer Agreement (MTA).
Does your activity involve low and/or lower-middle income countries? *(n/a for DEP)* *If yes, detail the benefit-sharing actions planned*	☐	☐	1) Details on the benefit sharing measures. 2) Details on the responsiveness to local needs. 3) Details on the procedures to facilitate effective capacity building.	
Could the situation in the country put the individuals taking part in the activity at risk? *(n/a for DEP)*	☐	☐	1) Details of the safety measures you intend to take, including training for staff and insurance cover.	1) Insurance coverage (if relevant)

7. Environment, health & safety

7.1 Ethics issues checklist

7 ENVIRONMENT, HEALTH AND SAFETY	YES	NO	Information to be provided in the proposal	Documents to be provided on request
Does this activity involve the use of substances or processes (or technologies) 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)? *For activities involving animal experiments, see section 5.*	☐	☐	1) Risk-benefit analysis. 2) Show how you apply the precautionary principle (if relevant). 3) Details on safety measures to be implemented.	1) Safety classification of laboratory. 2) Copy of GMO and other authorisations (if required).
Does this activity deal with endangered fauna and/or flora / protected areas? *(n/a for DEP)*	☐	☐	1) Details on endangered fauna and/or flora / protected areas.	1) Specific authorisations (if required).
Does this activity involve the use of substances or processes (or technologies) 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, or the deployment of the technology as a possible impact)? *For activities involving human participants, see section 2.*	☐	☐	1) Details of the health and safety procedures.	1) Safety classification of laboratory. 2) Host Institution safety procedures.

8. Artificial intelligence

8.1 Ethics issues checklist

8 ARTIFICIAL INTELLIGENCE	YES/NO		Information to be provided	Documents to be provided/kept on file
Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?	☐	☐	1) Explanation as to how the participants and/or end-users will be informed about: - their interaction with an AI system/technology (if relevant); - the abilities, limitations, risks and benefits of the proposed AI system/technique; - the manner in which decisions are taken and the logic behind them (if relevant). 2) Details on the measures taken to avoid bias in input data and algorithm design; 3) Explanation as to how the respect to fundamental human rights and freedoms (e.g. human autonomy, privacy and data protection) will be ensured; 4) Detailed explanation on the potential ethics risks and the risk mitigation measures.	1) Detailed risk assessment accompanied by a risk mitigation plan (if relevant). These must cover the development, deployment and post-deployment phases. 2) Copies of ethics approvals (if relevant).

8 ARTIFICIAL INTELLIGENCE	YES/NO		Information to be provided	Documents to be provided/kept on file
Could the AI based system/technique potentially stigmatise or discriminate against people *(e.g. based on sex, race, ethnic or social origin, age, genetic features, disability, sexual orientation, language, religion or belief, membership to a political group, or membership to a national minority)*? *(only HE, EDF)*	☐	☐	1) Detailed explanation of the measures set in place to avoid potential bias, discrimination and stigmatisation.	
Does the AI system/technique interact, replace or influence human decision-making processes *(e.g. issues affecting human life, health, well-being or human rights, or economic, social or political decisions)*? *(only HE, EDF)*	☐	☐	1) Detailed explanation on how humans will maintain meaningful control over the most important aspects of the decision-making process; 2) Explanation on how the presence/role of the AI will be made clear and explicit to the affected individuals.	1) Information sheets/Template Informed consent forms (if relevant)
Does the AI system/technique have the potential to lead to negative social *(e.g. on democracy, media, labour market, freedoms, educational choices, mass surveillance)* and/or environmental impacts either through intended applications or plausible alternative uses? *(only HE)*	☐	☐	1) Justification of the need for developing/using this particular technology 2) Assessment of the ethics risks and detailed description of the measures set in place to mitigate the potential negative impacts during the research, development, deployment and post-deployment phase.	For serious and/or complex cases: Algorithmic impact assessment/human right assessment. These must cover the development, deployment and post-deployment phases.
Does this activity involve the use of AI in a weapon system? *(only EDF)*	☐	☐		

8 ARTIFICIAL INTELLIGENCE		YES/NO		Information to be provided	Documents to be provided/kept on file
If YES:	Is it possible to establish which specific function/functions are automated/autonomous in the weapon system? *(only EDF)*	☐	☐	1) Justification for the need 2) Detailed explanation on how humans will maintain meaningful control	1) Detailed overview of the automated functions
	If the weapon system has AI-enabled functions, could these functions render the weapon system indiscriminate? *(only EDF)*	☐	☐	1) Justification for the need 2) Detailed explanation on how humans will maintain meaningful control	1) Description of the automated navigation and its ability to discriminate targets
	Does the design include the possibility of an autonomous mode for self-protection? If yes, can the system reliably distinguish between targets (threats) and non-targets? *(only EDF)*	☐	☐	1) Justification for the need 2) Detailed explanation on how humans will maintain meaningful control	1) Detailed explanation on how the potential ethics algorithmic assessment will work
Does the AI to be developed/used in the project raise any other ethical issues not covered by the questions above *(e.g., subliminal, covert or deceptive AI, AI that is used to stimulate addictive behaviours, life- like humanoid robots, etc.)? (only HE and EDF)*		☐	☐	1) Detailed explanation on how the potential ethics issues will be addressed and the measures set in place to mitigate ethics risks.	1) Detailed risk assessment accompanied by a risk mitigation plan. These must cover the development, deployment and post-deployment phases.

9. Other ethics issues

9.1 Ethics issues checklist

9 OTHER ETHICS ISSUES	YES/ NO		Information to be provided in the proposal	Documents to be provided on request
Are there any other ethics issues that should be taken into consideration? *Please specify*	☐	☐	1) Any relevant information.	1) Any relevant document.

Funded by the European Union