Ethics Self-Assessment Form for applying to HAIF

One of the main objectives of the University of Turku is to promote ethically conducted research that complies with the methods and principles endorsed by the scientific community. The University of Turku follows the guidance of ALLEA (All European Academies) for the European Code of Conduct for Research Integrity. Like all universities in Finland, the University of Turku is committed to the ethical guidelines of the Finnish National Board on Research Integrity (TENK). **All research undertaken as part of HAIF activities will comply with legal and ethical requirements at both national and European levels, including the EU's AI Act, which aims to ensure that AI systems are developed and used responsibly.** The University of Turku has [guidelines on using artificial intelligence in research](https://utuguides.fi/artificialintelligence). These guidelines follow the responsible conduct of research principles set by TENK and the requirements for processing personal data stated in the EU General Data Protection Regulation. Researchers at the University of Turku must also comply with Finnish legislation and the Charter of Fundamental Rights of the European Union. More on the ethical values of the University of Turku can be read here: <https://www.utu.fi/en/fairutu>.

To ensure that the legal and ethical prerequisites of the research proposal are fulfilled, the ethics self-assessment following the [guidelines by European commission](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf) is evaluated in evaluation stage II. Scientific integrity and research ethics will also be covered as part of the interview stage of the selection and evaluation process. Selected doctoral researchers are expected to discuss the initial ethics self-assessment with their supervisors to identify best practices and potential next steps for ensuring the ethical code of conduct in doctoral research. The final research plan will include a section on research ethics to document the key takeaways from these discussions.

***How to fill in the HAIF ethics self-assessment:***

* STEP 1: fill in the checklist to identify the potential ethical considerations in your planned research. Read and follow the instructions from the [European Commission guidelines](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf) when filling out this self-assessment.
* STEP 2: If your answer to any of the categories is “YES”, please address required information from the EU guidelines “Information to be provided” in the text box below the table.

*E.g. if you have marked “YES” for “Will some of the activities be carried out in non-EU countries”, write the answers to: “1) Countries involved”; “2) Risk-benefit analysis”; 3) “Details on activities are carried out in non-EU countries” using these subheadings.*

* STEP 3: Add your name, the date and your location. Sign the form.

Please note the EU guidance from the guidelines: “In case it is not possible to identify the potential risks at this stage, describe the procedure you intend to use to detect, assess and address potential ethics issues (or explain why such a procedure is not needed).”

**Ethics issues checklist:**

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| **1 HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS** | | YES | NO |
| Does your activity involve Human Embryonic Stem Cells (hESCs)? | |  |  |
| If YES: | Will they be directly derived from embryos within this project? |  |  |
| Are they previously established cells lines? Are the cell lines registered in the European registry for human embryonic stem cell lines? |  |  |
| Does your activity involve the use of human embryos? | |  |  |
| If YES: | Will the activity lead to their destruction? |  |  |
| Does your activity involve the use of other human embryonic or foetal tissues / cells? | |  |  |

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| If you chose “YES” for any of the above, briefly outline here the answers to “Information to be provided in the proposal” (page 6 in the EU guidelines). Copy the numbered sections from the guidelines to use as subheadings. |
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| **2 HUMANS** | | YES | NO |
| Does your activity involve human participants? | |  |  |
| If YES: | Are they volunteers? |  |  |
| Are they healthy volunteers for medical studies? |  |  |
| Are they patients for medical studies? |  |  |
| Are they potentially vulnerable individuals or groups? |  |  |
| Are they children/minors? |  |  |
| Are there other persons unable to give informed consent? |  |  |
| 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.)? |  |  |
| Does it involve collection of biological samples? |  |  |
| 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)? | |  |  |
| If YES: | Is it a clinical trial? |  |  |
| Is it a low-intervention clinical trial? |  |  |

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| If you chose “YES” for any of the above, briefly outline here the answers to “Information to be provided in the proposal” (page 11-14 in the EU guidelines). Copy the numbered sections from the guidelines to use as subheadings. |
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| **3 HUMAN CELLS OR TISSUES** | | YES | NO |
| Does your activity involve the use of human cells or tissues (other than those covered by section 1)? | |  |  |
| If YES: | Are they human embryonic or foetal cells or tissues? |  |  |
| Are they available commercially? |  |  |
| Are they obtained within this project? |  |  |
| Are they obtained from another project, laboratory or institution? |  |  |
| Are they obtained from a biobank? |  |  |

