Ethics Issues Checklist

Postdoctoral Researchers International Mobility Experience (PRIME)

All research funded under PRIME must comply with the relevant national, EU, and international ethics-related rules and professional codes of conduct.

The following ethical issues are of special relevance:

- Human embryos & foetuses
- Human beings
- Human cells or tissues
- Personal data
- Animals
- Non-EU countries
- Environment, health & safety
- Dual use
- Exclusive focus on civil applications
- Potential misuse of research results
- Other ethics issues

In order to ensure that this is the case, it is mandatory for every PRIME applicant to fill in the Ethical Issues Table. We employ the same standard as operated by the EU under Horizon 2020. If necessary, please check the EU guideline on how to complete this ethics self-assessment.[1]

For those ethical issues which apply to your project please mark the YES column and enter the page(s) of the research proposal where the respective ethical issue is described.

Answering 'YES' to one or several boxes does not automatically result in a thorough ethical review, but in that case the PRIME committee will have to decide whether such a review is necessary and whether additional expertise is to be obtained.

- All research projects raising ethical issues will have to obtain approval from the relevant local/national ethical committee before the start of the research activities.[2]
- If the review and the discussion within the committee conclude that a violation of mandatory ethical standards does occur and cannot be prevented by minor changes of the experimental setup, the proposal will be rejected.
- If violations of the ethical principles have been identified but can easily be prevented by minor changes of the experimental setup or by not pursuing certain (non-essential) parts of the proposal, funding will be under the condition that these changes are implemented.
- If the ethical consequences of an otherwise positively reviewed project are not described adequately, the decision will be postponed until the requested clarification by the applicant is satisfactory.

[1] Horizon 2020 Programme, Guidance - How to complete your ethics self-assessment, Version 6.1, 4 February 2019.
[2] It is the institution where the research is conducted which must give the approval. For example, if a project involves animal research to be conducted both at a German university and a foreign institution, it is the ethical committee of the German university who has to give the ethical approval. For the outgoing phase, the national and EU ethical rules must be respected, whichever the stricter.

Ethics Issues Checklist

Section 1: Human Embryos/Foetuses		YES	NO	Page	Information to be provided	Documents to be provided/kept on file
Does your research involve Human Embryonic Stem Cells (hESCs)?		☐	☐			
If **YES**	Will they be directly derived from embryos within this project?	☐	☐		*Research not eligible for funding*	*Research not eligible for funding*
	Are they previously established cells lines?	☐	☐		Origin and line of cells. Details of licensing and control measures by the competent authorities of the Member States involved.	Copies of Ethics Approval. A statement that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hescreg.eu) — both for hESCs and human-induced pluripotent stem cell (hiPSC) lines. A statement confirming that the 6 specific conditions (see EU guideline) for research activities involving human embryonic stem cells are met.
Does your research involve the use of human embryos?		☐	☐		Origin of embryos. Details on recruitment, inclusion and exclusion criteria and informed consent procedures. Confirm that informed consent has been obtained.	Copies of ethics approval. Informed Consent Forms + Information Sheets.
If **YES**	Will the research lead to their destruction?	☐	☐		*Research not eligible for funding*	*Research not eligible for funding*
Does your research involve the use of human foetal tissues/cells?		☐	☐		Origin of human foetal tissues/cells. Details on informed consent procedures. Confirm that informed consent has been obtained.	Copies of ethics approval. Informed Consent Forms + Information Sheets.
Section 2: Humans		**YES**	**NO**	**Page**	**Information to be provided**	**Documents to be provided/kept on file**
Does your research involve human participants?		☐	☐		Confirm that informed consent has been obtained. **plus:**	Informed Consent Forms + Information Sheets. **plus:**
If **YES**	Are they volunteers for social or human sciences research?	☐	☐		Details of recruitment, inclusion and exclusion criteria and informed consent procedures.	Copies of ethics approvals (if required).

If **YES**	Are they persons unable to give informed consent (including children/minors)?	☐	☐		Details of your procedures for obtaining approval from the guardian/ legal representative and the agreement of the children or other minors. What steps will you take to ensure that participants are not subjected to any form of coercion?	Copies of ethics approvals.
	Are they vulnerable individuals or groups?	☐	☐		Details of the type of vulnerability. Details of recruitment, inclusion and exclusion criteria and informed consent procedures. These must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.	Copies of ethics approvals.
	Are they children/minors?	☐	☐		Details of the age range. What are your assent procedures and parental consent for children and other minors? What steps will you take to ensure the welfare of the child or other minor? What justification is there for involving minors?	Copies of ethics approvals.
	Are they patients?	☐	☐		What disease/condition /disability do they have? Details of recruitment, inclusion and exclusion criteria and informed consent procedures What is your policy on incidental findings?	Copies of ethics approvals.
	Are they healthy volunteers for medical studies?	☐	☐			Copies of ethics approvals.
Does your research involve physical interventions 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.)?	☐	☐		Risk assessment for each technique and overall.	Copies of ethics approvals.

