Research Executive Agency

SEVENTH FRAMEWORK PROGRAMME

THE 2012 PEOPLE PROGRAMME

GUIDE FOR APPLICANTS

Marie Curie Actions
(Ethics)

MC Ethics

To be read in conjunction with the Guides for Applicants, Common and Call-Specific Parts

Date of publication: 20/07/2011
Version Number: 2012.1

MARIE CURIE ACTIONS

Please note

The 2012 Marie Curie Actions are:

FP7-PEOPLE-2012-**CIG**
FP7-PEOPLE-2012-**COFUND**
FP7-PEOPLE-2012-**IAPP**
FP7-PEOPLE-2012-**IEF**
FP7-PEOPLE-2012-**IIF**
FP7-PEOPLE-2012-**IOF**
FP7-PEOPLE-2012-**IRSES**
FP7-PEOPLE-2012-**ITN**

Guides for Applicants for any other action in the PEOPLE programme, or indeed in any FP7 programme, can be found by following the links at **http://ec.europa.eu/research/participants/portal**

This Guide is based on the rules and conditions contained in the legal documents relating to FP7 (in particular the Seventh Framework Programme, Specific Programmes, Rules for Participation, and the Work Programmes), all of which can be consulted via the Participant Portal.

This Guide does not in itself have any legal value, and thus does not supersede those documents.

1. Introduction

All research activities in FP7 should respect fundamental ethics principles, including those reflected in the Charter of Fundamental Rights of the European Union[1]. 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://cordis.europa.eu/fp7/ethics_en.html. All proposals must provide ethics information and include an **Ethics Issues Table** in Part B, even if the proposers believe that there are no ethics issues, or that they have been properly addressed in proposal.

Proposals ignoring ethics concerns risk being rejected by the REA

2. Ethics Issues

Any ethics issues that may arise must be described in the proposal. In particular, you should 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:

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: ftp://ftp.cordis.europa.eu/pub/fp7/docs/human.embryos.doc

[1] Charter of Fundamental Rights of the European Union, 2000/C 364/01. See also http://www.europarl.europa.eu/charter/default_en.htm

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 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: ftp://ftp.cordis.europa.eu/pub/fp7/docs/informed-consent_en.pdf

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: ftp://ftp.cordis.europa.eu/pub/fp7/docs/privacy.doc

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: ftp://ftp.cordis.europa.eu/pub/fp7/docs/dual-use.doc

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:

1. be responsive to the needs of the country where research is carried out
2. be scientifically sound (as judged by the scientific evaluation)
3. abide by relevant EU and national legislation as well as by the relevant international guidelines.

For further information: ftp://ftp.cordis.europa.eu/pub/fp7/docs/developing-countries_en.pdf

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: ftp://ftp.cordis.europa.eu/pub/fp7/docs/research.animals.doc

Before completing the Ethics Section, the applicant should be aware of the legal requirements related to ethics (such as data protection, hESCs, animal protection, etc) that have to be met in the country where the research will take place.

3. Principles and Procedure for Ethics Review

Ethics Review and the reviewers

Ethics review aims to prevent EU funding being used for research activities that contravene fundamental rights. For this reason, the REA (together with the European Commission) will carry out an ethics review of research proposals when appropriate.

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

- Drafts of Information Sheet and Consent Form have to be submitted
- There is no need to submit copies of legislation.
- No additional information will be requested at Ethics Review.

Only in exceptional cases will additional information be sought for clarification. Clarification can be sought at any time during the cycle, including while the research is in progress.

Ethics Review is automatic if a proposal includes any of:

- Interventions on human beings[2]
- The use of human embryonic stem cells (hESC)
- The use of non-human primates.

NOTE: For the COFUND action, the ethics review is delegated to the fellowship programmes requesting co-funding (in accordance with the principle of subsidiarity). With the exception of the cases listed above, and for which an ethics review carried out by the REA/Commission will be needed before a fellowship scheme is funded, applicants must ensure that proposals which do not respect the ethics principles applied in FP7 are not co-funded by the EU. Applicants will be requested to explain in their programmes the ethics rules and scrutiny systems they will apply to research proposals applying for their fellowships. The treatment of ethics issues is included in evaluation criterion 1 "Selection process for the fellows under the programme" (subcriterion 1.3 Criteria and method of judging merit).

Programmes selected for co-funding will have to report to the REA on the handling of ethics issues as part of the usual reporting procedures in FP7. The Commission and REA reserve the right to carry out ethics audits on the funded Grant Agreements.

With regard to reviewers:

- Reviewers are selected on the basis of their expertise
- Reviewers have a wide range of skills. They include doctors, biologists and clinicians, ethicists, lawyers
- Gender balance is promoted
- Reviewers come from the European Union and other countries.

Every proposal receives an ethics report outlining the views of the reviewers. No marks are given, but if the proposal is unclear on ethics issues, clarification may be demanded.

Areas excluded from funding

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.

The Ethics Issues table is below. This is also included in the draft Part B of the Guide for Applicants (Call-Specific Part). If you indicate YES to any issue, please 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

[2] Such as clinical trials, and research involving invasive techniques on persons (e.g. taking of tissue samples, examinations of the brain).

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.

Ethics Issues Table

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

	Research on Human Embryo/ Foetus	YES	Page
*	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?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

	Research on Humans	YES	Page
*	Does the proposed research involve children?		
*	Does the proposed research involve patients?		
*	Does the proposed research involve people 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?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

	Privacy	YES	Page
	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?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

	Research on Animals	YES	Page
	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?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

	Research Involving Developing Countries	YES	Page
	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)?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

	Dual Use	YES	Page
	Research having direct military use		
	Research having the potential for terrorist abuse		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		