SCIENTIA FELLOWS

Ethics Guide

Call 1

Based on the 2013 People Programme
Guide for applicants - Ethics
Marie Curie Actions
Published by the European Commission 10/07/2012
Table of Contents

1. SCIENTIA FELLOWS – ethics ................................................................. 2
2. General principles ................................................................................. 2
3. Ethics Issues .......................................................................................... 3
   3.1 Human Embryonic Stem Cell (hESC) Research ................................. 3
   3.2 Informed Consent ................................................................................ 4
   3.3 Privacy and Data Protection ............................................................... 4
   3.4 Dual Use ............................................................................................. 5
   3.5 Research involving Developing Countries ........................................... 5
   3.6 Research on animals ........................................................................... 6
4. Principles for Ethics Review ................................................................. 6
   4.1 Areas excluded from funding under FP7 ............................................ 7
   4.2 Ethics Issues Table ............................................................................. 8
1. SCIENTIA FELLOWS – ethics

Securing ethical standards is of great importance due to complexity of the Programme that can involve projects from basic, translational and clinical research as well as health and society.

Scientia Fellows, as COFUND project cofounded by the EU’s FP7 Marie Curie Actions, will follow in this respect the European Commission’s principles. The following sections of this Guide reflect the principles described in the The 2013 People Programme Guide for applicants – Ethics, Marie Curie Actions, published by the EC on 10/07/2012.

All research proposals submitted by the Candidates must respect fundamental ethical principles. Both European FP7/Horizon 2020 and national ethics regulations of the country of the Host organisation have to be respected.

To ensure that the relevant national and EU rules are respected, the following procedures are followed:

- The ethics issues table (as used by the EC and the REA) is a part of the application documents. Candidates are informed in the Guide for Applicants that this form must be filled in.

- The potential host organisations are informed that it is their responsibility to help the fellows to request all ethics approvals needed for their research.

- If the proposal contains sensitive ethics issues the SFO will make sure that the proposal is, in addition to the regular experts, also reviewed by the Internal Ethical and Safety Board.

- The SFO ensures that ethically sensitive research does not start until all approvals (issued by the relevant authorities) have been received.

- In case SCIENTIA-FELLOWS receives a proposal using human embryonic stem cell the following procedure applies: the scientific experts must mention in their evaluation report, if the use of hESC is necessary for the success of the project. If the project is suggested for funding, SCIENTIA-FELLOWS will contact REA Project Officer who will forward the proposal for the EC Ethics review.

2. General principles

All research activities in FP7 should respect fundamental ethics principles, including those reflected in the Charter of Fundamental Rights of the European Union. These principles include the need to ensure the freedom of research and the need to protect the physical and moral integrity of individuals and the welfare of animals.

Ethics is central to scientific integrity, honesty and clarity. It is considered essential by the European Commission and the REA in the research activities that it funds or carries out.
This means that in any proposal submitted to the 7th Framework programme, ethics issues must be identified and addressed. For this reason, the REA (together with the European Commission) may carry out an ethics review when appropriate.

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, consider the impact of the research, not only in terms of scientific advancement, but also in terms of human dignity and social and cultural impact. They must also consider elements such as the ethical and social impact of the research and whether there is a balance between the objectives and the means.

The principles are described below, and more detail can be found at [http://ec.europa.eu/research/participants/portal/page/fp7_documentation](http://ec.europa.eu/research/participants/portal/page/fp7_documentation)

### 3. Ethics Issues

Any ethics issues that may arise must be described in the proposal. In particular, a researcher should explain the benefit and burden of the experiments and the effects these may have on the research subject.

Before completing the Ethics Section, the applicant should be aware of the legal requirements related to ethics that have to be met in the country where the research will take place.

The following special issues must be taken into account:

#### 3.1 Human Embryonic Stem Cell (hESC) Research

Each proposal using hESC is assessed by at least two independent ethics reviews: one in the country where the research is carried out and one at EU level. No system in the world offers a higher guarantee regarding the respect of fundamental ethics principles.