	Does it involve collection of biological samples?	☐	☐		What type of samples will be collected? What are your procedures for collecting biological samples?	Copies of ethics approvals.
Section 3: Human Cells/Tissues		**YES**	**NO**	**Page**	**Information to be provided**	**Documents to be provided/kept on file**
Does your research involve human cells or tissues (other than from Human Embryos/Foetuses, see section 1)**?**		☐	☐		Details of the cells or tissue types. **plus:**	Copies of relevant ethics approvals. Copies of accreditation /designation/authorisation/ licensing for using, processing or collecting the human cells or tissues (if required), **plus:**
If **YES**	Are they available commercially?	☐	☐		Details of provider (company or other).	Copies of import licences (if relevant).
	Are they obtained within this project?	☐	☐		Details of the source of the material, the amount to be collected and the procedure for collection. Details of the duration of storage and what you will do with the material at the end of the research. Confirm that informed consent has been obtained.	Informed Consent Forms + Information Sheets.
	Are they obtained from another project, laboratory or institution?	☐	☐		Country where the material is stored. Details of the legislation under which material is stored. How long will the material be stored and what will you do with it at the end of the research project? Name of the laboratory/institution. Country where the laboratory/institution is located. Confirm that material is fully anonymised or that consent for secondary use has been obtained.	Copies of import licences (if relevant). Statement of laboratory/institution that informed consent has been obtained.
	Are they obtained from a biobank?	☐	☐		Name of the biobank. Country where the biobank is located. Details of the legislation under which material is stored. Confirm that material is fully anonymised or that consent for secondary use has been obtained.	Copies of import licences (if relevant). Statement of biobank that informed consent has been obtained.

Section 4: Personal Data		YES	NO	Page	Information to be provided	Documents to be provided/kept on file
Does your research involve personal data collection and/or processing?		☐	☐		Details of your procedures for data collection, storage, protection, retention, transfer, destruction or re-use (including, collection methodology (digital recording, picture, etc.), methods of storage and exchange (LAN, cloud, etc.), data structure and preservation (encryption, anonymisation, etc.), data-merging or exchange plan, commercial exploitation of data sets, etc.). Details of your data safety procedures (protective measures to avoid unforeseen usage or disclosure, including mosaic effect, i.e. obtaining identification by merging multiple sources). Confirm that informed consent has been obtained. Details of data transfers to non-EU countries (type of data transferred and country to which it is transferred). **plus:**	Copies of notifications/authorisations for collecting and/or processing the personal data (if required). Informed Consent Forms + Information Sheets + Other consent documents (opt-in processes, etc.) (if relevant). Copy of authorisation for data transfer to non-EU country (if required) **plus:**
If **YES**	Does it involve the collection or processing of sensitive personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	☐	☐			Copy of notification/authorisation for processing sensitive data (if required)
	Does it involve processing of genetic information?	☐	☐			
	Does it involve tracking or observation of participants (e.g. surveillance or localization data, and Wan data, such as IP address, MACs, cookies etc.)?	☐	☐		Details of methods used for tracking or observing participants.	Copy of notification/authorisation for tracking or observation (if required).

Does your research involve further processing of previously collected personal data ('secondary use') (including use of pre-existing data sets or sources, merging existing data sets, sharing data with non-EU member states)**?**		☐	☐		Details on the database used or of the source of the data. Details of your procedures for data processing. Details of your data safety procedures (protective measures to avoid unforeseen, usage or disclosure, including mosaic effect, i.e. obtaining identification by merging multiple sources). Confirm that data is openly and publicly accessible or that consent for secondary use has been obtained (and details of how this consent was obtained (automatic opt-in, etc.)). Confirm permissions by the owner/manager of the data sets.	Evidence of open public access (e.g. print screen from website). Informed Consent Forms + Information Sheets + other consent documents (opt in processes, etc.). Copies of permissions (if required).
Section 5: Animals		**YES**	**NO**	**Page**	**Information to be provided**	**Documents to be provided/kept on file**
Does your research involve animals?		☐	☐		Details of species and rationale for their use, numbers of animals to be used, nature of the experiments, procedures and techniques to be used. Justification of animal use (including the kind of animals to be used) and why alternatives cannot be used. **plus:**	
If **YES**	Are they vertebrates?	☐	☐			
	Are they non-human primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc.)?	☐	☐		Why are NHPs the only research subjects suitable for achieving your scientific objectives? Explain. What is the purpose of the animal testing? Give details. Where do the animals come from? Give details.	Personal history file of NHP.

