European Research Council

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ERC Proof of Concept Grants

Information for applicants to the

Proof of Concept Grant 2015 Call

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http://ec.europa.eu/research/participants/portal/

EUROPEAN COMMISSION

Horizon 2020 Specific Programme
Part 1
Excellent Science

Purpose of this document[1]

This document provides practical information to potential applicants in preparing and submitting an application for an ERC Proof of Concept Grant.

The document is divided into two parts:

1: Applying for an ERC Proof of Concept Grant

2: Annexes

The present document is based on the legal documents setting the rules and conditions for the ERC frontier research grants and for other ERC actions, in particular the ERC Work Programme 2015[2], *the ERC Rules for the submission of proposals* and the related evaluation, selection and award procedures relevant to the Specific Programme of H2020 – the Framework programme for research and Innovation (2014-2020) (hereinafter ERC Rules for Submission), and the ERC Model Grant Agreement. This document does not supersede the afore-mentioned documents, which are legally binding. Should there be any discrepancies between the aforementioned legal documents and this document, the former will prevail. The European Commission, the ERC Executive Agency or any person or body acting on their behalf cannot be held responsible for the use made of this document.

This *Information for Applicants document* may be further modified based on the experiences gained from preceding calls for proposals, on changes applied to Proof of Concept grants and the submission processes.

Note: As with other parts of the EU's Horizon 2020 Framework Programme, National Contact Points (ERC NCPs) have been set up across Europe[3] by the national governments to provide information and personalised support to ERC applicants in their native language. The mission of the ERC NCPs is to raise awareness, inform and advise on ERC funding opportunities as well as to support potential applicants in the preparation, submission and follow-up of ERC grant applications. For details on the ERC NCP in your country please consult the ERC website at http://erc.europa.eu/national-contact-points or the Participant Portal on https://ec.europa.eu/research/participants/portal/desktop/en/support/national_contact_points.html.

[1] This document is referred to as the 'Information for Applicants' in the ERC Work Programme 2015.

[2] European Commission C(2014)5008 of 22 July 2014.

[3] This applies to EU Member States and Associated Countries. Some other countries also provide this service.

Highlights of important new features related to proposal submission and evaluation for the ERC Proof of Concept Grant 2015 call

Applications can be submitted at any time from the opening date of the call until the final deadline and will be evaluated and selected in three rounds, based on three specific deadlines. A Principal Investigator may submit only one eligible application per call.

New template for Proposal Part B as well as the host institution support letter available for download in PPSS includes the following change:

- ***The proposal template has been slightly updated (Part B)***

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1: Applying for an ERC Proof of Concept Grant

1.1 Preparing and submitting an ERC Proof of Concept Grant application

1.1.1 Objectives and principles of ERC Proof of Concept Grant 2015

The ERC Work Programme 2015 sets out the Objectives and Principles of ERC funding. The ERC Proof of Concept Grants aim to maximise the value of the excellent research that the ERC funds, by funding further work (i.e. activities which were not scheduled to be funded by the original ERC frontier research grant) to verify the innovation potential of ideas arising from ERC funded projects.

The objective is to provide funds to enable ERC-funded ideas to be brought to a pre-demonstration stage where potential commercialisation opportunities have been identified.

Innovations can be commercialised through licenses to a new or existing company or through a venture funded start-up, depending on the nature of the invention/idea, its potential markets, and the inventor's plans for future involvement in the commercialisation. Innovations can also feed into ventures aimed at addressing social and environmental goals including by social entrepreneurs and the voluntary and not-for-profit sectors.

This action is open to Principal Investigators (PI) already benefitting from an ERC frontier research grant (Starting, Consolidator, Advance and Synergy) of any nationality who intends to conduct their Proof of Concept activity in any EU Member State[4] or Associated Country[5].

Proof of Concept Grants are therefore on offer only to ERC grant holders (PI) whose proposals draw substantially on their ERC funded research.

The ERC Proof of Concept call aims at supporting ERC grant-holders to establish the innovation potential of their idea during the pre-demonstration phase.

This would help among others:

- establishing viability, technical issues and overall direction
- clarifying IPR position and strategy
- providing feedback for budgeting and other forms of commercial discussion
- providing connections to later stage funding
- covering initial expenses for establishing a company

[4] The EU Member States are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and United Kingdom.

