RESEARCH ETHICS SELF-ASSESMENT QUESTIONAIRE

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| **Section 1: HUMAN EMBRYOS/ FOETUSES** | | | YES/NO | | Page | | Information to be provided | | Documents to be provided | |
| **Does your research involve Human Embryonic Stem Cells (hESCs)?** | | |  |  | |  | |  | |  | |
| If  **YES:** | - Will they be directly derived from embryos within this project? | |  |  | |  | | *Research cannot be funded.* | | *Research cannot be funded.* | |
| - Are these previously established cells lines? | |  |  | |  | | Origin and line of cells.  Details on licensing and control measures by the competent authorities of the Member States involved. | | Copies of Ethics  Approval.   * A statement that the human embryonic stem cell lines used in the project are registered in the European hESC registry ([www.hescreg.eu](http://www.hescreg.eu) ) — both for hESCs and human-induced pluripotent stem cell (hiPSC) lines. | |
| **Does your research involve the use of human embryos?** | | |  |  | |  | | Origin of embryos.  Details on  recruitment, inclusion and exclusion criteria and informed consent procedures.   * Confirm that informed consent has been obtained. | | Copies of Ethics  Approval.  Informed Consent Forms   * + Information Sheets. | |
| If  **YES:** | | Will embrios be destroyed during the research project |  |  | |  | | The Project cannot receive the ethics research approval | | The Project cannot receive the ethics research approval | |
| **Does your research involve the use of human fetal tissues /**  **cells?** | | |  |  | |  | | Origin of human fetal tissues/cells.  Details on informed consent procedures.   * Confirm that informed consent has been obtained. | | Copies of Ethics  Approval.  Informed Consent Forms   * + Information Sheets. | |

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| **Section 2: HUMANS** | | YES/ NO | | Pa ge | Information to be provided | Documents to be provided |
| **Does your research involve human**  **participants?** | |  |  |  | Confirm that informed consent has been obtained.  **plus:** | Informed Consent Forms + Information Sheets (see text box below).  **plus:** |
| If  **YES:** | - Are they volunteers for social or human sciences research? |  |  |  | Details on 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 on your procedures to obtain approval from guardian/ legal representative.  Details on the measures you intend to take to ensure that there is no coercion on participants. | Copies of Ethics  Approvals. |
| - Are they vulnerable individuals or groups? |  |  |  | Details on the type of vulnerability.  Details on 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 on the age range.  Details on your children/minors assent procedures and parental consent.   * Details on the measures you intend to take to ensure welfare of the child/minor. | Copies of Ethics Approvals. |
| - Are they patients? |  |  |  | Details on the nature of disease/condition/disability.  Details on recruitment, inclusion and exclusion criteria and informed consent procedures   * Details on your policy for incidental findings. | Copies of Ethics  Approvals. |
| Are they healthy volunteers for medical studies? |  |  |  |  | Copies of Ethics  Approvals. |
| **Does your research also 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 as a whole | Copies of Ethics  Approvals. |
| - Does it involve collection of biological samples? |  |  |  | Details on the type of samples to be collected.  Details on your procedures for collection of biological samples. | Copies of Ethics  Approvals. |
| *For research involving processing of genetic information, see also section 4.* | | | | | | |

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| **Section 3: HUMAN CELLS / TISSUES** | | YES/ NO | | Pa ge | Information to be provided | Documents to be provided |
| Does your research Involve human cells or tissues (other than from Human Embryos/Foetuses, *see section 1*)? | |  |  |  | Details of the cells/  tissue types.  **plus:** | Copies of relevant  Ethics Approvals.  Copies of accreditation/designation/authorization/ licensing for using, processing or collecting the human cells or tissues (if required),  **plus:** |
| If  **YES:** | Are these commercially available? |  |  |  | Details for the source (firm, etc.) | Licenses (if necessary, in copy) |
| - Are they produced or collected by you as part of this project? |  |  |  | Details on the source of the material, the amount to be  collected and the  procedure for collection.  Details on 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. |
| - Do the originate from another laboratory/institution/bio bank |  |  |  | Name of the laboratory/institution/biobank.  Country in which the laboratory/institution/biobank is located.  Details of the legislation under which material is stored.   * Confirm that material is fully anonymized or that consent for secondary use has been obtained. | Copies of import licenses (if relevant).  Statement of laboratory/institution  /biobank that   * informed consent has been obtained. |
| - Were they produced or collected by you from previous research activities? |  |  |  | Country in which the material is stored.  Details on the legislation under which material is  stored.   * Details on the duration of storage and what you will do with the material at the end of the research. project. |  |

