ETHICAL ISSUES

Ethics is central to scientific integrity, honesty and clarity of science. It is considered essential by the FCT in the research activities that it funds; this means that in any proposal submitted to the programme, ethics issues must be identified and addressed. Proposals that pose ethics concerns will be flagged. If some aspects are incomplete, clarification may be sought, but this will cause delays in the application process.

Considering ethics issues from the concept stage of a proposal enhances the quality of research. Applicants must take time to consider the benefit/burden balance of each work package, not only in terms of scientific advancement, but also in terms of human dignity and social and cultural impact; consider elements such as the ethics and social impact of the research and whether there is a balance between the objectives and the means.

Ethics Procedures

- Together with the project proposal the applicant must identify the ethical issues of the project (see table below) and must include all relevant information.
- Whenever proposals involve ethical issues, a mandatory Statement on Ethics will be requested. A declaration duly signed by the host institution and the beneficiary, regarding the acknowledgement and observance of ethics under national rules together with ethical approvals (if applicable) will be a prerequisite to the contract celebration.
- Ethical or legal (data protection) approvals by the competent local/national Ethics Committees (Ethical Committees of the Hospitals, Universities or Research Institutions and data protection authority, respectively) must be submitted to the FCT prior to the commencement of the relevant part of the research. Originals or certified copies of ethical approvals by the competent local/national ethical bodies, together with copies of relevant authorizations for animal experiments must be forwarded to the FCT prior to the commencement of the research.

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- FCT will carry out pre-ethical screening of the proposals. Proposals selected for funding and in the reserve list that raise ethical issues will go through an ethics screening and, in case more information is required, a full ethics review will take place.

In order to write their applications, applicants must take into account a number of ethical issues:

Applicants must describe any ethical issues that may arise in the proposal. In particular, they must explain the benefit and burden of the experiments and the effects these may have on the research subject.

The following special issues must be taken into account:

Research in Humans

1. The procedures that will be used for the recruitment of participants (e.g. number of participants, inclusion/exclusion criteria, direct/indirect incentives for participation, the risks and benefits for the participants, etc.) and the nature of the material that will be collected (e.g. human biological samples, sensitive or personal data, etc.). It must be explicitly stated if children or adults unable to give informed consent will be involved and, if so, justification for their participation must be provided.

2. Detailed information must be provided on the informed consent procedures that will be implemented. Copies of examples of Informed Consent Forms and Information Sheets must be included (uploaded in pdf format in annexes). These must be in language and terms understandable to the participants. Participants must have the right:

    - To know that participation is voluntary
    - To ask questions and receive understandable answers before making a decision
    - To know the degree of risk and burden involved in participation
    - To know who will benefit from participation

- To know the procedures that will be implemented in the case of incidental findings
- To receive assurances that appropriate insurance cover is in place
- To withdraw themselves, their samples and data from the project at any time
- To know how their biological samples and data will be collected, protected during the project and destroyed at the end
- To know of any potential commercial exploitation of the research.

Obtaining consent and assent in research involving children

3. Before seeking consent and assent to involve children in research, it must be demonstrated that comparable research cannot be done with adults to the same effect and scientific impact.

   Once it has been determined that the research should be permissible, researchers must obtain parental/guardian consent for all children.

4. Detailed information must be provided on the source of the human biological samples and personal data and whether or not ethical approval has been obtained to cover their use in the present study.

5. The applicant must confirm that all the human samples used in this project are either legitimately available commercially or have been obtained following appropriate ethical approval.

6. Detailed information must be provided on privacy/confidentiality and the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation.

Human embryonic stem cells

Research proposals that will involve human embryonic stem cells (hESC) or surplus embryos will have to have the approval of Comissão Nacional de Procriação Medicamente Assistida and address all the following specific points:

7. the applicants must demonstrate that the project serves important research aims to advance scientific knowledge in basic research or to increase medical knowledge for the development of diagnostic, preventive or therapeutic methods to be applied to humans;

8. the necessity to use hESC in order to achieve the scientific objectives set forth in the proposal. In particular, applicants must document that appropriate validated alternatives (in particular, stem cells from other sources or origins) are not suitable and/or available to achieve the expected goals of the proposal. This latter provision does not apply to research comparing hESC with other human stem cells.

Research involving animals

9. Detailed information must be provided on why living animals have to be used and why that species has been chosen. In addition, information must be given on the numbers of animals to be used in experiments, the nature of the experiments, the procedures that will be carried out and their anticipated impact (e.g. potential for pain, suffering, distress and lasting harm) and how that has been minimised. Furthermore, details must be provided on what procedures have been implemented to ensure the welfare of the animals during their lives (e.g. husbandry, minimising harms, criteria for humane endpoints, inspection protocols). The applicant must provide evidence of awareness of relevant European legislation and regulations covering animal experimentation and that the Principle of the Three Rs will be rigorously applied.

Research with developing countries

10. The applicant must provide detailed information to confirm that fair benefit sharing arrangements with stakeholders from Developing Countries will be effectively managed during the project and that procedures will be implemented to facilitate effective capacity building;

11. The issues at stake when conducting research in Third Countries are linked with applying the same criteria to other cultures. This implies that you take into account the wide disparities in health systems, the burden of disease, the level of literacy and the scientific and ethics infrastructures.

Regarding the List of questions concerning ethical issues below, if you answer YES to any question, you need to address it in the Statement on ethical and legal questions in the section on Ethical Issues of the application form. Not all issues necessarily imply ethics review. It enables the independent experts to decide if an ethics review is required. If you are sure that none of the issues apply to your proposal, simply do not complete the Statement on ethical and legal questions.

Any ethics review will be performed solely on the basis of the information available in the proposal. ***In some cases*** additional information will be sought for clarification. Projects raising specific ethical issues such as research intervention on human beings; research on human embryos and human embryonic stem cells and non-human primates are automatically submitted for ethics review.

For more information

- Ethics Review guidance: http://cordis.europa.eu/fp7/dc/index.cfm
- Ethics Review: http://cordis.europa.eu/fp7/ethics_en.html
- Research on Animals: http://www.nc3rs.org.uk/category.asp?catID=3
- Research on Animals: http://www.vet.uu.nl/nca/links/databases_of_3r_models

Questions concerning ethical issues

Please mark with "x" the appropriated answer.

The use of human embryonic stem cells (hESC)	**Yes**	**No**
Does the proposed research involve human Embryos?		
Does the proposed research involve human Foetal Tissues/ Cells?		
Does the proposed research involve hESC?		
Does the proposed research on involve hESC in culture?		
Does the proposed research on hESC involve the derivation of cells from Embryos?		

Research on human beings	**Yes**	**No**
Does the proposed research involve children?		
Does the proposed research involve patients?		
Does the proposed research involve persons not able to give consent?		
Does the proposed research involve adult healthy volunteers?		
Does the proposed research involve Human genetic material?		
Does the proposed research involve Human biological samples?		
Does the proposed research involve Human data collection?		

Privacy and human data collection	**Yes**	**No**
Does the proposed research involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?		
Does the proposed research involve tracking the location or observation of people?		

Research on animals	**Yes**	**No**
Does the proposed research involve research on animals?		

Are those animals transgenic small laboratory animals?		
Are those animals transgenic farm animals?		
Are those animals non-human primates?		
Are those animals cloned farm animals?		

Research in developing countries	**Yes**	**No**
Does the proposed research involve the use of local resources (genetic, animal, plant, etc)?		
Is the proposed research of benefit to local communities (e.g. capacity building, access to healthcare, education, etc		