**ETHICS FORM**

Every applicant will be required to complete an initial ethics review (a self-assessment checklist) as part of the application process. The questions in this form are based on the Horizon 2020 Programme Guidance for completion of ethics self-assessment, covering key areas of:

(1) Human embryos and foetuses

(2) Human beings

(3) Human cells or tissues

(4) Personal data

(5) Animals

(6) Non-EU countries

(7) Environment, health & safety

(8) Dual use

(9) Exclusive focus on civil applications

(10) Potential misuse of research results and

(11) Other ethics issues

While respecting that the scope of the research is not yet known it is expected that no research under this programme will required detailed ethics considerations for items (1), (3) or (5), but these will remain included in the checklist for applicants to make a full declaration. The answer to questions should be “no” for section 1, 3 5 for valid proposals.

**Please respond to every question below.**

|  |  |  |
| --- | --- | --- |
|  | yes | no |
| Section 1: HUMAN EMBRYOS/ FOETUSES | | |
| 1. Does your research involve Human Embryonic Stem Cells (hESCs)? *Must be “no” for valid proposals.* |  |  |
|  | yes | no |
| Section 2: HUMANS | | |
| 1. Does your research involve human participants? *If yes, please answer the following questions.* |  |  |
| * 1. Are they volunteers for social or human sciences research? |  |  |
| * 1. Are they persons unable to give informed consent (including children/minors)? |  |  |
| * 1. Are they vulnerable individuals or groups? |  |  |
| * 1. Are they children/minors? |  |  |
| * 1. Are they patients? |  |  |
| * 1. Are they healthy volunteers for medical studies? |  |  |
| 1. Does your research involve physical interventions on the study participants? *If yes, please answer the following questions.* |  |  |
| * 1. Does it involve invasive techniques (e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)? |  |  |
| * 1. Does it involve collection of biological samples? |  |  |
|  |  |  |
|  |  |  |
|  | yes | no |
| Section 3: HUMAN CELLS / TISSUES | | |
| 1. Does your research involve human cells or tissues (other than from Human Embryos/Foetuses, see section 1)? *Must be “no” for valid proposals.* |  |  |
|  | yes | no |
| Section 4: PROTECTION OF PERSONAL DATA | | |
| 1. Does your research involve processing of personal data? *If yes, please answer the following questions.* |  |  |
| * 1. Does it involve the processing of special categories of personal data (e.g. genetic, health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.)? |  |  |
| * 1. Does it involve processing of genetic, biometric or health data? |  |  |
| * 1. 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? |  |  |
| 1. 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. Does your research involve publicly available data? |  |  |
| 1. Is it planned to export personal data from the EU to non-EU countries?   Specify the type of personal data and countries involved:  Click or tap here to enter text. |  |  |
| 1. Is it planned to import personal data from non-EU countries into the EU?   Specify the type of personal data and countries involved  Click or tap here to enter text. |  |  |
|  | yes | no |
| Section 5: ANIMALS | | |
| 1. Does your research involve animals? *Must be “no” for valid proposals.* |  |  |
|  | yes | no |
| Section 6: NON-EU COUNTRIES | | |
| 1. In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?   Specify the countries involved:  Click or tap here to enter text. |  |  |
| 1. 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.) |  |  |
| 1. 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.   If yes, specify the materials and countries involved:  Click or tap here to enter text. |  |  |
| 1. Is it planned to export any material from the EU to non-EU countries? For data exports, see section 4.   If yes, specify the material and countries involved:  Click or tap here to enter text. |  |  |
| 1. In case research involves low and/or lower-middle income countries, are any benefit sharing actions planned? |  |  |
| 1. Could the situation in the country put the individuals taking part in the research at risk? |  |  |
|  | yes | no |
| Section 7: ENVIRONMENT & HEALTH AND SAFETY | | |
| 1. 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. |  |  |
| 1. Does your research deal with endangered fauna and/or flora /protected areas? |  |  |
| 1. 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. |  |  |
|  | yes | no |
| Section 8: DUAL USE | | |
| 1. Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required |  |  |
|  | yes | no |
| Section 9: EXCLUSIVE FOCUS ON CIVIL APPLICATIONS | | |
| 1. Could your research raise concerns regarding the exclusive focus on civil applications? |  |  |
|  | yes | no |
| Section 10: MISUSE | | |
| 1. Does your research have a potential for misuse of research results? |  |  |
|  | yes | no |
| Section 11: OTHER ETHICS ISSUES | | |
| 1. Are there any other ethics issues that should be taken into consideration?   If yes, please specify:  Click or tap here to enter text. |  |  |