[5] The Associated Countries are: Albania, Bosnia and Herzegovina, Israel, the Faroe Islands, FYR Macedonia, Iceland, Israel, Montenegro, Norway, Republic of Moldova, Serbia and Turkey. Other countries may become associated during the course of H2020. The association of Switzerland to specific programmes of Horizon 2020 allows for applicants with Swiss Host Institutions to apply to the ERC as from September 2014..

Box 1 Guiding principles of the ERC Proof of Concept Grants

- Only Principal Investigators of an ERC frontier research grant may apply.
- Aim is to verify the innovation potential of an idea arising from an ERC-funded project.
- Clear separation between activities to be funded and activities already funded under the ERC frontier research grant is needed.
- Grants are awarded to the host institution that engages the PI.
- Host institutions must be established in an EU Member State[4] or Associated Country[5].

Size of ERC Proof of Concept Grants

Proof of Concept grants can be up to a maximum of **EUR 150 000** for a period of **18 months**. The ERC expects that normally, proof of concept projects should be completed within 12 months. However, to allow for those projects that require more preparation time, projects will be signed for 18 months. Given this initial flexibility, extensions of the duration of proof of concept projects may be granted only exceptionally.

The European Union financial contribution will take the form of the reimbursement of up to 100% of the total eligible and approved direct costs and of a flat-rate financing of indirect costs on the basis of **25% of the total eligible direct costs**[6].

Specific Eligibility Criteria

	Proof of Concept Grant
Specific Eligibility Criteria	The PI must be an ERC frontier research grant holder that is either on-going or where the project fixed in the ERC Grant Agreement has ended less than 12 month before the opening date of this call. The PoC proposal has to draw substantially on an ERC funded research. The relation between the idea to be taken to proof of concept and the ERC frontier research project (Starting, Consolidator, Advanced or Synergy) in question must be demonstrated.

Eligible Host Institutions

The host institution must engage the Principal Investigator for at least the duration of the project, as defined in the ERC model grant agreement. It must either be established in an EU Member State or Associated Country, or it may be an International European Interest Organisation (such as CERN, EMBL, etc.), the European Commission's Joint Research Centre (JRC) or any other entity created

[6] In H2020 it is not possible to ask lower percentages for the indirect costs. Eligible direct cost: excluding the direct costs for subcontracting and the costs of resources made available by third parties, which are not used on the premises of the host institution.

under EU law. Any type of legal entity, public or private, including universities, research organisations and undertakings can host Principal Investigators and their teams.
As part of the application, the host institution must provide a binding statement according to the template annexed to this document (see Annex 1), proving its engagement to the Principal Investigator for at least the duration of the proof of concept project. Proposals that do not include this institutional statement will be ruled ineligible and not considered for evaluation.

Ethical Issues

Some frontier research activities and methodologies may have ethics implications or may raise questions which will require sound ethical assessment in order to ensure that research supported by an ERC grant respects the fundamental ethics principles (see point 1.2.3 and Annex 2 to this document).

Research Integrity

Cases of scientific misconduct such as fabrication, falsification, plagiarism or misrepresentation of data will be considered as breaches of fundamental ethical principles and the proposals concerned may be excluded in accordance with section 3.11 of the ERC Rules for Submission.

Preparing and submitting an ERC Proof of Concept Grant application[7]

ERC grant applications can be submitted only in response to a '**call for proposals**'. Calls announced in the ERC Work Programme 2015 are published on the ERC website[8], the Research and Innovation Participant Portal[9], and in the Official Journal of the European Union[10].

It is a continuous call with three deadlines; an applicant may submit only one eligible application per call. The provisional timing of evaluation will be updated on a regular basis on the ERC website.

The submission deadlines foreseen are:

ERC-2015-PoC-1: 5th February 2015, 17.00 (Brussels local time)

ERC-2015-PoC-2: 28th May 2015, 17.00 (Brussels local time)

ERC-2015-PoC-3: 1st October 2015, 17.00 (Brussels local time)

Please note that the foreseen submission deadlines could be modified after the publication of the calls. You are therefore invited to periodically consult the Research and Innovation Participant Portal[9] where any modifications of the submission deadlines are indicated.

