



GUIDE FOR APPLICANTS

*COORDINATION AND SUPPORT ACTION
(SUPPORTING)*

Annexes, specific to call:

Call identifier FP7-2012-2013-1

This part of the guide contains the annexes for the specific call and funding scheme shown above. It should be read in conjunction with the common part of the guide, published as a separate document, which contains the general information for applying to FP7 under this funding scheme.

Specialised and technical assistance:

eFP7 Service Desk	http://ec.europa.eu/research/participants/portal/page/contactus
CORDIS help desk	http://cordis.europa.eu/guidance/helpdesk/home_en.html
EPSS Help desk	support@epss-fp7.org
IPR help desk	http://www.ipr-helpdesk.org
Ethics help desk	http://cordis.europa.eu/fp7/get-support_en.html

You may also wish to consult the following documents that can be found at
http://cordis.europa.eu/fp7/find-doc_en.html

FP7 Legal basis documents generally applicable

- Decision on the Framework Programme
- Rules for Participation
- Specific Programmes
- Work Programmes

Legal documents for implementation

- Rules for submission, evaluation, selection, award
- Standard model grant agreement
- Rules on verification of existence, legal status, operational and financial capacity

Guidance documents

- Guidance Notes on Audit Certification Guide for beneficiaries Guide to Financial Issues
- Guide to IPR
- Checklist for the Consortium Agreement
- Negotiation Guidance Notes and Templates for Description of Work

Other supporting information

- Brochure "The FP7 in Brief"
- European Charter for researchers and the Code of Conduct for their recruitment
- International cooperation
- Risk Sharing Financing Facility and the European Investment Bank

Ethics Review

- Ethics check list
- Supporting documents

- Participants are located either in a EU convergence region (including phasing out) or an outermost region.
- Subject to international instruments associating third countries to the 7th EC Framework Programme, other regions may become eligible for participation; the modalities for the identification of eligible regions will be defined in these international instruments (Associated countries to FP7). All regions of Albania, Bosnia-Herzegovina, Croatia, FYROM, Montenegro, Serbia, Turkey and Galilee region of Israel are eligible for participation.
- The participant should be an existing working unit either independent or functioning in the frame of a locally established public or private research organisation of a significant size.
- The participant should not be a subsidiary or a branch of an organisation established in another country than the participant's one.

Where a maximum number of pages have been indicated for a section of the proposal, or for the proposal as a whole, the experts will be instructed to disregard any excess pages.

The Commission/agency establishes a list of experts capable of evaluating the proposals that have been received. The list is drawn up to ensure:

- A high level of expertise;
- An appropriate range of competencies;

Provided that the above conditions can be satisfied, other factors are also taken into consideration:

- An appropriate balance between academic and industrial expertise and users;
- A reasonable gender balance;
- A reasonable distribution of geographical origins;
- Regular rotation of experts

In constituting the lists of experts, the Commission/agency also takes account of their abilities to appreciate the industrial and/or societal as well as innovation dimension of the proposed work. Experts must also have the appropriate language skills required for the proposals to be evaluated.

Commission/agency staff allocates proposals to individual experts, taking account of the fields of expertise of the experts, and avoiding conflicts of interest.

3. Evaluation of proposals

At the beginning of the evaluation, experts will be briefed by Commission/agency staff, covering the evaluation procedure, the experts' responsibilities, the issues involved in the particular area/objective, and other relevant material (including the integration of the innovation dimension).

Each proposal will first be assessed independently by at least three experts.

The proposal will be evaluated against pre-determined evaluation criteria.

Evaluation scores will be awarded for each of the three criteria, and not for the sub-criteria. The sub-criteria are issues which the expert should consider in the assessment of that criterion. They also act as reminders of issues to raise later during the discussions of the proposal.

The relevance of a proposal will be considered in relation to the work programme and to the objectives of a call. These aspects will be integrated in the application of the criterion "S/T quality", and the first sub-criterion under "Impact" respectively. When a proposal is partially relevant because it only marginally addresses the topic(s) of the call, or if only part of the proposal addresses the topic(s), this condition will be reflected in the scoring of the first criterion. Proposals that are clearly not relevant to a call ("out of scope") will be rejected on eligibility grounds.

