



EUROPEAN
COMMISSION

Community Research



NEGOTIATION GUIDANCE NOTES

for

Marie Curie International Research Staff Exchange Scheme

The People Programme

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Disclaimer

These guidance notes are aimed at assisting participants who are invited for project negotiation following the evaluation of their proposal. It outlines the information and procedures in the negotiation process. It is provided for information purposes only and its contents are not intended to replace consultation of any applicable legal sources or the necessary advice of a legal expert, where appropriate. Neither the Commission nor any person acting on its behalf can be held responsible for the use made of these guidance notes.

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FOREWORD

Definitions used throughout this Guideline:

Beneficiary: the legal entity who signs the *grant agreement* (*)

Home organisation: means the *beneficiary* or *partner organisation* from which the *researcher* is a staff member.

Host organisation: means the *beneficiary* or *partner organisation* hosting the *researcher* for the *secondment period*.

Person in charge for the project: leads and represents the *beneficiary* through the negotiation and the signature of the *grant agreement*. S/He will be the main contact point between the *beneficiary* and the Commission.

Partnership agreement: means an agreement signed between the *beneficiary* and the *partner organisations* for the purpose of the *project*. This agreement is deemed to have been signed before the signature of the *grant agreement*.

Partner organisation: means a signatory of the *partnership agreement* that participate in the *project*.

Researcher: means an *early stage* or an *experienced researcher* selected and appointed by his/her *home organisation* amongst the staff to benefit from the staff exchange under the *project*. Technical and managerial staff are assimilated to *early stage* or *experienced researcher* depending on their level of professional experience and are eligible if they are involved in research related activities

Secondment period: means the period(s) spent by a *researcher* at a *host organisation* under the *project*.

(*)The term "*beneficiary*" used throughout this document is meant as "*potential beneficiary*".

1. INTRODUCTION

These guidance notes are provided for beneficiaries who have been invited to enter into negotiation following the evaluation of proposals for Marie Curie International Research Staff Exchange Scheme (IRSES) actions under the 7th Framework Programme of the European Community¹.

It outlines the information and procedures in the negotiation process.

The overall purpose of negotiations is to finalise the details of the work to be carried out under the *grant agreement* within the associated budget, as well as to establish the legal and financial information needed to establish the *grant agreement*.

^{1a} Decision of the European Parliament and of the Council (EC) No 1982/2006 of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) - OJ L412 of 30.12.2006, p1.

^{1b} Decision of the European Parliament and of the Council (EC) No 973/2006 of 19 December 2006 concerning the specific programme People implementing the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013) – OJ L400/272 of 31.12.2006, p 272.

2. PREPARATION OF NEGOTIATIONS

Following the positive evaluation of a proposal and the Commission's definition of a maximum Community financial contribution for the work, the proposal *beneficiary* is invited by letter to commence negotiations with the European Commission (*Commission*) for a *grant agreement*.

A first letter providing details on the results of the evaluation and any aspects to be reviewed during negotiation will be sent to the applicants. The letter is accompanied by the Evaluation Summary Report (ESR) which summarises the results of the Evaluation Panel. The name and contact details of the Commission Project Officer(s) and Administrative Officer(s) will also be indicated here.

In a second step, successful applicants represented by the *person in charge for the project* will receive a letter of invitation to negotiation that shall indicate:

- The deadline by which the *beneficiary* must provide the first draft of Annex I (the Description of Work) and the *grant agreement* Preparation Forms (GPFs) including any relevant supporting documents.
- The deadline by which negotiations must be completed.

Proposals that have undergone an ethical review, will also receive an Ethical Review Report, which may contain recommendations to be taken into account in the negotiations and in the description of work (for more details on the negotiation of ethical issues please refer to Appendix 2).

The letter of invitation also points to web addresses for:

- A copy of these guidance notes (http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=usersite.FP7DetailsCallPage&CALL_ID=98)
- The *grant agreement* and its Annexes and any special conditions that could apply (http://cordis.europa.eu/fp7/calls-grant-agreement_en.html#people_ga)
- The "Guide to Financial Issues relating to FP7 Indirect Actions" (ftp://ftp.cordis.europa.eu/pub/fp7/docs/financialguide_en.pdf)
- The "Rules to ensure consistent verification of the existence and legal status of participants, as well as their operational and financial capacities" (ftp://ftp.cordis.europa.eu/pub/fp7/docs/rules-verif_en.pdf)
- The Guide to Intellectual Property Rules for FP7 projects (ftp://ftp.cordis.europa.eu/pub/fp7/docs/ipr_en.pdf)

Please note that the *Commission* reserves the right to terminate negotiations at any time and to reject the proposal in the event of inadequate progress in negotiations.

2.1. *The grant agreement*

Before beginning negotiation, the applicants are invited to carefully read the *grant agreement* (mono-beneficiary) specific for 'People' Programme and its Annexes

(http://cordis.europa.eu/fp7/calls-grant-agreement_en.html#people_ga) that establish the legal framework for the project's funding and administration.

2.2. The Beneficiary

The *beneficiary* leads the negotiations with the *Commission*. That legal entity² will identify the *person in charge for the project* within its staff. S/He is responsible for all contacts between the *beneficiary* and the *Commission*. If meetings are planned, s/he attends all meetings.

The *beneficiary* submits all documents to the *Commission*. The *beneficiary* will also be responsible for submitting the project's financial statements, reports and deliverables, and will receive all payments from the *Commission*.

2.3. The Project Officer

The Project Officer leads and represents the *Commission* in the negotiations with the *beneficiary*.

The Project Officer is identified in the letter of invitation and carries out the negotiations with the *person in charge for the project*, being responsible for all contacts between the *Commission* and the beneficiary. Thus the Project Officer shall be the sole recipient of all correspondence related to the negotiations.

2.4. Preparation of documents for negotiations

At the beginning of negotiations, applicants are invited to submit a draft Annex I (the Description of Work) to the *grant agreement*. This is largely an updated version of part B of the proposal, taking account of the comments made by the *Commission*. Likewise the Grant agreement Preparation Forms (GPFs) need to be provided.

The GPFs are standard forms that collect the information that the *Commission* needs in order to prepare the *grant agreement* and gather programme-wide statistical information. These forms are compatible with the forms used in the proposal submission, so that much of the proposal information may be directly transferred into the GPFs.