When involving the use of hESC in their research project, researchers should take into account and specify:

- that it does not destroy embryos (including to procure stem cells)
- that the consortium has taken into account the legislation, regulations, ethics rules and/or codes of conduct in the countries where the research using the hESC will take place, including the procedures for obtaining informed consent
- the source of the hESC
- the protection of personal data (genetic data and privacy)
- the nature of financial inducements, if any
- the positive opinion from a Committee constituted by Member States’ representatives
- the approval of the relevant national or local ethics committee prior to the start of the research activities.

For further information: [http://ec.europa.eu/research/participants/portal/page/fp7_documentation](http://ec.europa.eu/research/participants/portal/page/fp7_documentation)
3.2 Informed Consent

When describing issues relating to informed consent, it is necessary to illustrate an appropriate level of ethics sensitivity, and consider issues of insurance, incidental findings and the consequences of individuals leaving the study prematurely.

**What factors cause it to be needed?**
When the following are involved
- When children are involved
- Healthy volunteers
- Human genetic material
- Human biological samples
- Human data collection.

**What must be in a consent form?**
- A statement confirming that this is a research project
- The purpose of the research, the duration, procedures to be used and identification of any experimental procedure
- A description of the foreseen risks and benefits
- A statement describing the extent to which the confidentiality of records identifying subjects will be maintained
- A disclosure of any alternative procedures that might be beneficial
- For research involving more than minimal risk, an explanation as to whether there are any treatments or compensation if injury occurs and, if so, what they consist of or where further information can be obtained
- Identify the contact person for answers to questions about the research and research subjects’ rights, and who to contact in the event of injury to any subject
- A statement that participation is voluntary, withdrawal from the research can be undertaken at any time without loss of benefits to which the subject is otherwise entitled.

**How to deal with informed consent in practice?**
Ensure that:
- it is understood. Explain how you check the critical part of the process
- it excludes vulnerable people, prisoners, mentally impaired people, severely-injured patients, very young children, but avoid lost opportunities for these people. The framework should guarantee their participation (through a surrogate legal/therapeutic representative)
- you address the fact that people rarely recall what they have agreed to when signing an informed consent form.

For further information:
[http://ec.europa.eu/research/participants/portal/page/fp7_documentation](http://ec.europa.eu/research/participants/portal/page/fp7_documentation)

3.3 Privacy and Data Protection

Privacy problems exist if uniquely identifiable data relating to a person are collected or stored, in digital form or otherwise. Improper disclosure control can be the root cause of privacy issues.
Data affected by privacy issues

- Health information
- Financial and genetic information
- Criminal justice information
- Location information
- Data privacy/sharing data while protecting identifiable information.

How to address Data Protection and Privacy?

- Describe the procedures for informed consent confidentiality
- Informed consent should have clearly limited duration, and the purpose to which data will be put clearly specified
- Encode, or make anonymous, banked biomaterial, ensure security for storage and handling and make sure it is lawfully processed
- Check for accuracy, and security. Check for data transferred abroad unprotected.

For further information:
http://ec.europa.eu/research/participants/portal/page/fp7_documentation

3.4 Dual Use

Dual use is a term often used to refer to technology which can be employed for both peaceful and military aims, usually in regard to the proliferation of nuclear weapons.

Ethics issues of dual use might arise in cases where:

- Classified information, materials or techniques are used in research
- Dangerous or restricted materials, e.g. explosives, are used in research
- The specific results of the research could present a danger to participants, or to society as a whole, if they were improperly disseminated

For further information:
http://ec.europa.eu/research/participants/portal/page/fp7_documentation

3.5 Research involving Developing Countries

Many of the ethics issues that are specific to research projects carried out in developing countries originate from the potential vulnerability of local people, such as that of:

- study participants
- the local research team or of the local Ethics Review Committee.

Three overall considerations should apply to all research projects involving these countries. The proposed research must:

- be responsive to the needs of the country where research is carried out
- be scientifically sound (as judged by the scientific evaluation)
- abide by relevant EU and national legislation as well as by the relevant international guidelines.
3.6 Research on animals

- Explain your choices of species
  - Make a detailed and convincing explanation for the application of the 3Rs: Reduction, Replacement, and Refinement
  - Justify species and give an estimate of numbers of animals you will use
- Define humane end points
- Check for alternatives.

