EUHUBS4DATA

ETHICS REQUIREMENTS FOR 2ND OPEN CALL

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Abstract:

Ethics requirements that Open call participants need to fulfil in case any 'yes' is declared in the Ethics Self-Assessment

Keywords:

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REVISION HISTORY

Revision	Date	Description	Author (Organisation)
V0.1	23.11.2021	First version of the document.	Lucas Sanjuán (ITI)
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1 INTRODUCTION

1.1 PURPOSE OF THE DOCUMENT

This document establishes the Ethics requirements that the participants un the EUHubs4Data open call must meet in function of their answers of the Open Call Ethics Self-Assessment. This document must be read and understood prior submission, so the participants understand and plan the efforts needed to meet ethics requirements for their proposed experiments.

1.2 SCOPE OF THE DOCUMENT

The document scope is the 2nd open call of the EUHubs4Data project and will appliable from ins publication to the end of the project.

1.3 STRUCTURE OF THE DOCUMENT

The document describes the ethics requirements divided in the following sections:

2.1 Section 1: HUMAN EMBRYOS/ FOETUSES

2.2 Section 2: HUMANS

2.3 Section 3: HUMANS CELLS / TISSUES

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2.7 Section 7: ENVIRONMENTAL & HEALTH AND SAFETY

2.8 Section 8: DUAL USE

2 ETHICS REQUIREMENTS

The following sections are extracted from Guidance How to complete your ethics self-assessment from the Horizon 2020 program, version 6.1, from February 4th 2019. [1]. Please refer to the mentioned document for any doubts.

2.1 SECTION 1: HUMAN EMBRYOS/FOETUSES

Section 1: HUMAN EMBRYOS/ FOETUSES		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 the licensing and control measures by the competent authorities of the Member States involved.	Copies of Ethics Approval. Declaration 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. Declaration confirming that the 6 specific conditions (see below) for research activities involving human embryonic stem cells are met.
Does your research involve the use of human embryos?		Origin of embryos. Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.	Copies of ethics approval. Informed Consent Forms + Information Sheets.

		Confirm that informed consent has been obtained.	
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 issues/cells. Details of the informed consent procedures. Confirm that informed consent has been obtained.	Copies of ethics approval. Informed Consent Forms + Information Sheets.

Table 1: Ethics requirements for human embryos & foetuses

2.2 SECTION 2: HUMANS

Section 2: HUMANS		Information to be provided	Documents to be provided/kept on file
Does your research involve human participants?		Confirm that informed consent has been obtained.	Informed Consent Forms + Information Sheets.
If YES:	- Are they volunteers for social or human sciences research?	1) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.	Copies of ethics approvals (if required).
	- Are they persons unable to give informed consent (including children/minors)?	Details of the 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 the 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.	Copies of ethics approvals.

		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?	
	- Are they patients?	What disease/condition /disability do they have? Details of the 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.

Table 2: Ethics requirements for humans.

2.3 SECTION 3: HUMAN CELLS/TISSUES

Section 3: HUMANS CELLS / TISSUES		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.	Copies of relevant ethics approvals. Copies of accreditation /designation/authorisation/ licensing for using, processing or collecting the human cells or tissues (if required).
If YES:	- Are they available commercially?	Details of the provider (company or other).	Copies of import licenses (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 hat will you do with it at the end of the research project? Name of the laboratory/institution. Country where the laboratory/institution is located.	Copies of import licenses (if relevant). Statement of laboratory/institution that informed consent has been obtained.

		Confirm that material is fully anonymised or that consent for secondary use 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 licenses (if relevant). Statement of biobank that informed consent has been obtained.

Table 3: Ethics requirements for human cells or tissues.

2.4 SECTION 4: PROTECTION OF PERSONAL DATA

Section 4: PROTECTION OF PERSONAL DATA	Information to be provided	Documents to be provided/kept on file
Does your research involve processing of personal data?	Details of the technical and organisational measures to safeguard the rights of the research participants.	Informed Consent Forms + Information Sheets used (if relevant).