Annex I is the reference document for the work and the effort to be executed by the *beneficiary* in carrying out the project. It forms part of the *grant agreement*, and must facilitate the implementation and meaningful monitoring of the project for both the *beneficiary* and the *Commission*.

The first drafts of Annex I and the GPFs are submitted by the *beneficiary* to the *Commission* Project Officer, through a web based tool (NEF) which weblink is indicated in the letter of invitation to negotiation within the deadline indicated in the letter of invitation to negotiations. Upon receipt, the Project Officer will indicate changes or improvements that are required to which the *beneficiary* responds in an

² The legal entity shall be based in a Member State or Associated Country only

iterative process until agreement is reached. The entire process should be concluded before the deadline for completion of negotiations.

If not already registered in the Unique Registration Facility <http://ec.europa.eu/research/participants/urf/welcome.do;jsessionid=FwscL01Gv2XXDH9GB6tGMxtp2mQphQ9JVKvQdRJGFHN8Gjc4zGd!984643392>, the *beneficiary* has to provide supporting documents to enable the *Commission* to verify its legal existence and status. For that purpose it will be contacted by the validation team of the *Commission* (or by the project Officer). Each legal entity having already participated as a beneficiary in FP7 has been attributed a Participant Identification Code (PIC). If the beneficiary has a PIC³, then the *Commission* considers the registration/ validation process is terminated and may conclude the negotiations. The list of organisations and the corresponding PIC's is available at http://cordis.europa.eu/fp7/urf-pic_en.html.

Please note that to modify the legal entity data of its organisation, the *beneficiary* must appoint one person (the so-called LEAR – Legal Entity Appointed Representative) for being the correspondent towards the *Commission* on all issues related to the legal status of the entity (http://cordis.europa.eu/fp7/urf-lear_en.html). The LEAR is the representative of the *beneficiary* responsible for all contacts between the *beneficiary* and the URF team.

2.5. Partnership agreement

A *partnership agreement* is mandatory in IRSES projects. It is highly advisable that the *partnership agreement* (in a first version that could be updated later) **be finalised before the grant agreement is signed** and each *partner organisation* should have entered into the *partnership agreement* when the *beneficiary* accedes to the *grant agreement*.

The *partnership agreement* is a legally binding agreement between the *partner organisations* and the *beneficiary* of the project. The contents are their sole responsibility.

The *Commission* is not party to the *partnership agreement* and does not verify or check the content of the *partnership agreement*. In case of conflict between the *beneficiary* and the *partner organisations*, this will be resolved internally.

If the *Commission* detects that the *partnership agreement* is far to be concluded or there are serious obstacles, the *Commission* may decide to intervene and consider the suspension and/or termination of the negotiations.

The terms of the *partnership agreement* cannot contradict or attempt to negate the provisions of the *grant agreement*. The conclusion of such an agreement is necessary for the implementation of the project. This agreement must clearly identify the relationship between the beneficiary and the partner organisations. In particular, it should specify the internal organisation of the work to be carried out under the project, (technical management of the project), establish decision-making process as well as dispute settlement procedures.

³ Note that provisional PIC's are attributed to applicants. They must be validated to be accepted in the context of grant agreement negotiations.

In addition, the *partnership agreement* is important for determining the provisions for distribution of the financial contribution including the pre-financing.

Also should identify the particular provisions relating to the protection, transfer, use and dissemination of the foreground as well to confidentiality and treatment of information.

The *partnership agreement* may further develop those provisions or clarify details, as well as rules regarding liability and indemnification in case of non-respect of the provisions. Bear in mind that the beneficiary is the sole liable towards the *Commission*.

2.6. Support during Negotiations

To facilitate efficient proceeding of the negotiations and to ensure the preparation of a high quality *grant agreement* the *Commission* offers different support and assistance services to the *beneficiary*.

Assistance with legal and financial issues

The letter of invitation to negotiations may specify the name(s) and contact details of *Commission* official(s) in charge of the negotiations. This person(s) will be able to assist with specific questions on the technical, legal and financial issues. Should beneficiaries have general questions relating to the FP7 *grant agreement*, or to general legal and financial issues, they are advised to submit these by following the link <http://ec.europa.eu/research/enquiries/> and selecting the option '*Legal/Financial aspects of the FP*'.

Intellectual properties issues

Beneficiaries will find an overview of the FP7 intellectual property (IPR) provisions in the Guide to Intellectual Property Rules for FP7 projects (ftp://ftp.cordis.europa.eu/pub/fp7/docs/ipr_en.pdf). This document is intended to act as a guide to the various issues and pitfalls that participants may encounter. Furthermore, an IPR-Helpdesk is available to assist potential and current beneficiaries taking part in Community funded projects on Intellectual Property Rights issues. It operates a free helpline offering a first line assistance on IPR related issues. The helpline is run in English, French, Italian, German, Spanish and Polish. It can be contacted at:

<http://www.ipr-helpdesk.org>
Telephone +34 96 590 97 18
Telefax +34 96 590 97 15
E-mail ipr-helpdesk@ua.es

Ethical Issues

The ethical issues are one of the crucial elements that have to be addressed during the negotiations. Apart from instructions and links provided in Appendix 2, there is general information on the Ethics in FP7 on the webpage:

http://cordis.europa.eu/fp7/ethics-ict_en.html

Gender Issues

The detailed information on the gender mainstreaming in research and FP7 projects is provided on the *Commission's* webpage: <http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=37>

3. THE NEGOTIATIONS PROCESS

The *grant agreement* negotiation process comprises two main aspects:

- (i) Technical (*scientific*) negotiations
- (ii) Financial and legal negotiations.

Negotiations take place principally via the web base tool (NEF) but also telephone, fax and e-mail between the Project Officer and the *person in charge for the project*. It is therefore **very important to establish contact as soon as possible with the Project Officer whose contact details are provided in the letter that invites applicants to enter into negotiations.**

In the event that the *Commission* requires special clarifications from the *beneficiary* and judges it necessary, a **negotiation meeting** may be held. This will be decided by the *Project Officer in charge of the project* negotiation and will be communicated to the *person in charge*. S/He normally attends all negotiation meetings, and the *Commission* may be assisted by external expert(s).

Please note that the *Commission* does not fund costs related to the effort expended by the beneficiary in preparing the proposal or conducting the negotiations. The cost of travel and subsistence of the partnership members to negotiation meetings is not reimbursed.