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| If you chose “YES” for any of the above, briefly outline here the answers to “Information to be provided in the proposal” (page 18-19 in the EU guidelines). Copy the numbered sections from the guidelines to use as subheadings. |
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| **4 PROTECTION OF PERSONAL DATA** | | | YES | NO |
| Does your activity involve processing of personal data? | | |  |  |
| 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)? | |  |  |
|  | If YES: | Does it involve processing of genetic, biometric or health data? |  |  |
|  | 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.)? | |  |  |
| Does your activity involve further processing of previously collected personal data (including use of pre-existing data sets or sources, merging existing data sets)? | | |  |  |
| 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 | | |  |  |
| 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 | | |  |  |
| Does your activity involve the processing of personal data related to criminal convictions or offences? | | |  |  |

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| If you chose “YES” for any of the above, briefly outline here the answers to “Information to be provided in the proposal” (page 22-25 in the EU guidelines). Copy the numbered sections from the guidelines to use as subheadings. |
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| **5 ANIMALS** | | YES | NO |
| Does your activity involve animals? | |  |  |
| If YES: | Are they vertebrates? |  |  |
|  | Are they non-human primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc.)? |  |  |
|  | Are they genetically modified? |  |  |
|  | Are they cloned farm animals? |  |  |
|  | Are they an endangered species? |  |  |

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| If you chose “YES” for any of the above, briefly outline here the answers to “Information to be provided in the proposal” (page 28-29 in the EU guidelines). Copy the numbered sections from the guidelines to use as subheadings. |
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| **6 NON-EU COUNTRIES** | YES | NO |
| Will some of the activities be carried out in non-EU countries? Specify the countries |  |  |
| In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues? Specify the countries |  |  |
| 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.)? |  |  |
| 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? For data imports, see section 4. For imports of human cells or tissues, see section 3. Specify the material and countries involved |  |  |
| Is it planned to export any material (other than data) from the EU to non-EU countries? For data exports, see section 4. Specify the material and countries involved |  |  |
| Does your activity involve low and/or lower-middle income countries? If yes, detail the benefit-sharing actions planned |  |  |
| Could the situation in the country put the individuals taking part in the activity at risk? |  |  |

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| If you chose “YES” for any of the above, briefly outline here the answers to “Information to be provided in the proposal” (page 32-33 in the EU guidelines). Copy the numbered sections from the guidelines to use as subheadings. |
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| **7 ENVIRONMENT, HEALTH AND SAFETY** | YES | NO |
| 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. |  |  |
| Does this activity deal with endangered fauna and/or flora / protected areas? |  |  |
| 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. |  |  |

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| If you chose “YES” for any of the above, briefly outline here the answers to “Information to be provided in the proposal” (pages 36-37 in the EU guidelines). Copy the numbered sections from the guidelines to use as subheadings. |
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| **8 ARTIFICIAL INTELLIGENCE** | YES | NO |
| Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems? |  |  |
| 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)? |  |  |
| 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)? |  |  |
| 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? |  |  |
| 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.)? |  |  |

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| If you chose “YES” for any of the above, briefly outline here the answers to “Information to be provided in the proposal” (pages 42-44 in the EU guidelines). Copy the numbered sections from the guidelines to use as subheadings. |
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| **9 OTHER ETHICS ISSUES** | YES | NO |
| Are there any other ethics issues that should be taken into consideration? Please specify |  |  |

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| If you chose “YES” for any of the above, briefly outline here the answers to “Information to be provided in the proposal” (page 47 in the EU guidelines). Copy the numbered sections from the guidelines to use as subheadings. |
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I confirm I have read the [European Commission’s guidelines for how to fill in the ethics self-assessment](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf), I have declared any potential ethical concerns in my research project, and have described how these are addressed in my research project as outlined in the European Commission’s self-assessment guidelines:

Applicant signature:

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Applicant name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place and date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_