FCT Fundação para a Ciência e a Tecnologia

ETHICS SELF-ASSESSMENT GUIDE

Scientific Research and Technological Development Projects

REPÚBLICA PORTUGUESA

ETHICS ISSUES

Ethics issues and how they are addressed in the research process should be clearly stated in the proposal (under Ethics Issues). Some ethics issues may require specific information (see footnotes).

Some ethics issues require specific documents (e.g., approvals) that should be collected by the Principal Investigator and the host institution. Please refer to footnotes.
Upon approval, these documents may be requested by FCT.

Evaluators will be asked to signal unidentified ethics issues.

Please self-assess the ethics issues of your research project using the questions provided below.

ETHICS ISSUE 1: HUMAN EMBRYOS/FOETUS

1. Does this research involve Human Embryonic Stem Cells (hESCs)?
   - **1.1** If yes, will they be directly derived from embryos within this project? [1]
   - **1.2** If yes, are they previously established cells lines? [2]
2. Does this research involve the use of human embryos?
   - **2.1** If yes, will the research lead to their destruction? [1]
3. Does this research involve the use of human foetal tissues/cells? [3]

ETHICS ISSUE 2: HUMANS

1. Does this research involve human participants?
   - **1.1** If yes, are they volunteers for social or human sciences research? [4]
   - **1.2** If yes, are they persons unable to give informed consent? [4,5]
   - **1.3** If yes, are they vulnerable individuals or groups (children, patients, discriminated people, minorities, persons unable to give consent, people of dissenting, immigrant or minority communities, sex workers, etc.)? [4,6]
   - **1.4** If yes, are they children/minors? [4,7]
   - **1.5** If yes, are they patients? [4]
   - **1.6** If yes, are they healthy volunteers for medical studies? [4]
2. Does this research involve physical interventions on the study participants?
   - **2.1** If yes, does it involve invasive techniques? [8]

ETHICS ISSUE 3: HUMANS CELLS/TISSUES

1. Does this research involve human cells or tissues? (other than from Human Embryos/Foetuses, see section 1)
   - **1.1** If yes, are they available commercially? [9, 10]
   - **1.2** If yes, are they obtained within this project? [9, 11]
   - **1.3** If yes, are they obtained from another project, laboratory or institution? [9, 12]
   - **1.4** If yes, are they obtained from biobank? [9, 13]

ETHICS ISSUE 4: PROTECTION OF PERSONAL DATA

1. Does this research involve personal data collection and/or processing?
   - **1.1** If yes, does it involve the collection and/or processing of sensitive personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)? [14]
   - **1.2** If yes, does it involve processing of genetic information? [14]
   - **1.3** If yes, does it involve tracking or observation of participants? [14]
2. Does this research involve further processing of previously collected personal data (secondary use)? [15]

ETHICS ISSUE 5: ANIMALS

1. Does this research involve animals?
   - **1.1** If yes, are they vertebrates? [16]
   - **1.2** If yes, are they non-human primates (NHPs)? [16, 17]
   - **1.3** If yes, are they genetically modified? [16, 18]
   - **1.4** If yes, are they cloned farm animals? [16, 19]
   - **1.5** If yes, re they endangered species? [16, 20]

ETHICS ISSUE 6: THIRD COUNTRIES

1. In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues? [21]
2. 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.)? [22]
3. Is it planned to import any material – including personal data – from non-EU countries into the EU? [23]
4. Is it planned to export any material, including personal data –from the EU to non-EU countries? [23]
5. In case the research involves low and/or lower-middle income countries, are any benefit-sharing actions planned? [24]
6. Could the situation in the country put the individuals taking part in the research at risk? [25]

ETHICS ISSUE 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? [26]
2. Does your research deal with endangered fauna and/or flora/protected areas? [27]
3. Does your research involve the use of elements that may cause harm to humans, including research staff? [28]

ETHICS ISSUE 8: DUAL USE

1. Does this research involve dual-use items (goods, software, technology that can be used for both civilian and military applications and/or can contribute to the proliferation of weapons of mass destruction) in the sense of Regulation 428 / 2009, or other items for which an authorisation is required? [29]