3.1. Technical Negotiations

The aim of the technical negotiations is to agree on the final content of Annex I (the Description of Work) of the *grant agreement*.

Based upon the Evaluation Summary Report, the Negotiation Mandate, the Ethical Review Report (if applicable) and any further discussion with the *Commission* Project Officer, the *person in charge* should make a first draft of the Annex I and circulate it to the other *partner organisations* for approval, with the option to already send it in parallel to the Project Officer for "preliminary comments". The final version of this document will form an integral part of the *grant agreement*. The requirements for the production of this Annex I are given in Chapter 6 of this document.

During this part of the negotiation process:

- The proposal may need to be adapted to meet the recommendations indicated by the *Commission*.
- The full work plan of the project will need to be defined in sufficient detail.
- The work to be carried out by each of the *partner organisations*
- Agreement will need to be reached on the overall number of researchers, timing and implementation modalities (see box below for examples).
- Agreement will need to be reached on the project milestones and their relative assessment criteria.

- An indicative time schedule will need to be established for the project reviews (if not pre-defined in the special conditions of the *grant agreement*) – which ideally should be synchronised with the reporting periods.

Implementation modalities may include:

- Dedicate website;
- Production of a leaflet presenting the IRSES programme to be distributed at conferences, meetings;
- Production of any other dissemination means, e.g. video, poster, DVD.

3.2. Financial and Legal Negotiations

Financial negotiations focus mainly on reaching agreement on budgetary matters such as the budget for the full duration of the project and the budget breakdown for the different project periods. They will also cover the establishment of the amount of the initial pre-financing, timing of project periods and reviews.

Given that in IRSES, the Community contribution is a fixed amount per exchanged researcher-month, the main element of the financial negotiation is a table with all exchanged periods between all partners.

Legal negotiations include the analysis and review of the legal status of each applicant and the final composition of the partnership, any special clauses required for the project, and other aspects such as the project start date.

The list of special clauses applicable to the Marie Curie *grant agreement* is provided at ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-mga-clauses_en.pdf.

During this part of the negotiation process:

- The total costs, total eligible costs and maximum Community financial contribution will be determined.
- A table of the estimated breakdown of budget and Community financial contribution per activity to be carried out by each of the *partner organisations* will be established.
- The amount of pre-financing will be established.
- The start date and the duration of the project will be agreed upon.
- The *Commission* will verify the management capacity of the *beneficiary*.
- The *beneficiary* will ensure, where applicable⁴, that the involved *partner organisations* based in third countries have their own resources to implement the *project*.
- The need for the inclusion in the *grant agreement* of any special clauses will be established: (ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-mga-clauses_en.pdf)

⁴ In specific and well justified cases for *partner organisations* based in ICPC countries, in particular countries covered by the European Neighbourhood policy, a Community contribution towards travel and subsistence may be envisaged.

- The timing of the reporting periods will be established (normally every 24 months).
- The legal status of each applicant will be reviewed.
- The timing for the mid-term interim progress report of the *beneficiary* will be determined.
- The financial viability of the *beneficiary* with an EC contribution exceeding €500,000 will be assessed, as outlined in the "Rules to ensure consistent verification of the existence and legal status of participants, as well as their operational and financial capacities" (ftp://ftp.cordis.europa.eu/pub/fp7/docs/rules-verif_en.pdf)⁵.

Person in charge of the project also have the opportunity, during negotiations, to consider any gender aspect that might be relevant to the project and include this as a work package or task within a work package. Projects should ensure an open and impartial selection procedure, as well as fair working conditions, to researchers recruited on projects funded under FP7⁶.

3.3. Completion of negotiations

At the end of the negotiations, agreement should be reached on all technical, financial and legal issues related to the *grant agreement* and the beneficiary should be in the position to prepare and send a final version of the relevant documents to the Project Officer.

Where paper copies are requested as the case is for the GPFs (to be printed from NEF), these should be unbound, on white paper, with original signatures.

The *Commission* should receive a declaration signed by the legal representative stating that no double financing from any other sources is applied (costs cannot be covered twice) and that no other Community funding is going to be used for the same project.

The beneficiary shall provide information on the expected sources of funding for the action and declare any other than Community funding that receives for carrying out the project. Moreover s/he shall provide the eligibility of the costs criteria as stated in the Council Financial Regulation⁷ and make sure that the Implementation Rules are applied during the negotiation phase (Article 113 of Financial Regulation and Article 172 of Implementation Rules).

When all the necessary legal and financial information required has been received and validated by the *Commission*, a grant agreement is drafted and sent to the

⁵ This does not apply to public bodies.

⁶ The *Commission* Recommendation of 11 March 2005 on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers should be applied as a reference framework for recruitment (http://ec.europa.eu/eracareers/index_en.cfm)

⁷ Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation (Financial Regulation) applicable to the general budget of the European Communities – OJ L 248, 16.09.2002, p.1, as amended by Regulation (EC, Euratom) No 1995/2006 (OJ L 390, 30.12.2006, p.1) and Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) OJ L 357, 31.12.2002, p.1 as last amended by Commission Regulation 1248/2006 of 7 August 2006, OJ L 227/3 19/8/2006.

beneficiary for signature. A negotiation checklist is provided in Appendix 3 in order to assist the *beneficiary* in the negotiation process.

3.4. Applicable law

The *Community* financial contribution is a contribution from the *Community* research budget with the aim to implement the 7th Research Framework Programme (FP7) and it is incumbent on the *Commission* to execute FP7. Accordingly, the *grant agreement* shall be governed by the terms of the *grant agreement*, the *Community* acts related to FP7, the Financial Regulation applicable to the general budget and its implementing rules and other *Community* law and, on a subsidiary basis, by the law of Belgium⁸.

Furthermore, the *Commission* may take a decision to impose pecuniary obligations, which shall be enforceable in accordance with Article 256 of the Treaty establishing the *European Community*.

Notwithstanding the *Commission's* right to directly adopt the recovery decisions referred to in the previous paragraph, the Court of First Instance, or on appeal, the Court of Justice of the European Communities, shall have sole jurisdiction to hear any dispute between the *Community* and any *beneficiary* concerning the interpretation, application or validity of the *grant agreement* and the validity of the decision mentioned in the second paragraph.

