

# FCT

Fundação para a Ciência e a Tecnologia  
MINISTÉRIO DA CIÊNCIA, TECNOLOGIA E ENSINO SUPERIOR

## WELCOME II (Portugal)

Promoting the return of researchers to the European Research Area

### Ethical Issues

September 2010



## **Ethical Issues**

Considering that the Welcome II Programme is cofunded by the Marie Curie Action Cofund, of the People Programme of the 7th Framework Programme of the European Commission, all the research activity carried out under this Programme shall be in compliance with fundamental ethical principles and the ethics framework of FP7.

### **Ethical issues will be handled by the Foundation, as follows:**

- Application forms will request information regarding ethics in their proposals;
- Panel coordinators will carry out the screening of proposals during the evaluation exercise and will require the ethical review of proposals in case of doubt;
- Whenever proposals that have been selected for funding raise ethical issues, the ethics review by experts will take place on a case-to-case basis;
- 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 ethical rules under national and FP7 rules together with ethical approvals (when applied) will be a prerequisite to the contract celebration;
- Ethical or legal (data protection) approvals by the competent local/national Ethics Committees 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 ethical bodies, together with copies of relevant authorizations for animal experiments must be forwarded to the FCT prior to the commencement of the research.

### **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 should explain the benefit and burden of the experiments and the effects these may have on the research subject.

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 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.

### **Human biological samples and personal data**

- (3) 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.
- (4) 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.
- (5) 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.

### **Research involving animals**

- (6) Detailed information should be provided on why living animals have to be used and why that species has been chosen. In addition, information should 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 should 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 should 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**

- (7) 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;
- (8) 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.

### **Human embryonic stem cells**

Research proposals that will involve human embryonic stem cells (hESC) will have to address all the following specific points: 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;

- 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;
- the applicants should take into account the legislation, regulations, ethical rules and/or codes of conduct in place in the country(ies) where the research using hESC is to take place, including the procedures for obtaining informed consent;
- the applicants should ensure that for all hESC lines to be used in the project were derived from embryo's of which the donor(s)' express, written and informed consent was provided
- freely, in accordance with national legislation prior to the procurement of the cells.
- that result from medically-assisted *in vitro* fertilization designed to induce pregnancy, and were no longer to be used for that purpose.
- of which the measures to protect personal data and privacy of donor(s), including genetic data, are in place during the procurement and for any

use thereafter. Researchers must accordingly present all data in such a way as to ensure donor anonymity;

- of which the conditions of donation are adequate, and namely that no pressure was put on the donor(s) at any stage, that no financial inducement was offered to donation for research at any stage and that the infertility treatment and research activities were kept appropriately separate;

### **Dual use**

Dual use is a term used to refer to technology which can be used for both peaceful and military aims.

## **ETHICS REVIEW AND THE REVIEWERS**

Since the research will be undertaken in Portugal, the Foundation will appoint an ethical committee and other regulatory organisations that will need to be approached during the life of the project.

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.**

Only in exceptional cases will additional information be sought for clarification. Projects raising specific ethical issues such as research intervention on human beings<sup>7</sup>; research on human embryos and human embryonic stem cells and non-human primates are automatically submitted for ethics review.

To ensure compliance with ethical principles, the Foundation Services will undertake ethics audit(s) of selected projects at its discretion.

A dedicated website that aims to provide clear, helpful information on ethical issues is now available at: [http://cordis.europa.eu/fp7/ethics\\_en.html](http://cordis.europa.eu/fp7/ethics_en.html)

Ethics is central to scientific integrity, honesty and clarity of science. It is considered essential by the European Commission and FCT in the research activities that it funds or carries out itself. 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 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; 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 REVIEW IS AUTOMATIC IF A PROPOSAL INCLUDES:**

- Interventions on human beings;
- The use of human embryonic stem cells (hESC);
- The use of animals and/or
- The use of non-human primates.

Ethics Review may be necessary if the proposal is flagged by the scientific expert as raising specific ethics issues.

### **FOR MORE INFORMATION**

- Ethics Review guidance: <http://cordis.europa.eu/fp7/dc/index.cfm>
- Ethics Review: [http://cordis.europa.eu/fp7/ethics\\_en.html](http://cordis.europa.eu/fp7/ethics_en.html)
- Research on Animals:  
<http://www.nc3rs.org.uk/category.asp?catID=3>  
[http://www.vet.uu.nl/nca/links/databases\\_of\\_3r\\_models](http://www.vet.uu.nl/nca/links/databases_of_3r_models)

### **LIST OF QUESTIONS CONCERNING ETHICAL ISSUES**

(Note: Research involving activities marked with an asterisk \* in the left column in the table below will be referred automatically to Ethics Review)

- \* Does the proposed research involve human Embryos?
- \* Does the proposed research involve human Foetal Tissues/ Cells?
- \* Does the proposed research involve human Embryonic Stem Cells (hESCs)?
- \* Does the proposed research on human Embryonic Stem Cells involve cells in culture?
- \* Does the proposed research on Human Embryonic Stem Cells involve the derivation of cells from Embryos?
  
- \* 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?

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?

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?

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)?