ETHICS ISSUE 9: EXCLUSIVE FOCUS ON CIVIL APPLICATIONS

1. Could your research raise concerns regarding the exclusive focus on civil applications? [30]

ETHICS ISSUE 10: MISUSE

1. Does your research have a potential for misuse (potential for malevolent/criminal/terrorist abuse) of research results? [31]

INFORMATION AND DOCUMENTS TO BE PROVIDED FOR SPECIFIC ETHICS ISSSUES

Please refer to the Ethics Self-Assessment list

- **INFORMATION should be provided in the application form (under Ethics Issues)**
- **DOCUMENTS should be provided if required by FCT (only in the case of funded projects)**

ETHICS ISSUE 1: HUMAN EMBRYOS/FOETUS

[1] INFORMATION TO BE PROVIDED: demonstrate that the project serves important research aims to advance scientific knowledge, the origin of the embryos and the justification to use embryos and not validated appropriate alternatives.
DOCUMENTS TO BE PROVIDED: Approval of Comissão Nacional de Procriação Medicamente Assistida.

[2] INFORMATION TO BE PROVIDED: the origin of the cell lines and, if commercially available, details on the provider.

[3] INFORMATION TO BE PROVIDED: origin of human foetal tissues/cells. For commercial available tissues/cells, see [10]; for cells that will be obtained within this project, see [11]; for previous collected cells, see [12]; for biobanked cells, see [13].

ETHICS ISSUE 2: HUMANS

[4] INFORMATION TO BE PROVIDED: recruitment criteria (e.g. detail information on the participants, number of participants, inclusion/exclusion criteria, direct/indirect incentives for participation, the risks and benefits for the participants).
DOCUMENTS TO BE PROVIDED: informed consent procedures and Informed Consent Forms and Information Sheets (incidental/ unexpected findings policy should be included); Copies of Ethics Approvals.

[5] INFORMATION TO BE PROVIDED: justification for the participation of adults unable to give informed consent; details of the procedures for the consent of the legal representative.

[6] INFORMATION TO BE PROVIDED: details on the recruitment and inclusion/exclusion criteria and the measures to prevent the risk of enhancing vulnerability/stigmatization of individuals/groups.

[7] INFORMATION TO BE PROVIDED: justification for the participation of children, the assent procedures for children and the procedures for obtaining the consent from the guardian/legal representative.

[8] INFORMATION TO BE PROVIDED: Details on the risk of the procedures.

ETHICS ISSUE 3: HUMANS CELLS/TISSUES

[9] INFORMATION TO BE PROVIDED: Details on the cells or tissue types.

[10] INFORMATION TO BE PROVIDED: Details of provider.

[11] INFORMATION TO BE PROVIDED: source and amount of the material and the procedures for collection. Details on the storage and destination, reuse of the material at the end of the research.
INFORMATION TO BE PROVIDED (if the material will be collected only for the propose of the project) further information must be provided: recruitment criteria (e.g. detail information on the participants, number of participants, inclusion/exclusion criteria, direct/indirect incentives for participation, the risks and benefits for the participants).
DOCUMENTS TO BE PROVIDED: informed consent procedures and Informed Consent Forms and Information Sheets (incidental/unexpected findings policy should be included); Copies of Ethics Approvals.

[12] INFORMATION TO BE PROVIDED: Confirmation that the material is full anonymised or that consent for secondary use has been obtained. DOCUMENTS TO BE PROVIDED: Copies of authorisations for using/processing the cells or tissues.

ETHICS ISSUE 4: PROTECTION OF PERSONAL DATA

[13] INFORMATION TO BE PROVIDED: Details on the biobank (name and country), Confirmation that the material is fully anonymised or that consent for secondary use has been obtained. DOCUMENTS TO BE PROVIDED: Copies of authorisations for using/processing the cells or tissues.