3.5. Frequently asked Negotiation questions (FAQs)

A regularly updated list of FAQs on participation and *grant agreement* issues is available and beneficiaries should consult this periodically, as this will assist them in their negotiations (<http://ec.europa.eu/research/faq>).

A list of commonly-occurring issues which may arise during the negotiations is described below.

Project preparation/negotiation costs: The *Commission* does not fund costs related to proposal preparation or to conducting negotiations even if the fixed start date of the project is prior to the date that the *grant agreement* enters into force. This means also that the *Commission* will not reimburse the cost of travel and subsistence to negotiation meetings.

Bank account: The *beneficiary* should establish a separate bank account in Euro to allow that the *Community* financial contribution and related interest are identified. All payments are made in Euro.

Legal establishment prerequisite for *grant agreement*: The *Commission* can only negotiate with, and offer *grant agreements* to, existing entities and the legal existence of a participant must pre-date the *grant agreement* signature or accession

⁸ Country of the seat of the authorising officer responsible under the internal rules on the execution of the general budget of the European Communities.

to the *grant agreement*. This implies that applicants should be legally established – by the time of the signature of the *grant agreement*.

Partnership agreements: *Partner organisations* need to give the highest possible priority to completing the internal *partnership agreement* before signing the *grant agreement* and certain provisions relating to intellectual property must be agreed before signing the *grant agreement*.

Changes in partnership/work plan: During the negotiation the *beneficiary* may find it necessary to propose changes in the description of work, in particular, the work plan or the composition of the partnership as a consequence of events which have occurred since they prepared the proposal. Changes may also be required as a consequence of the evaluation results. The *Commission* will consider these changes, **but the evaluation result must be respected**. If the revised description of work differs to the extent that the evaluation might have yielded a different result, the *Commission* will refuse the changes, or, ultimately, terminate negotiations.

Change of beneficiary during negotiations and up to the signature of the grant agreement: In case that it is proposed such a change the *Commission* needs to agree on it and in no case will lead to an unequal treatment of the other applicants; also under very exceptional and duly justified cases the *Commission* has reasons to question the requested management and financial stability of the chosen organisation. The *Commission* will try to find appropriate solutions on a case-by case basis.

Reduction of human resources: The evaluation result of the proposal is based on a certain level of human resources and the level of funding is essentially linked to this. If during the negotiations the *beneficiary* proposes to change the human resources requirements (or any other significant cost), the *Commission* will consider these changes. In any case, the proposed Community financial contribution may change but will not be increased.

Estimation of costs: The GPFs and Annex I require the *beneficiary* to estimate essential details of costs over the lifetime of the project in order for the *Commission* to establish the maximum Community financial contribution and calculate its pre-financing.

Community financial contribution: Funding in the Marie Curie actions is based on a fixed amount per researcher and the *grant agreement* (mono-beneficiary) for 'People' Specific Programme can be found at:

http://cordis.europa.eu/fp7/calls-grant-agreement_en.html#people_ga .

Participant contribution: the *beneficiary* must ensure that third country partner organisations have the necessary own resources to carry out the *project*. Please note that as far as eligible ICPC countries, and in particular countries covered by the European Neighbourhood policy, are concerned, in specific and well justified cases, a Community financial contribution towards travel and subsistence for these participants may be envisaged.

Pre-financing (advance payments): The *Commission* will make a pre-financing payment within 45 days of the entry into force of *grant agreement* or the start date of the project.

Amendments: The *Commission* (with the possible assistance of external experts, e.g. in the case of significant changes) will consider requests for reasonable amendments to the *grant agreement*, provided that they do not change the essential character of the *project*⁹. Nevertheless significant changes to the technical content of the description of the work will require the approval of the *Commission*, in particular for changing of the *partner organisations* identified in Annex I. Amendments must be made in writing and signed by the legal representative of the *beneficiary*.

3.6. Some Important Points to Remember

- An invitation to commence negotiation does not, under any circumstance, guarantee the funding of a project or the offer of a *grant agreement*.
- The funding of the proposal may depend on the beneficiary's acceptance of changes requested by the *Commission* services.
- Funding is conditional upon compliance with the *grant agreement*.
- The *Partnership Agreement* must be finalised and signed by all partners no later than the start date of the *grant agreement* or the *entering into force*.
- In some cases the *Commission* may not be able to enter into a *grant agreement* with certain legal entities because of financial insecurity, other limitations imposed by the *Commission* Financial Regulation or for reasons of irregularity or violation of fundamental ethical principles.
- If the *Commission* cannot obtain reasonable assurance that the *beneficiary* has proof that there are the necessary financial and human resources to carry out the proposed work (including that work carried out by the other partner organisations), it is possible that the negotiations be terminated or that a change in Annex I is requested.
- The *Commission* aims at shortening the *time to grant agreement* (i.e. the time between deadline of the call for proposals and the signature of the *grant agreement*). As a result, the letter of invitation to a negotiation specifies a time limit for negotiations. If negotiations are not completed within the given time limit, the *Commission* may terminate negotiations.

⁹ In case of change of the beneficiary during the implementation of the grant agreement, the Commission will find solutions on a case-by case basis.

4. GRANT AGREEMENT

4.1. Grant agreement signature

Upon receipt of the *grant agreement*, the authorised representative of the *beneficiary* signs **two originals of the *grant agreement*** on behalf of its organisation and returns them to the *Commission*. The *Commission* can only sign these once all its internal procedures have been successfully completed and will return one duly signed original to the *beneficiary*. The *Commission grant agreement* covers the project as a whole and binds the *beneficiary* that has acceded to it.

4.2. Start of the project

The *grant agreement* will enter into force after its signature by first the *beneficiary* and then the *Commission*, on the day of the last signature.

However, the relevant provisions of the *grant agreement* will determine the start date of the project. This may be the first day of the month following the entry into force of the *grant agreement*, a fixed starting date as negotiated or a notified starting date. Where the beneficiary requires a specific fixed start date for the project that precedes the entry into force of the *grant agreement*, full details regarding the justification for the request should be made in writing to the Project Officer prior to the finalisation of Annex I to *grant agreement* and of the GPFs. The *Commission* may refuse this request if no sufficient and acceptable justification is provided.