The elaboration of a strategic Intellectual Property development plan and innovation capacity building will be evaluated under the evaluation criterion "S/T Quality".

The innovation dimension of a proposal as a whole will be evaluated under the evaluation criterion "Impact".

Each criterion will be scored out of 5. Half marks can be given.

The scores indicate the following with respect to the criterion under examination:

- | | |
|-----|--|
| 0 - | <i>The proposal fails to address the criterion under examination or cannot be judged due to missing or incomplete information.</i> |
| 1 - | <i>Poor. The criterion is addressed in an inadequate manner, or there are serious inherent weaknesses.</i> |
| 2 - | <i>Fair. While the proposal broadly addresses the criterion, there are significant weaknesses.</i> |
| 3 - | <i>Good. The proposal addresses the criterion well, although improvements would be necessary.</i> |
| 4 - | <i>Very good. The proposal addresses the criterion very well, although certain improvements are still possible.</i> |
| 5 - | <i>Excellent. The proposal successfully addresses all relevant aspects of the criterion in question. Any shortcomings are minor.</i> |

No weightings will be applied.

Thresholds will be applied to the scores. The threshold for individual criteria will be 3. The overall threshold, applying to the sum of the three individual scores, will be 10.

Examples of the evaluation forms and reports that will be used by the experts in this call will be made available on CORDIS and on the Participant Portal.

Conflicts of interest: Under the terms of the appointment letter, experts must declare beforehand any known conflicts of interest, and must immediately inform a Commission/agency staff member if one becomes apparent during the course of the evaluation. The Commission/agency will take whatever action is necessary to remove any conflict.

Confidentiality: The appointment letter also requires experts to maintain strict confidentiality with respect to the whole evaluation process. They must follow any instruction given by the Commission/agency to ensure this. Under no circumstance may an expert attempt to contact an applicant on his own account, either during the evaluation or afterwards.

Outcome of consensus

The outcome of the consensus step is the consensus report. This will be signed/approved (either on paper, or electronically) by all experts, or as a minimum, by the "rapporteur" and the moderator. The moderator is responsible for ensuring that the consensus report reflects the consensus reached, expressed in scores and comments. In the case that it is impossible to reach a consensus, the report sets out the majority view of the experts but also records any dissenting views.

The Commission/agency will take the necessary steps to assure the quality of the consensus reports, with particular attention given to clarity, consistency, and appropriate level of detail. If important changes are necessary, the reports will be referred back to the experts concerned.

The signing of the consensus report completes the consensus step.

Evaluation of a resubmitted proposal

In the case of proposals that have been submitted previously to the Commission/agency, the moderator gives the experts the previous evaluation summary report at the consensus stage. If necessary, the experts will be required to provide a clear justification for their scores and comments should these differ markedly from those awarded to the earlier proposal.

6. Panel review

This is the final step involving the independent experts. It allows them to formulate their recommendations to the Commission/agency having had an overview of the results of the consensus step.

The main task of the panel is to examine and compare the consensus reports in a given area, to check on the consistency of the marks applied during the consensus discussions and, where necessary, propose a new set of scores.

The panel comprises experts involved at the consensus step. One panel will cover the whole call. The tasks of the panel will also include recommending a priority order for proposals with the same consensus score.

The panel is chaired by the Commission/agency. The Commission/agency will ensure fair and equal treatment of the proposals in the panel discussions. A panel rapporteur will be appointed to draft the panel's advice.

A ranked list will be drawn up for every indicative budget as shown in the call fiche. The panel can deal with one or more ranked lists for the proposals under evaluation, following the scoring systems indicated above.

