**HRC Living Lab Grants 2021**

***Hidden Rivers as social, spatial and ecological continuities in the Lausanne-Morges Agglomeration***
Ethics Issues Form – Deadline 01.09.2021 (12:00 CET)

This ethics issues form[[1]](#footnote-1) will help to identify any ethics issues that may arise from your proposed project and will help to clarify which ethical authorizations need to be obtained.

Please indicate below if your project involves any of the following ethics issues. If yes, then please provide more details in the ethics self-assessment at the end of this form.

|  |
| --- |
| **Project title/Acronym:** |
|  |
|  **Name of the Two PIs of the project:** |
|  |
|  |

|  |  |  |
| --- | --- | --- |
| **Research on Human Embryonic Stem Cells and Human Embryos** | **Yes** | **No** |
| Does the proposed research involve human embryos? | [ ]  | [ ]  |
| Does the proposed research involve human Embryonic Stem Cells (hESCs)? | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
| **Research on Humans** | **Yes** | **No** |
| Does this activity involve human participants? | [ ]  | [ ]  |
| Are they adult healthy volunteers? | [ ]  | [ ]  |
| Are they patients? | [ ]  | [ ]  |
| Are they potentially vulnerable individuals or groups? | [ ]  | [ ]  |
| Are they children/minors? | [ ]  | [ ]  |
| Are they other persons unable to give informed consent? | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
| **Collection / use of biological material** | **Yes** | **No** |
| Does this project involve the collection and/or use of human cells/tissues or other biological material? | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
| **Personal data** | **Yes** | **No** |
| Does this activity involve processing of personal data[[2]](#footnote-2)? | [ ]  | [ ]  |
| Does this activity involve further processing of previously collected personal data (including use of pre-existing data sets or sources, merging existing data sets)? | [ ]  | [ ]  |
| Is any data transfer (to/from Switzerland to/from another country) planned? (If yes, specify the type of personal data, the provider and countries involved in the self-assessment below). | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
| **Artificial intelligence** | **Yes** | **No** |
| Does this activity involve the development, deployment and/or use of Artificial Intelligence? (If yes, detail in the self-assessment below whether that could raise ethical concerns related to human rights and values and explain how this will be addressed in the project). | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
| **Research on Animals** | **Yes** | **No** |
| Does this activity involve research on animals? (If yes, specify in the assessment which type and quantity.) | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
| **Research Involving Developing Countries**  | **Yes** | **No** |
| Will some of the activities be carried out in low and/or lower middle-income countries? (If yes, indicate which country and describe the benefit sharing actions in the self-assessment). | [ ]  | [ ]  |
| In case other countries are involved, do the activities undertaken in these countries raise potential ethics issues? | [ ]  | [ ]  |
| Does the proposed research involve the use of 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.)?  | [ ]  | [ ]  |
| Does the proposed project involve any import/export to/from Switzerland of any material? (If yes, describe in the self-assessment.) | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
| **Environment, Health and Safety**  | **Yes** | **No** |
| Does this activity involve the use of substances or processes that may have a negative impact on the environment, animals or plants? (During the implementation of the activity or as a possible impact)? | [ ]  | [ ]  |
| Does this activity deal with endangered fauna and/or flora / protected areas? | [ ]  | [ ]  |
| Does this activity involve the use of substances or processes that may have a negative impact on humans, including those performing the activity? (During the implementation of the activity or as a possible impact)? | [ ]  | [ ]  |
| Do you plan to do field work outside the EPFL campus? (If yes, describe where/what in the self-assessment below.) | [ ]  | [ ]  |

Pag

|  |  |  |
| --- | --- | --- |
| **Dual Use** | **Yes** | **No** |
| Does your proposed research have direct military use? | [ ]  | [ ]  |

e

|  |  |  |
| --- | --- | --- |
| **Other ethics issues**  | **Yes** | **No** |
| Are there any other ethics issues that should be taken into consideration? (If yes, describe in the ethics self-assessment below.) | [ ]  | [ ]  |

|  |
| --- |
| **Ethics self-assessment**  |
| If you have confirmed in the table above that your project involves any ethical issues, please give a more detailed description below. Please provide more details about the ethical issues, how you will address them, the protocol (i.e. interviews, measurements, environmental impact), and any ethics authorizations that you have obtained/will obtain. |
|  |

**Ethics Guidance**

‘HRC Living lab grants’ 2021 applicants who intend to perform research that poses ethical concerns must declare this in this ethics self-assessment form.

* **Research on humans**

All research involving human subjects must be conducted in accordance with the three fundamental guiding ethical principles: respect for persons, beneficence, and justice.

Research projects involving human beings and/or health-related data that fall within the scope of the **Federal Act on Research Involving Human Beings** (Human Research Act, HRA) must be submitted for approval to the cantonal ethics committee (either the ‘**Commission cantonale d’éthique de la recherche sur l’être humain (CER-VD**)’ of the canton of Vaud or the ‘**Commission cantonale d’éthique de la recherche (CCER)’** of the canton of Geneva).

For more information, please see the CER-VD web-site (<http://www.cer-vd.ch/>) or the CCER web-site (<https://www.ge.ch/obtenir-autorisation-recherche-medicale-etre-humain>).