Only those costs incurred from the start date of the project but not before can be considered as eligible. Where the start date of the project precedes the entry into force of the *grant agreement*, the future *beneficiary* takes the risk that the *grant agreement* might not be signed. In such a case costs will not be reimbursed by the *Commission*.

4.3. Pre-Financing

Once the *grant agreement* is in force, the *Commission* can make the pre-financing payment to the *beneficiary*. The amount will be established during the negotiations and is intended to provide the *beneficiary* with sufficient cash flow to carry out the first part of the project.

A pre-financing will be paid to the *beneficiary* within 45 days following the date of entry into force of the *grant agreement* or the start date of the project, whichever is the later.

The pre-financing amount specified in the *grant agreement* includes the *beneficiary* contribution to the Participant Guarantee Fund. This represents 5% of the requested total Community financial contribution and is transferred directly to the Guarantee Fund by the *Commission*.

4.4. What is the Participant Guarantee Fund?

The Participants' Guarantee Fund is a mutual benefit instrument establishing solidarity among beneficiaries in indirect actions at the level of the Framework Programme. It aims primarily at covering the financial risks incurred by the Community and the beneficiaries during the implementation of the indirect actions of FP7.

Moreover, it allows the Community to exempt beneficiaries from *ex-ante* financial viability controls (except in a limited number of cases¹⁰) and from the imposition of any sort of financial securities, including bank guarantees or retention of pre-financing.

The Guarantee Fund also allows the *Commission* to limit the financial responsibility of each participant to its own debt.

It will therefore ease the implementation of FP7 actions for the *Commission* and participants, by reducing paperwork and time required to sign the *grant agreement*.

The Guarantee Fund will thus allow small actors such as SMEs to access Community funding without additional administrative burden.

The Guarantee Funds functions as follows.

- All beneficiaries to indirect actions taking form of the *grant agreement* must contribute to the Guarantee Fund for the duration of the action.
- When transferring the initial pre-financing to a partnership, the *Commission* will deduct the relevant contribution and transfer it to the depository bank. This deduction will be equal to 5% of the Community financial contribution foreseen in Article 4 of the *single-beneficiary grant agreement* or Article 5 of the *multi-beneficiary grant agreement*.
- At the time of the final payment, beneficiaries will recover their capital unless the Guarantee Fund has incurred losses. In such a case, the *Commission* will deduct a maximum of 1% of the Community financial contribution owed to them¹¹.
- Where amounts are due to the Community by a participant, the *Commission* may, beside penalties which may be imposed on the defaulting participant, either transfer the amount to the *beneficiary* of the indirect action if it is still on-going and the remaining participants agree to implement it; or recover effectively the amount from the Fund should the indirect action be terminated or already completed.

¹⁰ The *Commission* shall verify *ex-ante* only the financial capacity of participants other than the public bodies, applying for a Community financial contribution in an indirect action in excess of EUR 500 000, unless there are exceptional circumstances, when, on the basis of information already available, there are justified grounds to doubt the financial capacity of these participants.

¹¹ Except in case of public bodies (as defined by Article 2,13 of the Regulation (EC) 1906/2006 of the European Parliament and the Council of 18 December 2006, laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013), OJ L 391/1, 30.12.2006) and legal entities whose participation in indirect actions is guaranteed by Member State or an Associated State, and higher and secondary education establishments.

4.5. Project monitoring and Follow-up

For the follow-up and monitoring of a project, the *Commission* will, if possible, appoint the same official(s) who acted as Project Officer(s) during the negotiation as Project Officer(s) for the project, so as to take advantage of the in-depth knowledge of the project's work gained during the negotiation phase. He/she is the project's key link to the *Commission* throughout the execution of the work.

Certain tasks concerning project management, financial statements or legal and financial matters may be handled by specialist staff within the *Commission*, who communicates directly with the Project Officer(s) or the *beneficiary*. As the FP7 programmes are funded with public funds, a public database of basic information concerning the projects is maintained. Information for this database is taken principally from forms A1 and A2 of the final GPFs, forming part of a "Project Fact Sheet" of non-confidential information such as project acronym, objectives, project summary, project beneficiary, Community funding etc.

As this Project Fact Sheet is prepared by the *Commission*, no additional input is required from the project beneficiary, though by arrangement with the negotiating Project Officer the project may substitute a revised version of their A1 and A2 text specifically for the Project Fact Sheet.

4.6. Reports and deliverables

According to the *grant agreement* the *beneficiary* is obliged to submit periodic reports, as well as a final report to the *Commission*.

The reporting comprise the submission of financial statements (cost claims) during the course of the work. The frequency and format of these (and the cases where they need to be certified by an independent auditor) are defined in the *grant agreement*. The financial statements form the basis for any payments made by the *Commission*.

Considering that IRSES projects will be entirely financed on the basis of fixed amounts, and in accordance with Article 34.2 of the *Rules for participation*¹², projects do not need to submit certificates on the financial statements.

Moreover under this action the *beneficiary* shall report at the end of each reporting period on some concrete information regarding each seconded *researcher* according to Annex III of the *grant agreement*. Furthermore the *beneficiary* shall submit for each reporting period a mid-term interim progress report.

Beneficiary shall report on horizontal project related issues (including gender and science & society related aspects) at the end of the project.

Beneficiary is requested to include, when appropriate, the setting up of a project webpage in their deliverables list which they will update on a regular basis.

¹² REGULATION (EC) No 1906/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013) –OJ L 391/1 of 30.12.06, p.1

4.7. Technical audits and reviews

Based on the project reports and deliverables, the *Commission* with the assistance of independent experts may conduct technical audits or reviews of project at any time during the implementation of the project and up to 5 years after the end of the project in accordance to Article II.21. These are used by the *Commission* to assess the project progress and to decide the most appropriate action.

The review may also lead the *beneficiary*, or the *Commission*, to require changes to Annex I (to reflect evolving circumstances in the marketplace, for example). In these cases, the *beneficiary* will be required to revise Annex I.

A schedule for any planned reviews may be included in Annex I to *grant agreement* (description of work).

4.8. Financial Statements

The *beneficiary*, via the *person in charge for the project*, will be required to submit financial statements (cost claims) during the course of the project. The frequency and format of these (and the cases where they need to be certified by an independent auditor) are defined in the *grant agreement*. The financial statements form the basis for any payments made by the *Commission*.