Box 2 Key features of the ERC grant application procedure

- Applications should be submitted by a single PI in conjunction with and on behalf of her/his host institution, which is the applicant legal entity.
- Submission is accepted only via the web-based Participant Portal Submission Service (PPSS). The application procedure consists of a **single submission stage**.
- A complete ERC PoC proposal consists of three separate components:
  - **The online administrative 'Proposal Submission Forms'**
  - **The proposal (Part B), and**
  - **The supporting documentation (host institution support letter, and any further documentation related to eligibility and ethics).**
- Proposal format and number of pages are strictly limited.

[7] The working language of the ERC evaluation panels is English. Please note that accordingly the evaluation reports will be available in English only. If the proposal is not in English, a translation of the full proposal would be of assistance to the experts. An English translation of the abstract must be included in the proposal.
[8] http://erc.europa.eu/
[9] http://ec.europa.eu/research/participants/portal
[10] http://eur-lex.europa.eu/JOIndex.do?ihmlang=en

1.1.2 How to complete the grant application

1.1.2.1 Instructions for completing the online administrative Proposal Submission Forms [11]

Proposals must be submitted electronically via the web-based Participant Portal Submission Service (PPSS). Please read point 1.1.3 of this document before starting the pre-registration process. The PPSS Guide is available online at
http://ec.europa.eu/research/participants/data/support/sep_usermanual.pdf

In the submission forms, the PI is asked to fill the administrative data online that will be used in the evaluation and further processing of the proposal. The administrative forms are an integral part of the proposal. The proposal submission forms are divided in 5 Sections:

1 – General Information
2 – Administrative data of participating organisations
3 – Budget
4 – Ethics
5 – Call specific questions

Section 1 – General Information contains information about the proposal, including an abstract of the project proposal. Furthermore, section 1 contains declarations related to the proposal and the participation in H2020.

Section 2 – Administrative data of participating organisations contains information about the PI and the PI's host institution[12].

Section 3 – Budget contains information about the total estimated project costs and the requested EU contribution. The amount given in the online financial form (section 3) must correspond exactly to the information provided in the proposal text (Part B, section 4.a resources).

Please ensure that all costs are given in whole Euros (integer), not thousands of Euros.

Section 4 – Ethics serves to identify any ethical aspects of the proposed work. This table has to be completed even if there are no issues (simply confirm that none of the ethical issues apply to the proposal). Please note that, in case you answer YES to any of the questions, you are requested to provide an Ethics Self-Assessment and additional ethics documentation – if applicable, as detailed in the Ethics Issues Table (in Annex 2 to this document).

Section 5 – Call specific questions contains the explanation of the relation between the existing ERC frontier research grant and the proposed PoC (answer to this question is compulsory and will be used for eligibility check) and declarations related to eligibility and permission statements on data-related questions and data protection. Please note that these consents are entirely voluntary.

[11] The Specific Privacy Statement on the protection of personal data related to the "ERC- Proposals Evaluation, Grants Management and Follow-up" is available on the ERC website. Applicants are reminded not to provide irrelevant and excessive data (mainly with regards to health data).
[12] The filling of additional section 2 forms, corresponding to other institutions of team members ('additional participants'), may be necessary.

The following notes are for information only. They should assist you in completing the online proposal Submission forms of your proposal. On-line guidance will also be available. The precise questions and options presented in PPSS may differ slightly from these below.
Please regularly consult the Research and Innovation Participant Portal call page for updated information or contact the PPSS Service Desk by using the Horizon 2020 Help Desk http://ec.europa.eu/research/index.cfm?pg=enquiries or the Participant Portal IT Helpdesk http://ec.europa.eu/research/participants/api/contact/index.html or by contacting the SEP helpdesk on +32 (2) 29 92222.

1 – General information (notes for information ONLY)

Topic	[pre-filled] Chosen upfront on the participant portal call page ERC-PoC-2015.
Call identifier	[pre-filled] The call identifier is the reference number given in the call or part of the call you are applying for, as indicated in the publication of the call in the Research and Innovation Participant Portal – H2020 Calls. A call identifier looks like this: *ERC-2015-PoC*.
Type of Action	[pre-filled] Definition for 'type of action', ERC-PoC.
Proposal Acronym	[pre-filled but editable] The short title or acronym will be used to identify your proposal efficiently in this call. It should be of no more than 20 characters (use standard alphabet and numbers only; no spaces, symbols or special characters please). The same acronym should appear on each page of the proposal.