Priority order for proposals with the same score

If necessary, the panel will determine a priority order for proposals which have been awarded the same score within a ranked list. Whether or not such a prioritisation is carried out will depend on the available budget or other conditions set out in the call fiche. The following approach will be applied successively for every group of *ex aequo* proposals requiring prioritisation, starting with the highest scored group, and continuing in descending order:

Annex 3:

Instructions for completing "Part A" of the proposal

Proposals in this call must be submitted electronically, using the Commission's Electronic Proposal Submission System (EPSS). The procedure is given in section 3 of this guide.

In Part A you will be asked for certain administrative details that will be used in the evaluation and further processing of your proposal. Part A forms an integral part of your proposal. Details of the work you intend to carry out will be described in Part B (annex 4).

Section A1 gives a snapshot of your proposal, section A2 concerns you and your organisation, while section A3 deals with money matters.

Please note:

- The coordinator fills in sections A1, A2 and A3.
- Subcontractors should not fill in section A2 and should not be listed separately in section A3.

Check that your budget figures are correctly entered in Part A. Make sure that:

- Numbers are always rounded to the nearest whole number.
- All costs are given in Euros. Do not express your costs in thousands of Euros ("KEUROS") etc. This can affect decisions on the eligibility of your proposal.
- You have inserted zeros ("0") if there are no costs, or if no funding is requested. Do not leave blanks.
- Costs do not include value added tax.

Note:

The following notes are for information only. They should assist you in completing Part A of your proposal. On-line guidance will also be available. The precise questions and options presented on EPSS may differ slightly from these below.

Section A2: Participants	
Participant number	The number allocated by the consortium to the participant for this proposal. The co-ordinator of a proposal is always number one .
Participant Identification Code	The Participant Identification Code (PIC) enables organisations to take advantage of the Participant Portal. Organisations who have received a PIC from the Commission are encouraged to use it when submitting proposals. By entering a PIC, parts of section A2 will be filled in automatically. An online tool to search for existing PICs and the related organisations is available at http://ec.europa.eu/research/participants/portal . Organisations not yet having a PIC are strongly encouraged to self-register (at http://ec.europa.eu/research/participants/portal) before submitting the proposal and insert in section A2 the temporary PIC received at the end of the self-registration.
Legal name	<p>For Public Law Body, it is the name under which your organisation is registered in the Resolution text, Law, Decree/Decision establishing the Public Entity, or in any other document established at the constitution of the Public Law Body;</p> <p>For Private Law Body, it is the name under which your organisation is registered in the national Official Journal (or equivalent) or in the national company register.</p> <p>For a natural person, it is e.g. Mr Adam JOHNSON, Mrs Anna KUZARA, and Ms Alicia DUPONT.</p>
Organisation Short Name	<p>Choose an abbreviation of your Organisation Legal Name, only for use in this proposal and in all relating documents.</p> <p>This short name should not be more <u>than 20 characters</u> exclusive of special characters (./;...), e.g. CNRS and not C.N.R.S. It should be preferably the one commonly used, e.g. IBM and not Int.Bus.Mac.</p>
Legal address	<p>For Public and Private Law Bodies, it is the address of the entity's Head Office.</p> <p>For Individuals it is the Official Address.</p> <p>If your address is specified by an indicator of location other than a street name and number, please insert this instead under the "street name" field and "N/A" under the "number" field.</p>
Non-profit organisation	Non-profit organisation is a legal entity qualified as such when it is recognised by national or, international law.
Public body	Public body means any legal entity established as such by national law, and international organisations.
Research organisation	Research organisation means a legal entity established as a non-profit organisation which carries out research or technological development as one of its main objectives.
NACE code	<p>NACE means "<u>N</u>omenclature des <u>A</u>ctivités économiques dans la <u>C</u>ommunauté <u>E</u>uropéenne".</p> <p>Please select one activity from the list that best describes your professional and economic ventures. If you are involved in more than one economic activity, please select the one activity that is most relevant in the context of your contribution to the proposed project. For more information on the methodology, structure and full content of NACE (rev. 1.1) classification please consult EUROSTAT at: http://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=LST_CLS_DLD&StrNom=NACE_1_1&StrLanguageCode=EN&StrLayoutCode=HIERARCHIC</p>
Small and Medium-Sized Enterprises (SMEs)	<p>SMEs are micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC in the version of 6 May 2003. The full definition and a guidance booklet can be found at http://ec.europa.eu/enterprise/enterprise_policy/sme_definition/index_en.htm</p> <p>To find out if your organisation corresponds to the definition of an SME you can use the on-line tool at http://ec.europa.eu/research/sme-techweb/index_en.cfm</p>