5. GRANT AGREEMENT PREPARATION FORMS (GPFs) Why GPFs?

The Grant agreement Preparation Forms (GPFs) have been designed to facilitate the project negotiations and the production of the *grant agreement*. Essentially the forms are used to identify the *beneficiary* who will sign the *grant agreement* and to determine the eligible costs and Community financial contribution.

Certain details, principally from forms A1 and A2, are used to generate a Project Fact Sheet (see previous chapter on Project monitoring and Follow-up). The budget forms and the deliverables form are included as part of Annex I of *grant agreement*. The GPFs may also be used as a reference base by the *Commission* when receiving financial statements during the lifetime of the project.

Thus, although the GPFs are not part of the *grant agreement*, it is important that the information in the forms is exact.

5.1. Completing the GPFs

The *grant agreement* Preparation Forms have to be completed in a web-based IT tool – NEF (Negotiation Forms). The details of access to the tool will be given in the letter of invitation to negotiations. For the preparation of the *grant agreement*, the document Grant agreement Preparation Forms should be used.

The use of the NEF tool for completing GPFs is mandatory. It allows the *beneficiary* to exchange several versions with the *Commission* in an iterative process of negotiation.

5.2. Where to send the GPFs?

A first draft of the GPFs must be prepared and submitted electronically through NEF to the *Commission's* Project Officer before the first negotiation round or meeting. The final agreed version of the GPFs should be submitted to the Project Officer, upon her/his request, as soon as agreement is achieved, in one unbound copy on white paper with original signatures, and in electronic format using the NEF application. Any required supporting documentation should be provided in one copy, if not requested differently by the Project Officer.

6. THE DESCRIPTION OF WORK – ANNEX I TO THE *GRANT AGREEMENT*

The following sections provide the structure of Annex I to the *grant agreement* (description of work) for the International Research Staff Exchange Scheme (IRSES). The Annex I is an integral part of the *grant agreement*.

Noncompliance or non-fulfilment of its content will have the same legal consequences as for any default of the other contractual conditions. It should be negotiated between the *beneficiary* and the Project Officer.

It should be written in a clear, precise and concise manner. It should specify all the tasks to be undertaken and the corresponding deliverables, but with sufficient flexibility in order to be able to modify the work arrangements so as to achieve the stated objectives, should this be necessary, without the need for a formal modification of the text (i.e. amendment). This flexibility is required both for the *Commission* as well as for the partnership.

Annex I to the *grant agreement* (Description of Work) consists of the description of the work to be carried on, the implementation process, the budget breakdown and the list of deliverables.

Annex I – Table of contents

1. *Grant agreement* details
2. List of *partner organisations*
3. Project summary
4. Quality of the Exchange Programme
5. Transfer of Knowledge
6. Implementation
7. Impact
8. Ethics (if any)
9. Overall Maximum Community Contribution (*tables A3.1 and A3.2 from the GPFs*)

All pages of Annex I must be numbered and each page should be headed with the project acronym, proposal number and actual drafting date.

Annex I is drafted on information from the proposal and on any information contained in the Evaluation Summary Report. It should also take into consideration any financial and technical issues that may arise during negotiation.

Although certain parts of the proposal description can be taken as the basis for the drafting of this description of work, during the negotiation stage several sections of the original proposal need to be updated and the partnership may be requested to shorten certain sections of the proposal and elaborate on others. The Annex I should exclude all background material in support of the selection of the proposal, and not essential for the implementation of the selected project. For example, references to publications or previous work undertaken and future intentions of the partnership should be excluded. Any reference to “the proposal” should be omitted. A template (see Appendix 4) sets out the layout that must be used when drafting Annex I.

7. APPENDICES

7.1. Appendix 1 – Layout of Negotiation Mandate

1. **Proposal N°:**
2. **Strategic Objective:** Marie Curie Actions International Research Staff Exchange Scheme, call FP7-PEOPLE-IRSES-2008
3. **Project Officer** (to whom all documents must be returned):
4. **Duration of the project:**
5. **Recommendations from the expert evaluators:**
6. **Action for Commission services:**
7. **Maximum budget:**
8. **Timetable for negotiation:**

Indicative end of negotiations defined at the official launch of negotiations

7.2. Appendix 2 – Negotiation of ethical issues

http://ec.europa.eu/research/science-society/page_en.cfm?id=3198

Ethics is central to scientific integrity, honesty and clarity of science. It is considered essential by the *Commission* 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 activity; 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.

Proposals with serious ethical issues together with those that did not address ethical issues adequately will have been identified by the scientific evaluation as needing additional attention by an ethical review panel.

If a project has been subject to ethical review, *grant agreement* negotiation can not be concluded without taking full account of the ethics review report which should also form part of the technical annex to the grant agreement.

The ethical review within FP7 has two important functions:

1. To ensure that the Commission can be confident that it is not funding any research that is ethically unsound.
2. To continually raise awareness amongst researchers of ethical issues that may be raised by their research and enable them to adequately address these. This is particularly important for new and developing areas of research and technology (Genomics, IT, Nanotechnology and Security Technologies for example), which previously may have had little need to address ethical issues in research projects but where new developments are leading to innovative research in areas where ethical considerations become important.

Normally an ethics review will have been carried out and the Ethics Review Report will be available by the time grant agreement negotiations begin. However, for some proposals requiring an ethical review this may not be the case. In this event, the beneficiary will be informed that an ethical review is still in progress and that the outcome of the ethical review will need to be taken into account and may change or may add to the final result of the scientific evaluation.

If the proposal contravenes the fundamental ethical rules of FP7 and this is unable to be resolved, the project may be stopped at any point in the evaluation/ negotiation/award process¹³.

Management

Where ethical issues are addressed by the project proposal, appropriate management of these issues should be guaranteed in the overall project management. This can be done in different ways, such as by involving one or more ethicist in the management board, by creating a separate management board for the ethical issues, by adding a work package to analyse in depth the important ethical issues involved or by working on an ethical impact assessment of the project. Sometime it might be advisable to choose a mixture of these measures.

Reporting

The annual report should devote a section to describing the handling of the ethical aspects of the project.

The ethical review report in grant agreement negotiation

The ethical review report has three elements that have to be taken into account in the negotiation of Annex I to grant agreement.

- **Requirements:** These conditions have been identified as necessary in order to fulfil FP7 ethical rules. The requirements will refer to the individual activities in which they must be incorporated. Annex I must demonstrate that these conditions have been accepted and are followed by the beneficiary.

