STARTPAGE

PEOPLE
MARIE CURIE ACTIONS

Intra-European Fellowships (IEF)
Call: FP7-PEOPLE-2010-IEF

PART B

"PROPOSAL ACRONYM"

Part B -Table of Contents of Proposals

To draft PART B of proposals applicants should take into account the following structure and subheadings.

If required for an adequate description of their project, applicants may wish to add further headings.

B1 SCIENTIFIC AND TECHNOLOGICAL QUALITY

- Scientific and technological quality, including any interdisciplinary and multidisciplinary aspects of the proposal
- Research methodology
- Originality and innovative nature of the project, and relationship to the 'state of the art' of research in the field
- Timeliness and relevance of the project
- Host scientific expertise in the field
- Quality of the group/supervisors

B2 TRAINING

- Clarity and quality of the research training objectives for the researcher
- Relevance and quality of additional scientific training as well as of complementary skills offered
- Host expertise in training *experienced researchers* in the field and capacity to provide mentoring/tutoring

B3 RESEARCHER

- Research experience
- Research results including patents, publications, teaching etc., taking into account the level of experience
- Independent thinking and leadership qualities
- Match between the *fellow*'s profile and project
- Potential for reaching a position of professional maturity
- Potential to acquire new knowledge

B4 IMPLEMENTATION

- Quality of infrastructures/facilities and international collaborations of host
- Practical arrangements for the implementation and management of the scientific project
- Feasibility and credibility of the project, including work plan
- Practical and administrative arrangements and support for the hosting of the *fellow*

B5 IMPACT

- Potential of acquiring competencies during the fellowship to improve the prospects of reaching and/or reinforcing a position of professional maturity, diversity and independence, in particular through exposure to complementary skills training with special attention to exposure to the industry sector, where appropriate
- Contribution to career development or re-establishment where relevant
- Contribution to European excellence and European competitiveness
- Benefit of the mobility to the European Research Area

B6 ETHICAL ISSUES

B1 SCIENTIFIC AND TECHNOLOGICAL QUALITY (maximum 8 pages)

Scientific and technological Quality, including any interdisciplinary and multidisciplinary aspects of the proposal

Outline the research objectives against the background of the state of the art, and the results hoped for. Give a clear description of the state-of-the-art of the research topic. Describe the scientific, technological or socio-economic reasons for carrying out further research in the field covered by the project. If relevant, provide information on interdisciplinary / multidisciplinary and/or inter-sectoral aspects of the proposal.

Research methodology

For each objective explain the methodological approach that will be employed in the project and justify it in relation to the overall project objectives. When any novel methods or techniques are proposed, explain their advantages and disadvantages.

Originality and innovative nature of the project, and relationship to the 'state of the art' of research in the field

Explain the contribution that the project is expected to make to advance the state-of-the-art within the project field. Describe any novel concepts, approaches or methods that will be employed.

Timeliness and relevance of the project

Describe the appropriateness of the research proposed against the state of the art and outline the benefit that will be gained from undertaking the project at Community level and how the fellowship will contribute to enhance EU scientific excellence and reintegrate the researcher.

Host scientific expertise in the field

The host institution must explain its level of experience on the research topic proposed and document its track record of work, including all international collaborations. Information provided should include participation in projects, publications, patents and any other relevant results. Similar information should be provided for the *scientist in charge* of the supervision of the project. Where relevant, show that any gender issues associated to the proposal have been adequately taken into account.

Quality of the group/supervisors

The host institution must demonstrate its track record of previous training achievements especially at an advanced level within the field of research.

B2 TRAINING (maximum 2 pages)

Clarity and quality of the research training objectives for the researcher

Explain in detail which will be the training objectives of the proposal and how these can be beneficial for the development of an independent research career.

Relevance and quality of additional scientific training as well as of complementary skills offered

Explain how the training provided will contribute to adding different/complementary scientific competencies to the career of the *fellow*. Outline complementary training and skills expected during the execution of the project (such as research management, presentation skills, ethics, etc.).

