 Attachment 4

# SCIENTIA FELLOWS II – Ethics attachment

*Please save the filled in document with your surname in the file name, e.g. SURNAME\_Att.4*

Scientia Fellows aims to secure high ethical standards and the Programme adheres to the European Commission’s ethical principles of Horizon 2020. All research projects in the programme must abide with EU and national/local ethics regulations of the Host organizations, both for outgoing and incoming mobility. The Ethics Issues table (attachment 4) is an integral part of applications. With the assistance of the Host, an Applicant should identify and abide by any appropriate national regulations concerning ethical issues in research. Applicants and Hosts are responsible to request all necessary ethics approvals for the research projects. If a proposal raises any ethical issues, the applicant has to present a plan and expected timing for obtaining any required permissions or documentation.

Projects may not start before the necessary ethics approvals are in place.

Research areas excluded from funding:

• Research activities aiming at human cloning for reproductive purposes.

• Research activities intended to modify the genetic heritage of human beings, which could make such changes heritable.

• Research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer

For guidance on ethics issues in Horizon 2020-funding, see:

"How to complete your ethics self-assessment"

<http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf>

## ETHICS SELF-ASSESSMENT – PART A – ETHICS ISSUES TABLE

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Human embryo/foetus | | YES | NO |
| Does the proposed research involve human embryos? | |  |  |
| Does the proposed research involve human foetal tissue/cells? | |  |  |
| Does the proposed research involve human embryonic stem cells (hESCs)? | |  |  |
|  | Are the hESCs previously established cells lines? |  |  |
|  | Will the hESCs be directly derived from embryos within this project? |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL | |  |  |

*Please note: Research projects that plan to use Human embryonic stem cells must obtain an approval of The Regional Committees for Medical and Health Research Ethics in Norway (REC). Scientia Fellows projects cannot start before they have gone through EC ethics review and obtained an approval in writing from the Research Executive Agency (REA).*

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| 2. Human cells/tissues | | YES | NO |
| Does your research involve human cells or tissues (*other than from Human Embryos/ Foetuses, see section 1*)? | |  |  |
|  | Are they available commercially? |  |  |
|  | Are they obtained within this project? |  |  |
|  | Are they obtained within another project, lab or institution? |  |  |
|  | Are they deposited in a biobank? |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL | |  |  |

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| --- | --- | --- | --- |
| 3. Humans | | YES | NO |
| Does your research involve human participants? | |  |  |
|  | Are they volunteers for social or human sciences research? |  |  |
|  | Are they persons unable to give informed consent (including children/minors)? |  |  |
|  | Are they vulnerable individuals or groups? |  |  |
|  | Are they children/minors? |  |  |
|  | Are they patients? |  |  |
|  | Are they healthy volunteers for medical studies? |  |  |
| Does your research involve physical interventions on the study participants? | |  |  |
|  | 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 human biological samples or the use of already collected samples? |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL | |  |  |

*Please give details regarding informed consent that has been obtained or will be obtained in Part B. For research involving processing of genetic information, see also section 4.*

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| 4. Personal data | | YES | NO |
| Does your research involve processing of personal data? | |  |  |
|  | Does it involve the processing of special categories of personal data (*e.g. genetic, health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction*)? |  |  |
|  | Does it involve processing of genetic, biometric or health data? |  |  |
|  | Are the data anonymized? |  |  |
|  | Are the data de-identified? |  |  |
|  | Are the data pesudonymized? |  |  |
|  | Are the data identifiable? |  |  |
| 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, geolocation tracking etc.) or any other data processing operation that may result in high risk to the rights and freedoms of the research participants*? | |  |  |
|  | Is the profiling, systematic monitoring of individuals or processing of large scale of special categories of data, intrusive methods of data processing done manually or via artificial intelligence? |  |  |
|  | Does the project have a Data protection impact assessment (DPIA), or is a DPIA planned? |  |  |
| Does your research involve further processing of previously collected personal data (*including use of preexisting data sets or sources, merging existing data sets*)? | |  |  |
| Does your research involve publicly available data? | |  |  |
| Is it planned to import personal data from non-EU countries into the EU? | |  |  |
| CLICK TO ENTER TEXT – specify the countries involved | | | |
| Is it planned to export personalata from the EU to non-EU countries? | |  |  |
| CLICK TO ENTER TEXT – specify the countries involved | | | |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL | |  |  |

*Norway is considered an EU country with regards to the import/export of research/personal data.*

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| 5. Animals | | YES | NO |
| Does your research involve animals? | |  |  |
|  | Are they vertebrates? |  |  |
|  | Are they non-human primates? |  |  |
|  | Are they genetically modified? |  |  |
|  | Are they cloned farm animals? |  |  |
|  | Are they endangered species? |  |  |
|  | CLICK TO ENTER TEXT - Please indicate the endangered species involved | | |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL | |  |  |

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| 6. Third countries | YES | NO |
| In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues? |  |  |
| CLICK TO ENTER TEXT – specify the countries involved | | |
| 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.)? |  |  |
| Do you plan to import any material from non-EU countries into the EU?  *For data imports, please fill in also section 4.*  *For imports concerning human cells or tissues, fill in also section 3.* |  |  |
| CLICK TO ENTER TEXT – specify material and countries involved | | |
| Do you plan to export any material from the EU to non-EU countries?  *For data exports, please fill in also section 4.*  *For exports concerning human cells or tissues, fill in also section 3.* |  |  |
| CLICK TO ENTER TEXT – specify material and countries involved | | |
| If your research involves low and/or lower middle income countries, are benefits-sharing actions planned? |  |  |
| Could the situation in the country put the individuals taking part in the research at risk? |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |

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| 7. Environment, health and safety | YES | NO |
| Does your research involve the use of elements that may cause harm to the environment, to animals or plants?  *For research involving animal experiments, please fill in also section 5.* |  |  |
| Does your research deal with endangered fauna and/or flora and/or protected areas? |  |  |
| Does your research involve the use of elements that may cause harm to humans, including research staff?  *For research involving human participants, please fill in also section 2.* |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |

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| 8. Dual use | YES | NO |
| Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required? |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |

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| 9. Exclusive focus on civil applications | YES | NO |
| Could your research raise concerns regarding the exclusive focus on civil applications? |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |

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| 10. Misuse | YES | NO |
| Does your research have a potential for misuse of research results? |  |  |
| Are there any other ethics issues that should be taken into consideration? |  |  |
| CLICK TO ENTER TEXT – please specify additional ethics issues |  |  |

## ETHICS SELF-ASSESSMENT – PART B – ADDITIONAL INFORMATION

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| **If you have identified ethical issues in the Ethical Issues Table - Part A, you may fill in this part. For further guidance, see the document:** [How to complete your ethics self-assessment](http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf)" |
| The description must:  a) describe how the proposal meets the national legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out;  b) explain in detail how you intend to address the issues in the ethical issues table, in particular as regards:   * + research objectives (e.g. study of vulnerable populations, dual use, etc.)   + research methodology (e.g. clinical trials, involvement of children and related consent procedures, protection of any data collected, etc.)   + the potential impact of the research (e.g. dual use issues, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing, misuse, etc.).   c) provide the documents that you need under national law (if you already have them), e.g.:   * + an ethics committee opinion;   + the document notifying activities raising ethical issues or authorising such activities   If these documents are not in English, you must also submit an English summary of them (containing, if available, the conclusions of the committee or authority concerned). If you plan to request these documents specifically for the project you are proposing, your request must contain an explicit reference to the project title. |