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| **Section 4: PROTECTION OF PERSONAL DATA** | | YES/NO | | Pa ge | Information to be provided | Documents to be provided |
| **ATTENTION! (GDPR)!** | | | | | | |
| **Does your research involve personal data collection and/or processing?** | |  |  |  | Details on your procedures for data collection, storage,  protection, retention,  transfer, destruction or re-use (including, collection methodology (digital recording, picture, etc.), methods of storage and exchange (LAN, cloud, etc.), data structure and preservation (encryption, anonymization, etc.), data-merging or exchange plan, commercial exploitation of data sets, etc.).  Details on your data safety procedures (protective measures to avoid unforeseen, usage or disclosure, including mosaic effect, i.e. obtaining identification by merging multiple sources).  Confirm that informed consent has been obtained.  Details on data transfers to third countries (type of data transferred and country to which it is transferred; for US/Canada: information if  recipient is ‘safe harbor recipient’).  **plus:** | Copies of notifications/authorizations for the  collection and/or  processing of the personal data (if required).  Informed Consent Forms + Information Sheets + Other consent documents (opt in processes, etc.) (if relevant).  Copy of authorization for  data transfer to third country (if required)  For US/Canada: print-out from [safe harbor list](https://safeharbor.export.gov/list.aspx)  **plus:** |
| If **YES:** | - Does it involve the collection or processing  of sensitive personal data  *(e.g. health, sexual lifestyle, ethnicity,*  *political opinion, religious*  *or philosophical conviction)*? |  |  |  |  | Copy of notification/authorization for processing of sensitive data (if required) |
| Does it involve processing of genetic information? |  |  |  |  |  |
| - Does it involve tracking or observation of participants *(e.g.*  *surveillance or*  *localization data, and Wan data, such as IP address, MACs, cookies etc.)?* |  |  |  | Details on methods used for tracking or observing  participants. | Copy of notification/authorization for tracking or  observation (if  required) |
| **Does your research involve further processing of previously collected personal data**  **(‘secondary use’)** *(including use of*  *pre-existing data sets or sources, merging existing data sets, sharing data with non-EU member states)***?** | |  |  |  | Details on the database used or of the source of the data.  Details on your procedures for data processing.  Details on your data safety procedures (protective measures to avoid unforeseen, usage or disclosure, including mosaic effect, i.e. obtaining identification by merging multiple sources).  Confirm that data is openly and publicly accessible or that consent for secondary use has been obtained (and details on how this consent was obtained (automatic opt in, etc.)).  Confirm permissions by the  owner/manager of the data sets. | Evidence of open public access *(e.g. print screen from website)*.  Informed Consent Forms + Information Sheets + other consent documents (opt in processes, etc.).  Copies of permissions (if required). |

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| **Section 5: ANIMALS** | | YES/  NO | | Pa ge | Information to be provided | Documents to be provided |
| **Does your research involve animals?** | |  |  |  | Details on 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.  **plus:** |  |
| **Does your research involve research procedures that may**  **cause pain, suffering, distress or lasting harm to live non-human**  **vertebrate animals** *(including*  *independently feeding larval forms, fetal forms of mammals in the last trimester of their normal development and cephalopods)***?** | |  |  |  | Details on implementation of the  Three Rs  (Replacement, Reduction and Refinement).  Details on measures you intend to apply to ensure animal welfare during their lifetime and during the experiment and how its impact will be minimized.  Details on fate of animals (method of killing with minimum pain, suffering, distress).  Details on severity classification and justification.  **plus:** | Copies of authorizations for  the supply of animals and the animal  experiments.  Copies of training certificates/ personnel licenses of the staff involved in animal experiments.  Personal history file of cats, dogs  **plus:** |
| If  **YES:** | - Are they vertebrates or live cephalopods? |  |  |  |  |  |
| - Are they non-human primates (NHP) (e.g. monkeys, chimpanzees,  gorillas, etc)? |  |  |  | Explanation why NHPs are the only suitable research  subjects to achieve  the scientific objectives.  Details on the  purpose of the animal testing.   * Details on provenance of the animals. | Personal history file of NHP |
| - Are they genetically modified? |  |  |  | Details of the phenotype and any  inherent suffering expected.  Details on scientific justification for producing such animals.   * Details on measures you intend to apply to minimize suffering in the breeding, maintenance of the colony and use of the GM animals. | Copies of GMO  authorizations. |
| - Are they cloned farm animals? |  |  |  | Details of the phenotype and any inherent suffering expected.  Details on scientific justification for producing such animals.   * Details on measures you intend to apply to minimize suffering in the breeding, maintenance of the colony and use of the GM animals. | Copies of authorizations for cloning (if required). |
| - Are they from an endangered species? |  |  |  | Details on why there  is no alternative to the use of this species.   * Details on the purpose of the research. | Copies of authorizations for supply of endangered animal species (including CITES). |