[14] INFORMATION TO BE PROVIDED: Details of 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, anonymisation, etc.), data merging or exchange plan, commercial exploitation of data sets, etc.). Details of data safety procedures (protective measures to avoid unforeseen usage or disclosure). DOCUMENTS TO BE PROVIDED: Copies of notifications/authorisations for collecting and/or processing the personal data (CNPN – Comissão Nacional de Proteção de Dados)

[15] INFORMATION TO BE PROVIDED: Details on the database used or of the source of the data. Details of procedures for data processing. Details of data safety procedures.
Confirmation that data is openly and publicly accessible or that consent for secondary use has been obtained.
Permissions by the owner/manager of the data sets. DOCUMENTS TO BE PROVIDED (if the data is not full anonymised): Copies of notifications/authorisations for collecting and/or processing the personal data (CNPN – Comissão Nacional de Proteção de Dados).

ETHICS ISSUE 5: ANIMALS

[16] INFORMATION TO BE PROVIDED: Justification of animal use (including the kind of animals to be used) and why alternatives cannot be used. Details of species and rationale for their use, numbers of animals to be used, nature of the experiments, procedures and techniques to be used. Details on how the Principle of the Three Rs will be applied. DOCUMENTS TO BE PROVIDED: Copies of relevant authorisations (for breeders, suppliers, users, and facilities) for animal experiments. Copy of project authorisation (covering also the work with genetically-modified animals). Copies of training certificates/personal licenses of the staff involved.

[17] INFORMATION TO BE PROVIDED: Detailed justification for the use of NHPs and details on the provenience of the animals. DOCUMENTS TO BE PROVIDED: Personal history file of NHP.

[18] DOCUMENTS TO BE PROVIDED: Copies of GMO authorisations.

[19] DOCUMENTS TO BE PROVIDED: Copies of authorisations for cloning (if required).

[20] DOCUMENTS TO BE PROVIDED: Copies of authorisations for supply of endangered animal species (including CITES)

ETHICS ISSUE 6: THIRD COUNTRIES

[21] INFORMATION TO BE PROVIDED: Risk-benefit analysis (if applied). DOCUMENTS TO BE PROVIDED: Copies of ethics approvals and other authorisations or notifications (if required). Confirmation that the activity could have been legally carried out in an EU country (for instance, by submitting an opinion from an appropriate ethics structure in an EU country).

[22] INFORMATION TO BE PROVIDED: Details of the resources. DOCUMENTS TO BE PROVIDED: For human resources: copies of Ethics Approvals. For animals, plants, microorganisms and associated traditional knowledge: documentation demonstrating compliance with the UN Convention on Biological Diversity (e.g. access permit and benefit sharing agreement).

[23] INFORMATION TO BE PROVIDED: Details on the materials to import/export. DOCUMENTS TO BE PROVIDED: Copies of import/export licences.

[24] INFORMATION TO BE PROVIDED: Details of benefit sharing and capacity building.

[25] INFORMATION TO BE PROVIDED: Details on safety measures

ETHICS ISSUE 7: ENVIRONMENT & HEALTH AND SAFETY

[26] INFORMATION TO BE PROVIDED: Details on safety measures. DOCUMENTS TO BE PROVIDED: Safety classification of laboratory. Copy of GMO authorisations (if required).

[27] DOCUMENTS TO BE PROVIDED: Specific authorisations (if required).

[28] INFORMATION TO BE PROVIDED: Details on health and safety procedures. DOCUMENTS TO BE PROVIDED: Safety classification of laboratory.

ETHICS ISSUE 8: DUAL USE

[29] INFORMATION TO BE PROVIDED: Details on potential dual use implications of the project and risk-mitigation strategies. DOCUMENTS TO BE PROVIDED: Copies of export licences.

ETHICS ISSUE 9: EXCLUSIVE FOCUS ON CIVIL APPLICATIONS

[30] INFORMATION TO BE PROVIDED: Explanation of the exclusive civilian focus of research. Justification for the inclusion of military partners or military technologies.

ETHICS ISSUE 10: MISUSE

[31] INFORMATION TO BE PROVIDED: Details on potential misuses and details on measures to prevent abuse of research findings.
DOCUMENTS TO BE PROVIDED: Copies of authorisations (if required). Copies of security clearances (if applicable). Copies of ethics approvals (if applicable).