<p>Method of calculating indirect costs</p>	<p>Summary description (as displayed on EPSS)</p> <ul style="list-style-type: none"> Participants who have an analytical accounting system that can identify and group their indirect costs in accordance with the eligibility criteria (e.g. exclude non-eligible costs) must report their actual indirect costs (or choose the 20% flat rate option referred to below). For the purpose of calculating the actual indirect costs, a participant is allowed to use a simplified method of calculation of its full indirect eligible costs. Optionally, participants may opt for a flat rate for indirect costs of 20% of the direct costs (minus subcontracting and third party costs not incurred on the premises of the participant). A specific flat rate of 60% of the direct costs is foreseen for non-profit public bodies, secondary and higher education establishments, research organisations and SMEs which are unable to identify with certainty their real indirect costs for the project. <p>For Coordination and Support actions, whichever method is used, the reimbursement of indirect eligible costs may not exceed 7% of the direct eligible costs, excluding the direct eligible costs for subcontracting and the costs of reimbursement of resources made available by third parties which are not used on the premises of the participant.</p> <p>Further guidance</p> <p>In FP7 all departments, faculties or institutes which are part of the same legal entity must use the same system of cost calculation (unless a special clause providing for a derogation for a particular department/institute is included in the grant agreement). Under FP7, there are no cost reporting models.</p> <p>1. Participants which have an analytical accounting system that can identify and group their indirect costs (pool of costs) in accordance with the eligibility criteria (e.g. exclude non-eligible costs) must report their actual indirect costs (or choose the 20% flat rate option under 2. below). This method is the same as the "full cost" model used in previous Framework Programmes.</p> <p>For the purpose of calculating the actual indirect costs, a participant is allowed to use a simplified method of calculation of its full indirect eligible costs. The simplified method is a way of declaring indirect costs which applies to organisations which do not aggregate their indirect costs at a detailed level (centre, department), but can aggregate their indirect costs at the level of the legal entity.</p> <p>The simplified method can be used if the organisation does not have an accounting system with a detailed cost allocation. The method has to be in accordance with their usual accounting and management principles and practices; it does not involve necessarily the introduction of a new method just for FP7 purposes. Participants are allowed to use it, provided this simplified approach is based on actual costs derived from the financial accounts of the last closed accounting year.</p> <p>There is no "standard model"; each legal entity will use its own system. The minimum requirements for it to be considered a simplified method for FP7 purposes are the following:</p> <ul style="list-style-type: none"> - the system must allow the participant to identify and remove its direct ineligible costs (VAT, etc.); - it must at least allow for the allocation of the overheads at the level of the legal entity to the individual projects by using a fair "driver" (e.g. total productive hours); - the system applied and the costs declared according to it should follow the normal accounting principles and practices of the participant. Therefore, if the system used by a participant is more "refined" than the "minimum" requirements mentioned here, it is that system which should be used when declaring costs. <p><i>Example: if a participant's accounting system distinguishes between different overheads rates according to the type of activity (research, teaching...), then the overheads declared in an FP7 grant agreement should follow this practice and refer only to the concerned activities (research, demonstration...)</i></p> <p>The simplified method does not require previous registration or certification by the Commission.</p> <p>2. Optionally, participants may opt to declare their actual direct costs plus a flat rate for indirect costs of 20% of the direct costs (minus subcontracting and third party costs not incurred on the premises of the participant). This flat rate is open to any participant whatever the accounting system it uses. Accordingly, when this option is chosen, there is no need for certification of the indirect costs, only of the direct ones.</p> <p>3. Also, a specific flat rate is foreseen for certain types of organisations.</p> <p>The use of this flat rate is subject to three cumulative conditions :</p> <p>(i) Status of the organisation</p>
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	<p style="text-align: center;">Indirect Costs - Decision Tree</p> <p>Do either of these conditions apply? (1) your organisation possesses an analytical accounting system, or (2) you will declare overhead rates using a simplified method</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>YES</p> <p>↓</p> <p>Real indirect costs or costs calculated using a simplified method</p> <p>or</p> <p>20% of total direct eligible costs (1)</p> </div> <div style="text-align: center;"> <p>No</p> <p>↓</p> <p>60% of total direct eligible costs (1), for :</p> <ul style="list-style-type: none"> - Non-profit public bodies, secondary and higher education establishments, research organisations and SMEs - When participating in funding schemes which include research and technological development </div> </div> <p style="text-align: center;">or</p> <p style="text-align: center;">Coordination and support actions : In any case Maximum 7% of the direct eligible costs (1)</p> <p><i>(1) excluding direct eligible costs for subcontracting and the costs of reimbursement of resources made available by third parties which are not used on the premises of the beneficiary</i></p>
<p>International Cooperation Partner Country (ICPC)</p>	<p>International Cooperation Partner Country means a third country which the Commission classifies as a low-income, lower-middle income or upper-middle-income country and which is identified as such in Annex I to the work programmes.</p>
<p>Lump sum funding method</p>	<p>Legal entities established in an ICPC may opt for lump sums. In that case the contribution is based on the amounts shown below, multiplied by the total number of person-years for the project requested by the ICPC legal entity.</p> <ul style="list-style-type: none"> • Low-income ICPC: 8,000 Euro/researcher/year • Lower middle income ICPC: 9,800 Euro/researcher/year • Upper middle income ICPC 20,700 Euro/researcher/year <p>The maximum EC contribution is calculated by applying the normal upper funding limits shown under "requested EC contribution". This amount is all inclusive, covering support towards both the direct and the indirect costs.</p> <p>More information on ICPC lump sums can be found in the section II.18 of the "Guide to financial issues" http://cordis.europa.eu/fp7/find-doc_en.html or on the Participant Portal http://ec.europa.eu/research/participants/portal/page/home</p>