Where additional information is required such as the approval of a national authority or a local ethics committee, the beneficiary must ensure these are obtained prior to starting the relevant experiments. In order to avoid 'micro management' and over burdening the Project Officer the majority of such approvals can be retrospectively checked in each progress report.

- **Recommendations:** Recommendations from the Ethical Report panel for improving the ethical soundness of the project should be subject to the negotiation process.
- **Follow Up:** Identification of any aspects of the project where ethical issues may need to be considered or reconsidered at a later stage.

The beneficiary has to describe any ethical issues that may arise in the proposal. In particular, he/she 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:

¹³ COUNCIL REGULATION (EURATOM) No 1908/2006 of 19 December 2006 laying down the rules for the participation of undertakings, research centers and universities in actions under the Seventh Framework Programme of the European Atomic Energy Community and for the dissemination of research results (2007-2011), – OJ L400 of 30.12.2006.p.1, Regulation as last amended by Corrigendum OJ L54 of 22.02.2007, p4 - Article 14.2

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 beings¹⁴; 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 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

FOR MORE INFORMATION

- Guide for Applicants and Ethics Review guidance: <http://cordis.europa.eu/fp7/dc/index.cfm>
- Experts' registration: <https://cordis.europa.eu/emmp7/>
- 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

¹⁴ Such as clinical trials, and research involving invasive techniques on persons (e.g. taking of tissue samples, examinations of the brain).

7.3. Appendix 3 – Negotiation checklist template

The following template is designed to ensure that all information necessary to issue a *grant agreement* is discussed and delivered to the *Commission Services*.

Although the first negotiation meeting (or contact by phone /email, in case no meeting is planned) will mainly concentrate on the Annex I to *grant agreement* (description of work), it will also touch financial and legal issues. The partnership should therefore have prepared for discussion all the issues in the checklist for the first meeting. Indeed in some cases the *Commission* Project Officer will indicate in advance that he/she would like to tackle both aspects of discussion in a single meeting / contact.

CHECK LIST FOR PROJECT NEGOTIATIONS

Prior to first contact	
Agree other partners' roles	
Establish <i>Partnership Agreement</i>	
Complete first draft of Annex I and any appendices	
Complete first draft of GPFs, including bank account information	
Collect necessary supporting information / documents for GPFs (financial and legal information)	
Dispatch Annex I and GPFs to <i>Commission</i> Project Officer	
Discuss issues in draft Annex I	
Those addressed by ESR	
Those indicated by 'Negotiation Mandate' and arising during meeting/contact	
Those related to individual headings in Annex I 'table of contents'	
Meeting / Contact	
Set/agree date for submission of revised/final Annex I and GPFs	
Clarify financial/<i>grant agreement</i> issues	
Confirm resources that make up the counterpart funding for the project - clarify extent of beneficiary other involvement in FP7/other	

EU programmes	
Confirm agreement on management costs	
Confirm agreement on Budget breakdown summaries (including receipts)	
Confirm <i>Beneficiary's</i> direct/indirect costs	

Final submission	
Submit agreed final Annex I	
Submit agreed final GPFs	
Submit any annexes	
Copy of <i>Partnership agreement</i>	

7.4. Appendix 4 – Guidelines for the preparation of the description of work - Annex I to the grant agreement

The following sections provide the structure of Annex I to the *grant agreement* (description of work) for Marie Curie IRSES. The Annex I is an integral part of the *grant agreement*. Non-compliance or non-fulfilment of its content will have the same legal consequences as for any default of the other contractual conditions. It should be negotiated between the *Beneficiary* and the Project Officer.

It should be written in a clear, precise and concise manner. It should specify all the tasks to be undertaken and the corresponding Annex I, but with sufficient flexibility in order to be able to modify the work arrangements so as to achieve the stated objectives, should this be necessary, without the need for a formal modification of the text (i.e. *grant agreement* amendment). This flexibility is required both for the *Commission* as well as for the beneficiary.

Annotated Structure of Annex I to *grant agreement*

Annex I to the *grant agreement* consists of four parts: Part A (list of *partner organisations* and project summary), Part B (Description of the joint research training programme), Part C (Overall Maximum Community Contribution).

All pages must be numbered and each page should be headed with the project acronym, proposal number and actual drafting date. It must be written in the third person and should be typically of about ten pages in length, excluding tables and diagrams. It should be printed on single-sided, numbered A4 pages in Times New or Arial at least 12 point or similar font with single line spacing, margins of at least 2.0 cm and according to the following instructions and guidelines.

Part A of Annex I is comprised of copies of the list of *partner organisations* and project summary from form A1 of the GPF.

Part B of Annex I is based on information from Part B of the proposal, on any information contained in the Evaluation Summary Report and in the Negotiation Mandate. It should also take into consideration any financial and technical issues that may arise during negotiation.

However, during the negotiation stage several sections of the original proposal need to be updated and the partnership may be requested to shorten certain sections of the proposal and elaborate on others. The Part B of Annex I should exclude all background material in support of the selection of the proposal, and not essential for the implementation of the selected project. For example, references to publications or previous work undertaken and future intentions of the partnership should be excluded. Any reference to “the proposal” should be omitted.

Part C of Annex I is based on information from A3.1 and form A3.2 of the GPF.

The structure of Annex I to grant agreement (description of work) is similar for all funding schemes; however, in certain parts it is funding scheme specific. The

following sections provide an annotated structure of Annex I for Marie Curie Actions, IRSES.

Structure of Annex I to grant agreement for Marie Curie Actions

PART A

- A.1 *Grant agreement details*
- A.2 List of *partner organisations*
- A.3 Project summary

PART B

B 1 Quality of the Exchange Programme

- B 1.1 Objectives and relevance of the joint exchange programme
- B 1.2 Scientific quality of the partners
- B 1.3 Complementarities/synergies between the partners

B 2 Transfer of Knowledge

- B 2.1 Quality and mutual benefit of the transfer of knowledge
- B2.2 Adequacy and role of staff exchanged with respect to the transfer of knowledge

B 3 Implementation

- B 3.1 Capacities (expertise/human resources/facilities/infrastructure) to achieve the objectives of the planned cooperation
- B 3.2 Appropriateness of the plans for the overall management of the exchange programme

B 4 Impact

- B 4.1 Relevance of the proposed partnership to the area of collaboration and for the ERA
- B 4.2 Potential to develop lasting collaboration with the eligible Third Country partners.