Host expertise in training *experienced researchers* in the field and capacity to provide mentoring/tutoring
Give a short outline of the host's expertise in training, mentoring/tutoring researchers

B3 RESEARCHER (maximum 7 pages which includes a CV and a list of main achievements)

Research experience
The applicant must present a comprehensive description of his/her research experience.
A scientific/professional CV must be provided and should mention explicitly:
- academic achievements
- list of other professional activities
- any other relevant information

Research results
Outline the major achievements of the researcher. These may also include results in the form of funded projects, publications, patents, reports, invited participation in conferences etc., taking into account the level of experience. To help the expert evaluators better understand the level of skills and experience it is advisable to write a short description (250 words) of maximum three of the major accomplishments mentioning the purpose, results, skills acquired, derived applications etc.

Independent thinking and leadership qualities
Describe the activities that reflect initiative, independent thinking, project management skills and leadership since these are qualities that will be taken into account in the evaluation. Outline the potential for future development of the applicant.

Match between the fellow's profile and project
Show that the applicant's skills and experience are suitable for the project proposed.

Potential for reaching a position of professional maturity
Describe which measures are foreseen to help the researcher to reach professional maturity.

Potential to acquire new knowledge
Describe the researcher's ability to acquire new knowledge and skills.

B4 IMPLEMENTATION (maximum 6 pages)

Quality of infrastructures/facilities and international collaborations of host
The host institution needs to specify the available infrastructures and whether these can respond to the needs set by the execution of the project. The host institution should further demonstrate its participation in international collaborations

Practical arrangements for the implementation and management of the project
The applicant and the host institution must be able to provide information on how the implementation and management of the fellowship will be achieved. The experts will be examining the practical arrangements that can have an impact on the feasibility and credibility of the project.

Feasibility and credibility of the project, including work plan
Provide a work plan that includes the goals that can help assess the progress of the project. Where appropriate, describe the approach to be taken regarding the intellectual property that may arise from the research project.

Practical and administrative arrangements and support for the hosting of the fellow
Describe what practical arrangements are in place to host a researcher coming from another country. What support will be given to him/her to settle into their new host country (in terms of language teaching, help with local administration, obtaining permits, accommodation, schools, childcare etc.)

B5 IMPACT (maximum 2 pages)

Potential of acquiring competencies
Describe the *fellow*'s potential of acquiring (complementary) competencies and skills during the fellowship and which impact this will have on the prospects of reaching and/or reinforcing a position of professional maturity, diversity and independence.

Contribution to career development or re-establishment where relevant
How will the fellowship contribute in the medium- and long-term to the development of the *fellow*'s career?
In the case of a *fellow* returning to research, how will his/her re-establishment be helped by the fellowship?

Contribution to European excellence and European competitiveness
Describe the extent to which the project will increase the attractiveness of Europe for researchers, increase European competitiveness and produce long-term synergies and/or structuring effects

Benefit of the mobility to the European Research Area
Describe how the proposed mobility will be beneficial to the European Research Area and explain why the mobility is genuine. Genuine mobility is considered allowing the researcher to work in a significantly different geographical and working environment; different from the one in which he has already worked before.

B6 Ethical Issues

Describe any ethical issues that may arise 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 should be taken into account:

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

Data protection issues: Avoid the unnecessary collection and use of personal data. Identify the source of the data, describing whether it is collected as part of the research or is previously collected data being used. Consider issues of informed consent for any data being used. Describe how personal identity of the data is protected.

Use of animals: Where animals are used in research the application of the 3Rs (Replace, Reduce, Refine) must be convincingly addressed. Numbers of animals should be specified. Describe what happens to the animals after the research experiments.

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

- the necessity to use hESC in order to achieve the scientific objectives set forth in the proposal.
- whether the applicants have taken 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 source of the hESC
- the measures taken to protect personal data, including genetic data, and privacy;
- the nature of financial inducements, if any.

Identify the countries where research will be undertaken and which ethical committees and regulatory organisations will need to be approached during the life of the project.

Include the Ethical issues table below. If you indicate YES to any issue, please identify the pages in the proposal where this ethical issue is described. Answering 'YES' to some of these boxes does not automatically lead to an ethical review. It enables the independent experts to decide if an ethical 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.

(No maximum length for Section B.6: Depends on the number of such issues involved)

Notes:

Any ethical 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[1]; research on human embryos and human embryonic stem cells and non-human primates are automatically submitted for ethical review.

To ensure compliance with ethical principles, the Commission and the REA 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

Ethics is central to scientific integrity, honesty and clarity of science. It is considered essential by the European Commission and the REA in the research activities that it funds or carries out itself. This means that in any proposal submitted to the 7th Framework 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; 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; consider elements such as the ethics and social impact of the research and whether there is a balance between the objectives and the means.