For further information:
http://ec.europa.eu/research/participants/portal/page/fp7_documentation

4. Principles for Ethics Review

Ethics review aims to prevent EU funding being used for research activities that contravene fundamental rights.

However any project run by a cofunded fellowship scheme involving the use of hESC, in addition to the scientific justification for the use of hESC, must also have an ethics review carried out by the REA/Commission before the relevant phase of the project takes place.

The Commission reserves the right to carry out ethics audits on the funded Grant Agreements, in particular (but not limited to) where there are projects involving interventions on human beings or the use of non-human primates.

If an application raises ethical issues, the following approach will be applied:

1. An ethical expert will review it.
2. If the project proposal is approved, a copy of the ethical permit from national level has to be sent to the SF Office (in EN or NOR)
3. Funds will not be released before the above stage is completed.

Research using human embryonic stem cells (hESCs) undergoes specific procedures.

1. (Scientific) evaluators must mention in their report whether the use of hESCs is justified and necessary for the success of the project.
2. If the project is recommended for funding, the SF Office will contact the REA Project Officer who will forward the proposal and evaluation report for the EC Ethics Review.
3. Funds will not be released before the above stage is completed.

Any ethics review will be performed solely on the basis of the information available in the proposal.

- Drafts of Information Sheet and Consent Form have to be submitted
There is no need to submit copies of legislation. No marks are given to the proposals during ethics review, but if the proposal is unclear on ethics issues, clarification may be demanded.

The Ethics Issues table can be found below. It is also included in the Scientia Fellows Guide for Applicants Call 1. The template is available on the Programme website.

Applicants who indicate YES to any issue, are asked to identify the pages in the proposal where this ethics issue is described.

Answering 'YES' to some of these boxes does not automatically lead to an 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 tick the YES box in the last row.

### 4.1 Areas excluded from funding under FP7

Several areas are explicitly excluded from funding irrespective of their legality in individual Member States.

- Research activity aiming at human cloning for reproductive purposes
- Research activity intended to modify the genetic heritage of human beings which could make such changes heritable (research related to cancer treatment of the gonads can be financed)
- Research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.
### Ethics Issues Table

#### Research on Human Embryos/Foetus

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the proposed research involve human Embryos?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the proposed research involve human Foetal Tissues/Cells?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the proposed research involve human Embryonic Stem Cells (hESCs)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the proposed research on Human Embryonic Stem Cells involve cells in culture?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the proposed research on Human Embryonic Stem Cells involve the derivation of cells from Embryos?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Research on Humans

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the proposed research involve children?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the proposed research involve patients?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the proposed research involve persons not able to give consent?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the proposed research involve adult healthy volunteers?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the proposed research involve Human genetic material?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the proposed research involve Human biological samples?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the proposed research involve Human data collection?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Privacy

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the proposed research involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the proposed research involve tracking the location or observation of people?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Research on Animals

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the proposed research involve research on animals?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are those animals transgenic small laboratory animals?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are those animals transgenic farm animals?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are those animals non-human primates?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are those animals cloned farm animals?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Involving non-EU Countries (ICPC Countries)</td>
<td>YES</td>
<td>Page</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>-----</td>
<td>------</td>
</tr>
<tr>
<td>Is the proposed research (or parts of it) going to take place in one or more of the ICPC Countries?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is any material used in the research (e.g. personal data, animal and/or human tissue samples, genetic material, live animals, etc):&lt;br&gt; a) Collected and processed in any of the ICPC countries?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Exported to any other country (including ICPC and EU Member States)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dual Use</th>
<th>YES</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research having direct military use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research having the potential for terrorist abuse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 In accordance with Article 12(1) of the Rules for Participation in FP7, ‘International Cooperation Partner Country (ICPC) means a third country which the Commission classifies as a low-income (L), lower-middle-income (LM) or upper-middle-income (UM) country. Countries associated to the Seventh EC Framework Programme do not qualify as ICP Countries and therefore do not appear in this list.