Total Budget	<p><i>Note: The "total budget" is not the requested EC contribution.</i></p> <p>A sum of all the eligible costs, under the respective types of activity.</p>
Requested EC contribution	<p>The requested EC contribution shall be determined by applying the upper funding limits indicated below, per activity and per participant to the costs accepted by the Commission/agency, or to the flat rates or lump sums.</p> <p>Maximum reimbursement rates of eligible costs</p> <ul style="list-style-type: none"> • Support activities = 100% • Other activities (including management) = 100% <p>(*) For participants that are non profit public bodies, secondary and higher education establishments, research organisations and SMEs.</p>
Total Receipts	<p><i>Note: "Receipts" are not the requested EC contribution.</i></p> <p>Receipts of the project may arise from:</p> <p style="padding-left: 40px;">a) Financial transfers or contributions in kind free of charge to the participant from third parties:</p> <p style="padding-left: 80px;">i. shall be considered a receipt of the project if they have been contributed by the third party specifically to be used on the project.</p> <p style="padding-left: 80px;">ii. shall <u>not</u> be considered a receipt of the project if their use is at the management discretion of the participant.</p> <p style="padding-left: 40px;">b) Income generated by the project:</p> <p style="padding-left: 80px;">i. shall be considered receipts for the participant when generated by actions undertaken in carrying out the project and from the sale of assets purchased under the grant agreement up to the value of the cost initially charged to the project by the participant;</p> <p style="padding-left: 80px;">ii. shall <u>not</u> be considered a receipt for the participant when generated from the use of foreground resulting from the project.</p> <p>The EU financial contribution may not have the purpose or effect of producing a profit for the participants. For this reason, the total requested EC funding plus receipts cannot exceed the total eligible costs.</p>

Proposal

1. Scientific and/or technical quality, relevant to the topics addressed by the call

1.1 Concept and objectives

Explain the concept of your project. What are the main ideas that led you to propose this work?