Proposal Title (max. 200 char.) (non- confidential information)	The title should be no longer than 200 characters and should be understandable to the non-specialist in your field. **In order to best review your application, your agreement is needed below so that this non-confidential title can be used when contacting potential reviewers.**
Free Keywords	Please enter free text keywords that you consider best characterise the scope of your proposal. The choice of keywords should take into account any multi-disciplinary aspects of the proposal.
Duration in months	The estimated duration of the project in full months (0-18 months).
Related ERC project ID number	Mandatory: This is the reference number (6-digit ID number) of the related ERC project. This number can be found in the Grant Agreement or, alternatively, on our website http://erc.europa.eu under the "Funded Projects" link.

End date of the related ERC project (DD/MM/YYYY)	The End date of the Grant Agreement for the ERC related project (which ID was provided before) should be stated. (DD/MM/YYYY)

Abstract (min.100/ max. 2000 char.) (non-confidential information)	The abstract should, at a glance, provide the reader with a clear understanding of the objectives of the proposal and how they will be achieved. The abstract will be used as the short description of your proposal in the evaluation process **and in communications to contact in particular the ERC experts and/or inform the Commission and/or the programme management committees and/or relevant national funding agencies (**The consent for disclosing to relevant national funding agencies the evaluation results of your proposal in case it is recommended for funding is requested below.**). It must therefore be short and precise and should not contain confidential information.** Please use plain typed text, avoiding formulae and other special characters. **The abstract must be written in English**. There is a limit of 2000 characters (spaces and line breaks included).
In order to best review your application, do you agree that the above non confidential proposal title and abstract can be used, without disclosing your identity, when contacting potential reviewers?	[Yes/No] – In the course of the evaluation procedure, the non-confidential title and abstract of your proposal may be communicated to potential remote experts, should your proposal be retained for the evaluation process. Please specify your agreement or disagreement.
Has this proposal (or a very similar one) been previously submitted/funded to a call for proposals of FP7/Horizon 2020/other EU programmes?	[Yes/No] – Please give the proposal reference or contract number.

Failure to respond to the first question below will block the submission. Please select the applicable response in point 4.

Declarations	
1. The Principal Investigator declares to have the explicit consent of all applicants on their participation and on the content of this proposal.	[Yes/No]
2. The information contained in this proposal is correct and complete.	[Yes/No]
3. This proposal complies with ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct).	[Yes/No]
4. The Principal Investigator hereby declares that: **-, in case of multiple participants in the proposal, the coordinator has carried out the self-check of the financial capacity of the organisation on https://ec.europa.eu/research/participants/portal4/desktop/en/**	[Yes/No] – Please tick the one declaration (out of three options) that is applicable to your proposal

organisations/lfv.html. Where the result was "weak" or "insufficient", the coordinator confirms being aware of the measures that may be imposed in accordance with the H2020 Grants Manual (Chapter on Financial capacity check) **-, in case of multiple participants in the proposal, the coordinator is exempt from the financial capacity check being a public body including international organisations, higher or secondary education establishment or a legal entity, whose viability is guaranteed by a Member State or associated country, as defined in the H2020 Grants Manual (Chapter on Financial capacity check)** **- in case of a sole participant in the proposal, the applicant is exempt from the financial capacity check.**	
5. The Principal Investigator hereby declares that each applicant has confirmed: **to have the financial and operational capacity to carry out the proposed action.** **Where the proposal is to be retained for EU funding, each beneficiary applicant will be required to present a formal declaration in this respect.**	[Yes/No] - The Principal Investigator is only responsible for the correctness of the information relating to his/her own organisation. Each applicant remains responsible for the correctness of the information related to him and declared above. Where the proposal to be retained for EU funding, the coordinator and each beneficiary applicant will be required to present a formal declaration in this respect.

2 – Administrative data of participating organisations (notes for information ONLY)

The first sub-section lists the participating organisations. The first form is given for the host institution. If other organisations are involved, additional forms will appear for each partner added in step 4 of the online submission system. For each institution many fields will be read-only data as registered and/or validated in the central registry of organisations of the European Commission, linked to the given PIC number in the Beneficiary Register (previously the URF).