The following special issues should be taken into account:

ETHICS REVIEW AND THE REVIEWERS
Ethics review aims to prevent Community funding being used for research activities that contravene fundamental rights.

- Reviewers are selected on the basis of their expertise.
- Reviewers must first register online on CORDIS.
- 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 gets a report outlining the views of the reviewers. No marks are given, but if the proposal is unclear on ethics issues, clarification may be asked for.

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

ETHICS REVIEW IS AUTOMATIC IF A PROPOSAL INCLUDES:

- Interventions on human beings;
- The use of human embryonic stem cells (hESC); 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.

MAIN ETHICS ISSUES THAT MUST BE ADDRESSED

- Informed consent
- Human embryonic stem cells
- Privacy and data protection
- Use of human biological samples and data
- Research on animals
- Research in developing countries
- Dual use

AREAS EXCLUDED FROM FUNDING

- 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.

MAJOR CHANGES FROM FP6 TO FP7

The Ethic Review will be carried out on the proposal as it is submitted.

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

INFORMED CONSENT

When is it 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 to be included.
- A statement describing the extent to which confidentiality of records identifying the subject 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.

- Identity the contact person for answers to questions about the research and research subject's rights, and whom to contact in the event of injury to the subject.
- A statement that participation is voluntary, withdrawal from the research can be undertaken at any time without loss of benefits which the subject is otherwise entitled to.

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 persons, prisoners, mentally impaired persons, severely-injured patients, very young children, but avoid lost opportunities for these persons. The framework should guarantee their participation (notion of surrogate legal/ therapeutic representative);
- you address the fact that people rarely recall what they have agreed upon when signing an informed consent form.

PRIVACY AND DATA PROTECTION

Privacy problems exist wherever uniquely identifiable data relating to a person is collected or stored, in digital form or otherwise. Improper disclosure control can be the root cause for privacy issues.

Data affected by privacy issues

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

How to address Data protection and Privacy?

- Describe the procedures for informed consent confidentiality.
- Inform consent for duration and limited purposes.
- Encode or make anonymous banked biomaterial, security for storage and handling and make sure it is lawfully processed.
- Check for accuracy, and security Check for data transferred abroad unprotected.

DUAL USE

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

DOUBLE STANDARDS

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 CELL RESEARCH (HESC)

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 the 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:

- if it does not destroy embryos (including to procure stem cells);
- if the consortium has taken into account the legislation, regulations, ethics rules and/or codes of conduct in place 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;
- positive opinion from a Committee constituted by Member States representatives;
- approval of the relevant national or local ethics committee prior to the start of the research activities.

ELEMENTS FOR A GOOD APPROACH

- Foresee Ethics Responsibility at the level of Work-Package Leadership.
- Include a flowchart of the Ethics review process within the partnership.
- Include an appropriate periodic report on ethics.
- Ethics consideration is reflected in the structure of the proposal.
- Include an Ethics Standing Committee or at least a periodic monitoring for ethics.
- Include a Work Package on Ethics (if relevant).
- Specifically include: Insurance of participants, Conflict of interest, Incidental findings.
- The content of the Ethics part of the proposal should reflect that the issue was thought of thoroughly.
- Address possible ethics issues, even if to justify that they are not applicable, give justification.
- Justify the choice of animals, estimate the numbers.
- Take into account data, data transfer, banks, collecting samples, future clinical trials.

RESEARCH ON ANIMALS

- Address the question of animal by explaining 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.
- Refer humane end points and pain suffering.
- Check for alternatives.

FOR MORE INFORMATION

- Guide for Applicants and Ethics Review guidance: http://cordis.europa.eu/fp7/dc/index.cfm
- Experts' registration: https://cordis.europa.eu/emmfp7/
- Ethics Review: 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

Include the Ethical issues table below. If you indicate YES to any issue, please identify the pages in the proposal where this ethical issue is described. Answering 'YES' to some of these boxes does not automatically lead to an ethical review. It enables the independent experts to decide if an ethical 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.

ETHICAL ISSUES TABLE

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

ENDPAGE

PEOPLE
MARIE CURIE ACTIONS

Marie Curie Intra-European Fellowships (IEF)
Call: FP7-PEOPLE-2010-IEF

PART B

"PROPOSAL ACRONYM"