	For instance: For organisations that must appoint a DPO under the GDPR: Involvement of the data protection officer (DPO) and disclosure of the contact details to the research participants. For all other organisations: Details of the data protection policy for the project (i.e. project-specific, not general). Details of the informed consent procedures. Details of the security measures to prevent unauthorised access to personal data. How is all of the processed data relevant and limited to the purposes of the project ('data minimisation' principle)? Explain. Details of the anonymisation /pseudonymisation techniques. Justification of why research data will not be anonymised/ pseudonymised (if relevant). Details of the data transfers (type of data transferred and country to which it is transferred – for both EU and non-EU countries).	

If YES:	- Does it involve the processing of special categories of personal data (*e.g. genetic, health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction*.)?	Justification for the processing of special categories of personal data. Why can the research objectives not be reached by processing anonymised/ pseudonymised data (if applicable)?	
	Does it involve processing of genetic, biometric or health data?		Declaration confirming compliance with the laws of the country where the data was collected
	Does it involve profiling, systematic monitoring of individuals or processing of large scale of special categories of data, intrusive methods of data processing (such as, tracking, surveillance, audio and video recording, geo-location tracking etc.) or any other data processing operation that may result in high risk to the rights and freedoms of the research participants?	1) Details of the methods used for tracking, surveillance or observation of participants. 2) Details of the methods used for profiling. 3) Risk assessment for the data processing activities. 4) How will harm be prevented and the rights of the research participants safeguarded? Explain. 5) Details on the procedures for informing the research participants about profiling, and its possible consequences and the protection measures.	Opinion of the data controller on the need for a data protection impact assessment (art.35 GDPR) (if relevant).
Does your research 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) How will the rights of the research participants be safeguarded? Explain.	Declaration confirming lawful basis for the data processing. Permission by the owner/manager of the data sets (e.g. social media databases) (if applicable).

	4) How is all of the processed data relevant and limited to the purposes of the project ('data minimisation' principle)? Explain. 5) Justification of why the research data will not be anonymised/ pseudonymised (if relevant).	Informed Consent Forms + Information Sheets + other consent documents (opt in processes, etc.). (if applicable).
Does your research involve publicly available data?	1) Confirm that the data used in the project is publicly available and can be freely used for the project.	1) Permission by the owner/manager of the data sets (e.g. social media databases) (if applicable).
Is it planned to export personal data from the EU to non-EU countries? *Specify the type of personal data and countries involved*	Details of the types of personal data to be exported. How will the rights of the research participants be safeguarded? Explain.	1) Declaration of confirming compliance with Chapter V of the GDPR.
Is it planned to import personal data from non-EU countries into the EU? *Specify the type of personal data and countries involved*	1) Details of the types of personal data to be imported.	1) Declaration confirming compliance with the laws of the country in which the data was collected.

Table 4: Ethics requirements for protection of personal data

2.5 SECTION 5: ANIMALS

Section 5: ANIMALS		Information to be provided	Documents to be provided/kept on file
Does your research involve animals?		Details of the 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.	
If YES:	- Are they vertebrates?		
	- Are they nonhuman 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.
	- 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).

Table 5: Ethics requirements for animals

2.6 SECTION 6: THIRD COUNTRIES

Section 6: THIRD COUNTRIES	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, 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 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.

Is it planned to export any material from the EU to non-EU countries? For data exports, see section 4.	Details of the type of materials to be exported.	Copies of export licences.
In case research involves low and/or lower-middle income countries, are any benefit-sharing actions planned?	Details of the benefit sharing measures. Details of the responsiveness to local research needs. Details of the procedures to facilitate effective capacity building.	
Could the situation in the country put the individuals taking part in the research at risk?	Details of the safety measures you intend to take, including training for staff and insurance cover.	

Table 6: Ethics requirements for third countries.

2.7 SECTION 7: ENVIRONMENTAL & HEALTH AND SAFETY

Section 7: ENVIRONMENT & HEALTH AND SAFETY	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).
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 the health and safety procedures.	Safety classification of laboratory.

Table 7: Ethics requirements environmental & Health and safety

2.8 SECTION 8: DUAL USE

Section 8: DUAL USE	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.

Table 8: Ethics requirements for dual use

3 REFERENCES AND ACRONYMS

3.1 REFERENCES

[1] European commission, “European Commission,” 4 February 2019. [Online]. Available: https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf.

3.2 ACRONYMS

Acronyms List	
WP	Work Packages
hESC	Human Embryonic Stem Cells
hiPSC	Human-induced Pluripotent Stem Cells
NHP	Nonhuman Primates

Table 9 – Acronyms