Describe in detail the S&T objectives. Show how they relate to the topics addressed by the call, which you should explicitly identify. The objectives should be those achievable within the project, not through subsequent development. They should be stated in a measurable and verifiable form, including through the milestones that will be indicated under section 1.3 below.

A clear and detailed analysis of Strengths, Weaknesses, Opportunities and Threats (SWOT) of the applicant research entity should be presented. This SWOT analysis should be the basis of the preparation of the *Action Plan* composed by a *coherent set of measures* indicated in the Work Programme.

1.2 Quality and effectiveness of the support mechanisms, and associated work plan

A detailed work plan should be presented, broken down into work packages³ (WPs) which should follow the logical phases of the implementation of the project, and include consortium management and assessment of progress and results. (Please note that your overall approach to management will be described later, in section 2).

Please present your plans as follows:

- i) Describe the overall strategy of the work plan.
- ii) Show the timing of the different WPs and their components (Gantt chart or similar).
- iii) Provide a detailed work description broken down into work packages:
 - Work package list (please use table 1.2a);
 - Deliverables list (please use table 1.2b);
 - List of milestones (please use table 1.2c);
 - Description of each work package, and summary (please use table 1.2d);
 - Summary effort table (please use table 1.2e)
- iv) Provide a graphical presentation of the components showing their interdependencies (Pert diagram or similar)
- v) Describe any significant risks, and associated contingency plans.

Note:

The number of work packages used must be appropriate to the complexity of the work and the overall value of the proposed project. The planning should be sufficiently detailed to justify the proposed effort and allow progress monitoring by the Commission.

Maximum length for the whole of Section 1: Thirty pages. This limit does not include the Gantt chart under 1.2 ii), the tables 1.2a- e, and the Pert diagram under 1.2 iv).

³ A work package is a major sub-division of the proposed project with a verifiable end-point - normally a deliverable or a milestone in the overall project.

Table 1.2 b: Deliverables List

Del. no. ¹	Deliverable name	WP no.	Nature ²	Dissemination level ³	Delivery date ⁴

¹ Deliverable numbers in order of delivery dates. Please use the numbering convention <WP number>.<number of deliverable within that WP>. For example, deliverable 4.2 would be the second deliverable from work package 4.

² Please indicate the nature of the deliverable using one of the following codes:

R = Report, **P** = Prototype, **D** = Demonstrator, **O** = Other

³ Please indicate the dissemination level using one of the following codes:

PU = Public

PP = Restricted to other programme participants (including the Commission Services).

RE = Restricted to a group specified by the consortium (including the Commission Services).

CO = Confidential, only for members of the consortium (including the Commission Services).

⁴ Measured in months from the project start date (month 1).

Table 1.2 d: Work package description

For each work package:

Work package number		Start date or starting event:						
Work package title								
Activity Type¹								
Participant number								
Participant short name								
Person-months per participant:								

Objectives

Description of work (possibly broken down into tasks), and role of participants
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Deliverables (brief description and month of delivery)

¹ Please indicate one activity per work package:
 SUPP = Support activities); MGT = Management of the consortium; OTHER = Other specific activities, if applicable.

2. Implementation

2.1 Management structure and procedures

Describe the organisational structure and decision-making mechanisms of the project. Show how they are matched to the complexity and scale of the project.

(Maximum length for Section 2.1: five pages)

2.2 Individual participants

For the applicant and each partnering organisation in the proposed project, provide a brief description of the legal entity, the main tasks they have been attributed, and the previous experience relevant to those tasks. Provide also a short profile of the staff members who will be undertaking the work.

(Maximum length for Section 2.2: two pages for the applicant and one page per partnering organisation. However, where two or more departments within an organisation have quite distinct roles within the proposal, one page per department is acceptable.)