Projects that do not fall within the Human Research Act but that do involve human participants and/or personal data need to be submitted to the **EPFL Human Research Ethics Committee** at EPFL (HREC). For more information on the HREC, please see: (<https://www.epfl.ch/research/ethic-statement/human-research-ethics-committee/>)

For guidance and support on where you would need to submit your project proposal, please contact research@epfl.ch (Research Office/Ethics Affairs team).

* **Personal data**

Research that involves collecting / processing personal data, regardless of the method through which data is/was collected, must comply with the law on privacy and data protection.

The **Swiss Federal Act on Data Protection** (FADP, RS 235.1) entered into force on 19th June 1992 (and is currently under revision). At European Union (EU) level, the **General Data Protection Regulation** (GDPR) is directly applicable in Switzerland subject to certain conditions (Art. 13 GDPR) since 25 May 2018.

The Swiss FADP defines **personal data** as “all information relating to an identified or identifiable person” (art. 3). (Examples are: name, address, e-mail, birth-date, body characteristics, information related to usage of internet-supported services, i.e. social networks.)

**Sensitive personal data** is defined as data on:

1. religious, ideological, political or trade union-related views or activities,

2. health, the intimate sphere or the racial origin,

3. social security measures,

4. administrative or criminal proceedings and sanctions.

Projects that involve the collection/processing of personal data need to be submitted to the EPFL HREC. For some projects, a Data Transfer Agreement or Data Processing Agreement might be needed.

* **Research involving animals**

Animal experiments must be justified on the basis of the 3Rs principles of replacement, refinement, and reduction.

Research projects involving animal experiments are regulated by the **Federal Law on the Protection of Animals** (455) and the Ordinance on the Protection of Animals (455.1). Animal experiments need to be authorised by the **Cantonal Veterinary Office**. At the institutional level, research projects involving animals must be submitted to EPFL’s **Centre for PhenoGenomics**, which provides advice and support for the implementation of research projects involving animal experiments.

The **EPFL Animal Research Ethics Committee (AREC)** performs an ethical review of animal experiments conducted by EPFL researchers abroad. The Committee is competent to approve or refuse, from a point of view of ethical acceptability, the research projects involving animals that are implemented abroad. In addition to the AREC review, such projects also need to be authorised by the relevant country’s competent authority on animal research.

For more information about the AREC, please see: <https://www.epfl.ch/research/ethic-statement/animal-research-ethics-committee/>

**In principle, no authorization is required for experiments with invertebrates (with the exception of Decapods and Cephalopods) and insects. In these cases, please always verify with the EPFL Center for PhenoGenomics whether an authorization is needed or not.**

* **GMO’s**

The **use of GMOs and/or alien organisms (vertebrates and invertebrates) that are: (1) genetically modified and/or, (2) alien organisms (i.e. not present in the natural fauna, for example the ‘rusty crayfish’), is regulated by the Ordinance on Handling Organisms in Contained Systems (OUC in French). If a researcher plans to use such organisms, this must be declared separately to the Federal Coordination Centre for Biotechnology (FCCB). At EPFL, the EPFL the DSPS Biosafety team can provide support.**

* **Research in collaboration with developing countries**

When research or part of it is implemented in developing countries and/or by partners from developing countries or when the results can be potentially applied in these countries, the researchers need to describe the arrangements for: (a) sharing the benefits and allocation of the **intellectual property rights,** (b) the contribution to the **capacity building** in the developing countries

Researchers implementing projects in developing countries with the involvement of human participants must obtain a local ethics authorizations. In addition, an HREC authorization may be required.

The regulations on Access and Benefit-sharing (ABS) of the Convention on Biological Diversity (CBD) and the Nagoya Protocol (NP) apply to all types of (industrial, academic) research that make use of **genetic resources of plant, animal bacterial or other origin and/or of traditional knowledge associated to these resources**.”

For more information, please contact the Swiss National Focal Point to the Nagoya Protocol.

Federal Office for the Environment (FOEN), e-mail: contact.np@bafu.admin.ch

* **Dual-purpose assets and technology and weapon-related assets and technology**

By virtue of the Swiss federal law concerning dual-purpose assets (LCB) and its ordinance (OCB): i) the export of dual-purpose assets, components, software, technology, and information is subject to the authorisation of the **Secretary of State for the Economy (SECO)**, ii) the export of assets, components, software, technology, and information which are known to be or could be used for the development, production, or use of nuclear, biological, or chemical weapons (ABC weapons) or for vector systems (missiles, rockets, drones, etc.) to be used as ABC weapons must be declared beforehand to the SECO. At EPFL, the transfer of knowledge, software, demonstrators, or prototypes which can fall within the scope of this legislation can occur in the context of technology transfer or research proposals, but also in informal personal contacts. Professors and staff members at EPFL must comply with the LCB and OCB in their proposals/contracts and in their contacts with foreign companies.

In case of doubt, please contact the VPA Legal Affairs Team via research@epfl.ch.

1. This form is based on the EU ethics self-assessment form. [↑](#footnote-ref-1)
2. The Swiss Federal Act on Data Protection (FADP) defines personal data (in art. 2) as “all information relating to an identified or identifiable person”. [↑](#footnote-ref-2)