If **YES**	Are they genetically modified?	☐	☐		Details of the phenotype and any inherent suffering expected. What scientific justification is there for producing such animals? Give details. What measures will you take to minimise suffering in breeding, maintaining the colony and using the GM animals? Give details.	Copies of GMO authorisations.
	Are they cloned farm animals?	☐	☐		Details of the phenotype and any inherent suffering expected. What scientific justification is there for producing such animals? Give details. What measures will you take to minimise suffering in breeding, maintaining the colony and using of the GM animals? Give details.	Copies of authorisations for cloning (if required).
	Are they an endangered species?	☐	☐		Why is there no alternative to using this species? Give details. What is the purpose of the research? Give details.	Copies of authorisations for supply of endangered animal species (including CITES).
Section 6: Third Countries		**YES**	**NO**	**Page**	**Information to be provided**	**Documents to be provided/kept on file**
In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues? Specify the countries involved:		☐	☐		Risk-benefit analysis. What activities are carried out in non-EU countries? Give details	Copies of ethics approvals and other authorisations or notifications (if required). Confirmation that the activity could have been legally carried out in an EU country (for instance, by submitting 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 remains, materials of historical value, endangered fauna or flora samples, etc.)**?**		☐	☐		What type of local resources will be used and how exactly? Give details.	For human resources: copies of ethics approvals. For animals, plants, micro-organisms and associated traditional knowledge: documentation demonstrating compliance with the UN Convention on Biological Diversity (e.g. access permit and benefit sharing agreement)

Is it planned to import any material – including personal data - from non-EU countries into the EU? For data imports, see section 4. For imports of human cells or tissues, see section 3.		☐	☐		What type of materials will you import? Give details.	Copies of import licences.
If **YES**	Specify the materials and countries involved:	☐	☐			
Is it planned to export any material – including personal data - from the EU to non-EU countries? For data exports, see section 4.		☐	☐		Details of type of materials to be exported.	Copies of export licences.
If **YES**	Specify material and countries involved:	☐	☐			
In case research involves low and/or lower-middle income countries, are any benefit-sharing actions planned?		☐	☐		Details of benefit sharing measures. Details of responsiveness to local research needs. Details of procedures to facilitate effective capacity building.	
Could the situation in the country put the individuals taking part in the research at risk?		☐	☐		Details of safety measures you intend to take, including training for staff and insurance cover.	
Section 7: Environment, Health & Safety		**YES**	**NO**	**Page**	**Information to be provided**	**Documents to be provided/kept on file**
Does your research involve the use of elements that may cause harm to the environment, to animals or plants? For research involving animal experiments, see section 5.		☐	☐		Risk-benefit analysis. Show how you apply the precautionary principle (if relevant). What safety measures will you take? Give details.	Safety classification of laboratory. Copy of GMO and other authorisations (if required). **plus:**
Does your research deal with endangered fauna and/or flora /protected areas?		☐	☐			Specific authorisations (if required).
Does your research involve the use of elements that may cause harm to humans, including research staff? For research involving human participants, see section 2.		☐	☐		Details of health and safety procedures you intend to apply.	Safety classification of laboratory.

Section 8: Dual Use	**YES**	**NO**	**Page**	**Information to be provided**	**Documents to be provided/kept on file**

Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?	☐	☐		What goods and information used and produced in your research will need export licences? How exactly will you ensure compliance? How exactly will you avoid negative implications?	Copies of export licences.
Section 9: Exclusive Focus on Civil Applications	**YES**	**NO**	**Page**	**Information to be provided**	**Documents to be provided/kept on file**
Could your research raise concerns regarding the exclusive focus on civil applications?	☐	☐		Explain the exclusive civilian focus of your research. Justify inclusion of military partners or military technologies (i.e. explain how they relate to civilian applications, e.g. in the context of law enforcement activities).	
Section 10: Misuse	**YES**	**NO**	**Page**	**Information to be provided**	**Documents to be provided/kept on file**
Does your research have a potential for misuse of research results?	☐	☐		Risk-assessment. **plus:** Details of the applicable legal requirements. Details of the measures you plan to take to prevent misuse.	Copies of authorisations (if required). Copies of security clearances (if applicable). Copies of ethics approvals (if applicable).
Section 11: Other Ethics Issues	**YES**	**NO**	**Page**	**Information to be provided**	**Documents to be provided/kept on file**
Are there any other ethics issues that should be taken into consideration? Please specify:	☐	☐		Any relevant information.	Any relevant document.

Name: _____ **Surname:** _____

Date: _____ **Signature:** _____