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| **Section 6: THIRD COUNTRIES** | | | | YES/ NO | | Pa ge | Information to be provided | Documents to be provided |
| **Does your research involve third countries?** | | | |  |  |  | Risk-benefit analysis.  **plus:** |  |
| **If YES:** | | |  |  |  |  | Details on activities  carried out in non-EU   * countries. | Copies of Ethics  Approvals and other Authorizations or Notifications (if required).  Confirmation that the activity could have been legally carried out in an EU Member States (for instance, by submitting an  ‘opinion’ of an appropriate ethics structure in an EU Member State). |
| **Do you plan 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, traditional knowledge, etc.)***?** | | | |  |  |  | Details on type of local resources to be used and modalities for their use. | 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*](http://www.cbd.int/) (e.g. access permit and benefit sharing agreement) |
| **Do you plan to import any material**  **from third countries into the EU?**  *For data imports, see section 4.*  *For imports of human cells or tissues, see section 3.* | | | |  |  |  | Details on type of  materials to be imported. | Copies of import  licenses. |
| If  **YES:** | | *Specify the materials and*  *countries involved* | |  |  |  |  |  |
| **Do you plan to export any material from the EU to third countries?**  *For data exports, see section 4.* | | | |  |  |  | Details on type of  materials to be exported. | Copies of export  licenses. |
| If  **YES**: | *Specify material and*  *countries involved:* | | |  |  |  |  |  |
| **If your research involves low and/or**  **lower-middle income countries, are any benefit-sharing actions planned?** | | | |  |  |  | Details on benefit sharing measures.  Details on responsiveness to local research needs.   * Details on procedures to facilitate effective capacity building. |  |
| **Could the situation in the country put the individuals taking part in the research at risk?** | | | |  |  |  | Details on safety   * measures you intend to apply, including personnel training and insurance cover. |  |

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| **Section 7: ENVIRONMENT & HEALTH AND SAFETY** | YES/NO | | Pa ge | Information to be provided | Documents to be provided |
| **Does your research involve the use of elements that may cause harm to humans, including**  **research staff?** |  |  |  | Details on health and safety procedures you   * intend to apply. | Safety classification of laboratory.  **plus:** |
| **Does your research involve the use of elements that may cause harm to the environment, animals or plants?**  *For research involving animal experiments, see section 5.* |  |  |  | Risk-benefit analysis.  Show how you apply the precautionary principle (if relevant).  Details on safety measures you intend to apply.   * **plus:** | Safety classification of  laboratory.  Copy of GMO and other authorizations (if required)  **plus:** |
| **Does your research deal with endangered fauna and/or flora /protected areas?** |  |  |  |  | Specific authorizations  (if required). |

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| **Section 8: DUAL USE** | YES/NO | | Pa ge | Information to be provided | Documents to be provided |
| **Does your research have the potential for dual use?**  Vezi  <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32009R0428> |  |  |  | 1. Name the gods and products used in your research Project that are susceptible of dual use. 2. How will you conform to the applicable law? 3. How will you avoid the negative effects of pt. 1? | Copies of export licenses. (if available) |
| **Does your research have the potential for malevolent or criminal or terrorist abuse?** |  |  |  | * Risk assessment. * Details on applicable law. * What measures will you take to avoid dual use. | * Security or other authorizations (if available) |

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| **Section 9: conflicts of interest** | YES/ NO | | Pa ge | Information to be provided |
| Please signal any case in which a researcher/member of the research team has any interest other than a scientific/philosophic/cultural one in the implementation of the research project submitted for ethics approval or in the results thereof. Conflicts of interest arise also when the interest pertains to a relative/ kin of the researcher/research team member up to and including the IVth degree of kinship. The conflict of interest does not arise in the due management of the project, performed with the strict conformity of the applicable law and financial norms, done within the confines of the program or financial grant in which the project is included |  |  |  | Details. |

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| **Section 10: OTHER ETHICS ISSUES** | YES/ NO | | Pa ge | Information to be provided | Documents to be provided |
| Are there any other ethics issues that should be taken into consideration?  *Please specify:* |  |  |  | Any relevant information. | Any relevant document. |

Signatures of the research team members

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| NAME, SURNAME | SIGNATURE |
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