2.3 Consortium as a whole

Describe how the applicant and its partnering organisations are together capable of achieving the project objectives, and how they are suited and are committed to the tasks assigned to them. Show the complementarity between participants. Explain how the composition of the consortium is well-balanced in relation to the objectives of the project.

Sub-contracting: If any part of the work is to be sub-contracted, describe the work involved and explain why a sub-contract approach has been chosen for it.

(No maximum length applies to this section)

2.4 Resources to be committed

Describe how the totality of the necessary resources will be mobilised, including any resources that will complement the EC contribution. Show how the resources will be integrated in a coherent way, and show how the overall financial plan for the project is adequate.

In addition to the costs indicated in Part A3 of the proposal, and the staff effort shown in section 1.3 above, please indicate any other major costs (e.g. equipment).

Please ensure that the figures stated in part B are consistent with those in Part A.

(No maximum length applies to this section)

3. Impact

3.1 Expected impacts listed in the work programme

Describe how your project will contribute towards the expected impacts listed in the work programme in relation to the topic in question. Mention the steps that will be needed to bring about these impacts. Explain why this contribution requires a European (rather than a national or local) approach. Indicate how account is taken of other national or international research activities. Mention any assumptions and external factors that may determine whether the impacts will be achieved.

(in particular, stem cells from other sources or origins) are not suitable and/or available to achieve the expected goals of the proposal. This latter provision does not apply to research comparing hESC with other human stem cells;

- the applicants should take into account the legislation, regulations, ethics rules and/or codes of conduct in place in the country(ies) where the research using hESC is to take place, including the procedures for obtaining informed consent;
- the applicants should ensure that for hESC lines to be used in the project were derived from embryo's
 - of which the donor(s)' express, written and informed consent was provided freely, in accordance with national legislation prior to the procurement of the cells;
 - that result from medically-assisted *in vitro* fertilisation designed to induce pregnancy, and were no longer to be used for that purpose;
 - of which the measures to protect personal data and privacy of donor(s), including genetic data, are in place during the procurement and for any use thereafter. Researchers must accordingly present all data in such a way as to ensure donor anonymity;
 - of which the conditions of donation are adequate, namely that no pressure was put on the donor(s) at any stage, that no financial inducement was offered to donation for research at any stage and that the infertility treatment and research activities were kept appropriately separate

Include the Ethics issues table below. If you indicate YES to any issue, please identify the pages in the proposal where this ethics issue is described. Answering 'YES' to some of these boxes does not automatically lead to an ethics review. It basically enables the independent experts to decide if an ethics review is required. If you are sure that none of the issues apply to your proposal, simply tick the YES box in the last row.

(No maximum length for Section 4: Depends on the number of such issues involved)

Notes:

Only in exceptional cases will additional information be sought for clarification, which means that any ethics review will be performed solely on the basis of the information available in the proposal.

Projects raising specific ethics issues such as research intervention on human beings¹; research on human embryos and human embryonic stem cells and non-human primates are automatically submitted for ethics review.

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

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

Additional information (reference documents, EU and International legislation etc) can be found in the EUROPA research site:

<http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1289&lang=1>

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

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 Animals¹		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 non-EU Countries (ICPC Countries²)		YES	Page
	Is any material used in the research (e.g. personal data, animal and/or human tissue samples, genetic material, live animals, etc) :		
	a) Collected and processed in any of the ICPC countries?		
	b) Exported to any other country (including ICPC and EU Member States)?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

Dual Use³		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		

¹ The type of animals involved in the research that fall under the scope of the Commission’s Ethical Scrutiny procedures are defined in the Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes, Official Journal L 358, 18/12/1986 p. 0001–0028.

² In accordance with Article 12(1) of the Rules for Participation in FP7, ‘International Cooperation Partner Country (ICPC)’ means a third country which the Commission classifies as a low-income (L), lower-middle-income (LM) or upper-middle-income (UM) country. Countries associated to the Seventh EC Framework Programme do not qualify as ICP Countries and therefore do not appear in this list.

³ ‘Dual-use items’ shall mean items, including software and technology, which can be used for both civil and military purposes (Ref: Article 3, Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.