B 5 Ethics

PART C

- C.1 Overall Maximum Community Contribution** (*tables A3.1 and A3.2 from the GPFs*)

Templates for Annex I

Cover Page

The cover page of Annex I to the grant agreement is based on proposal information and the project acronym used in the proposal should not be changed

SEVENTH FRAMEWORK PROGRAMME
Marie Curie Actions
People
International Research Staff Exchange Scheme

<i>Annex I - "Description of Work"</i>

DESCRIPTION OF WORK

PART A

1. *Grant agreement details*

Full Title:

Acronym:

Proposal Number:

Scientific Panel:

Grant Agreement Number:

Duration of the project:

2. List of *partner organisations*

Partner Number *	Partner name	Partner short name	Country
1 (<i>beneficiary</i>)			
2 partner organisations			
3			
...			

* Please use the same partner *beneficiary* numbering as that used in the grant agreement Preparation Forms

** Normally insert “month 1 (start of project)” and “month n (end of project)”

3. Project summary

(Provide a 1 page overview of the project in terms of overall objectives, state of the art, approach and methodology)

PART B

4. Quality of the Exchange Programme

This section should be based on Part B.1 of the original proposal.

4.1 Objectives and relevance of the joint research exchange programme

- Describe the objectives of the joint research exchange programme
- Give an overall description of the exchange scheme and the planned scientific activities

Please add to this section:

- § the description of the Work Packages divided by specific tasks
- § the list of milestones, where appropriate
- § the Gantt Chart of secondments

The tables which are proposed below can be taken as example:

Table 1- List of Work Packages

Work package No	Work package title	Lead Partner organisation short name	Start month	End month
1				
2				
..		
	TOTAL			

Table 2- Work Packages¹⁵

The work packages should be described one by one.

Work package number	1	Start date or starting event:	Month...
Work package title	...		
Partner short name	...		

Objectives
...

Description of work

Task 1.1 :
Task 1.2:
Task 1.3:

Deliverables

D1.1
D1.2
 ...

Researchers involved
 ...

¹⁵ The planning of a work package should be sufficiently detailed to justify the proposed effort and to allow progress monitoring by the Commission. A work package of an IRSES proposal may concern the exchange of researcher, the joint research and training activities or joint workshops and seminars, as well as other networking activities.

- Demonstrate that the numbers of exchanged staff and the duration of their exchange are adequate to achieve the objectives of the programme.

4.2 Scientific quality of the partners

- Describe the expertise of the partners in the scientific fields of the cooperation and list their experience in international cooperation

4.3 Complementarities/synergies between the partners

- Describe the complementarities and synergies between the partners. Illustrate how these complementarities and synergies will contribute to achieve the objectives of the programme

5. Transfer of Knowledge

This section should be based on Part B.2 of the original proposal.

5.1 Quality and mutual benefit of the transfer of knowledge

- Describe the programme for the transfer of knowledge between the partners. Please give detailed information about e.g. the number of workshops/conferences/training, the target audience, sustainability of the knowledge transfer, etc.
- Describe the added value (in terms of gained knowledge) for the partners involved

5.2 Adequacy and role of staff exchanged with respect to the transfer of knowledge

- Describe the role of the exchanged researchers and their specific expertise. Define the goals to be achieved through their exchange
- If applicable: describe the reasons for exchanging managerial/technical staff and explain their specific role and the goals to be achieved through their exchange

6. Implementation

This section should be based on Part B.3 of the original proposal.

6.1 Capacities (expertise/human resources/facilities/infrastructure) to achieve the objectives of the planned cooperation

- Give a detailed description of the expertise and the human resources/facilities/infrastructure at the partner institutions

6.2 Appropriateness of the plans for the overall management of the exchange programme

- Describe the detailed management plan of the exchange scheme (e.g. support for detached and incoming personnel (detailed table with expected exchanges))

- Demonstrate that the complementarities and synergies between the partners are well exploited

7. Impact

This section should be based on Part B.4 of the original proposal.

7.1 Relevance of the proposed partnership to the area of collaboration and for the European Research Area¹⁶

- Describe the partnership's contribution to the area of collaboration
- Describe the relevance of the exchange between the partner countries for ERA

7.2 Potential to develop lasting collaboration with the eligible Third Country partners

- Give a detailed overview over the measures taken to create or reinforce a lasting cooperation between the partners

8. Ethics

Ethics is central to scientific integrity, honesty and clarity of science. It is considered essential by the *Commission* 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.

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.

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.

¹⁶ Towards a European Research Area, 18 January 2000. COM(2000)6

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 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.
- Identify 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.
- Code or anonymise 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 partnership 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, 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/emmp7/>
- 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
- Ethics in EU Research Projects:
http://ec.europa.eu/research/science-society/page_en.cfm?id=3198

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

	YES	PAGE
Informed Consent		
Does the proposal involve children?		
Does the proposal involve patients or persons not able to give consent?		
Does the proposal involve adult healthy volunteers?		
Does the proposal involve Human Genetic Material?		
Does the proposal involve Human biological samples?		
Does the proposal involve Human data collection?		
Research on Human embryo/foetus		
Does the proposal involve Human Embryos?		
Does the proposal involve Human Foetal Tissue / Cells?		
Does the proposal involve Human Embryonic Stem Cells?		
Privacy		
Does the proposal involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)		
Does the proposal involve tracking the location or observation of people?		
Research on Animals		
Does the proposal involve research on animals?		
Are those animals transgenic small laboratory animals?		
Are those animals transgenic farm animals?		
Are those animals cloning farm animals?		
Are those animals non-human primates?		
Research Involving Developing Countries		
Use of local resources (genetic, animal, plant etc)		
Impact on a local community		
Dual Use and potential for terrorist abuse		
Research having direct military application		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

PART C

9. Overall Maximum Community Contribution (Tables A3.1 & A3.2)

Tables A3.1 and A3.2 from the GPFs.

Pre-financing: This amount is intended to provide the *beneficiary* with a float in between periods and it would be agreed during negotiations. As an indication, for projects with one of two reporting periods, the amount of the pre-financing could be between 60-80% of the total Community financial contribution.