INVESTIGADOR FCT

2015 FCT INVESTIGATOR GRANTS

GUIDE ON ETHICAL ISSUES

FCT Fundação para a Ciência e a Tecnologia
MINISTÉRIO DA EDUCAÇÃO E CIÊNCIA

GUIDE ON 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 application submitted, ethical issues should be identified and addressed. Applications that pose ethical concerns will be flagged. If some aspects are incomplete, clarification will be sought.

Considering ethical issues from the concept stage of an application enhances the quality of research. Applicants should 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; elements such as the ethics and social impact of the research and whether there is a balance between the objectives and the means should be considered.

ETHICS PROCEDURE

- Together with the application the applicant should identify the ethical issues of the research project (see the list below) and include all relevant information in the application form (section "Ethical Issues"), if applicable.

- Whenever applications involve ethical issues, a mandatory Statement on Ethics will be requested. A duly signed declaration by the host institution and the beneficiary, regarding the acknowledgement and observance of ethics guidelines under national rules will be a prerequisite for signing the contract.

- Ethical or legal (data protection) approvals by the competent local/national Ethics Committees (Ethics Committees of 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. Copies of ethical approvals by the competent local/national ethics bodies, together with copies of relevant authorisations for animal experiments must be forwarded to the FCT prior to the commencement of the research.

- After the evaluation exercise, FCT will carry out an internal pre-ethics screen of the applications. All those applications that are selected for funding and those on the reserve list that raise ethical issues will go through an ethics screening and if more information is required a full ethics review will take place.

THE ETHICS CLEARANCE PROCESS

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

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

The following special issues should 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 participants, etc.) and the nature of the material that will be collected (e.g. human biological samples, sensitive or personal data, etc.). If children or adults that are unable to give informed consent will be involved this should be explicitly stated and justification for their participation should be provided.

(2) Detailed information should be provided on the informed consent procedures that will be implemented. Copies of examples of Informed Consent Forms and Information Sheets should be included (uploaded in pdf format) in the application form. If children are to be involved the assent forms should also be provided. These must be in language and terms understandable to the participants. Participants 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 (or not) at the end;
- To know of any potential commercial use of the research.

Human biological samples and personal data

(3) Detailed information should 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 current study.

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

(5) Detailed information should 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.

Research involving animals

(6) Detailed information must be provided on why living animals have to be used and why a particular species has been chosen. In addition, information should be given on the number of animals to be used in experiments, the nature of the experiments, the procedures that will be carried out, their anticipated impact (e.g. potential for pain, suffering, distress and lasting harm) and how these have been minimised. Furthermore, details must be provided on what procedures have been implemented to ensure the welfare of the animals during their lifetime (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, as well as substantiation that the Principle of the Three Rs will be rigorously applied.

Research with developing countries

(7) The applicant should 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.

(8) The issues at stake when conducting research in third countries are linked with applying the same criteria to other cultures. This implies that researchers take into account the wide disparities in health systems, the burden of disease, the level of literacy and the scientific and ethics infrastructures that are in place.

Human embryonic stem cells

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

(9) The applicants should 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.

(10) The need to use hESC in order to achieve the scientific objectives must be set forth in the application. In particular, applicants should 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 application. This latter provision does not apply to research comparing hESC with other human stem cells.

Regarding the questions concerning ethical issues below, it is mandatory to fill in and upload the Ethical Issues Form. If you answer YES to any question, you need to address it in the respective box in the section "Ethical and legal issues" of the application form. If you are sure that none of the issues apply to your application, simply do not fill in this box. Supporting documents should also be uploaded in this section. Not all issues necessarily imply an ethics review. The supporting documents enable the independent experts to decide if an ethics review is required.

Any ethics review will be performed solely on the basis of the information provided with the application. In some cases additional information will be sought for clarification.

LIST OF QUESTIONS CONCERNING ETHICAL ISSUES

The use of human embryonic stem cells (hESC)

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 involve hESC lines?

Does the proposed research on hESC involve the derivation of cells from embryos?

Research on human beings

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

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

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

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,

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