Host institution (applicant legal entity)

Host Institution	
Participant Identification Code (PIC)	[pre-filled] Guidance: The Participant Identification Code (PIC) enables organisations to take advantage of the Participant Portal. PIC numbers are necessary for the submission of proposals. By entering a PIC, section 2 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/desktop/en/organisations/register.html (via the same page). Organisations not yet having a PIC must self-register (via the same page) before submitting the proposal. Failure to do so will block the submission of your proposal..
HI Legal name	[pre-filled]
HI short name	[pre-filled]
Address of the organisation	
Street	[pre-filled]
Town	[pre-filled]
Postcode	[pre-filled]
Country	[pre-filled]
Webpage	[pre-filled]
Legal Status of your organisation	
Legal person	[pre-filled]
Public body	[pre-filled]
Non-profit	[pre-filled]
International organisation	[pre-filled]
International organisation of European interest	[pre-filled]
Secondary or Higher education establishment	[pre-filled]
Small and Medium-sized Enterprises (SMEs)	[pre-filled]
Academic sector	[pre-filled]
Nace code	

	[pre-filled]

Departments Carrying out the Proposed Work	
Department/Faculty/ Institute/Lab Name	Please indicate the address of the main department/institute/ unit that belongs to the same legal entity carrying out the work. Please use Latin characters. Use the 'Add Department' button to add additional departments or units within the same institution
Street	Please enter the street name and number where the department/faculty/institute/laboratory is located, in English.
Town	The town where the department/faculty/institute/laboratory is located, in English (please avoid any district codes).
Postcode	Please add here the district code.
Country	The country where the department/faculty/institute/laboratory is located, in English.

Principal Investigator

The following information of the Principal Investigator is used to personalise the communications to applicants and the Evaluation Reports. Please make sure that your personal information is accurate and please inform the ERCEA in case your e-mail address changes (by using the call specific e-mail addresses ERC-PoC-APPLICANTS@ec.europa.eu .

The name and e-mail of the Principal Investigator is **read-only** in the administrative form (available on Step 5 of the application). Only additional details can be edited here. To edit the name of the PI please save and close the form, and **go back to Step 4** of the submission wizard and save the changes. By re-opening the form the data will be updated based on the Step 4 information. **Please note that the e-mail provisions the access rights, therefore it cannot be changed**. The name of the person can be edited on Step 4. Further details are available in the User Guide of the Submission system (PPSS).

Principal Investigator	
Researcher ID	If you have a researcher identifier number (e.g. Researcher ID, ORCID) please enter it here.
Last Name	[pre-filled from 'Contacts' at Step 4] Last name as given on Passport or Identity Card.
Last Name at Birth	Your last name at birth.
First Name(s)	[pre-filled from 'Contacts' at Step 4] Your first name(s) as given on Passport or Identity Card.
Title	Please choose one of the following: Prof., Dr., Mr., Mrs., Ms.
Gender Female(F)/Male(M)	This information is required for statistical and mailing purposes. Indicate F or M as appropriate.
Nationality	[drop-down menu] Please select one country.
Country of residence	[drop-down menu] Please select the country in which you legally reside.
Date of Birth (DD/MM/YYYY)	Please specify your date of birth using the format (DD/MM/YYYY).

Country of Birth	[drop-down menu] Please select the country in which you were born.
Town of Birth	The town in which you were born. Insert the name of the town in English (please avoid any district codes).

Contact Address	
Current Organisation name	Name under which your organisation is registered.
Current Department/Faculty/ Institute/Laboratory name	Name under which your department/faculty/institute/laboratory is registered.
Street name	The street name.
Number	The street number.
Town	The town, in English (please avoid any district codes).
Postcode/Cedex	The postal code.
Country	[drop-down menu] Please select one country.
Phone 1	Please insert the full phone number including country and city/area code. Example +32-2-2991111.
Mobile	Please insert the full mobile number including country and city/area code. Example +32-2-2991111. The mobile phone number is optional, but can be useful for contact regarding possible interview scheduling or last minute changes.
E-mail	[pre-filled from 'Contacts' at Step 4]

Contact address of the host institution and contact person for the ERC.

The name and e-mail of Host Institution contact persons are **read-only** in the administrative form, only additional details can be edited here. To give access rights and contact details of Host Institution, please go back to **Step 4 of the submission wizard** and save the changes. **Please note that submission is blocked without a main contact person and email address for the Host Institution.**

Contact address of the Host Institution and contact person	
Organisation legal name	[pre-filled from 'Contacts' at Step 4]
First name(s)	[pre-filled from 'Contacts' at Step 4]
Family name	[pre-filled from 'Contacts' at Step 4]

E-mail	[pre-filled from 'Contacts' at Step 4]
Position in organisation	e.g. senior administrative officer
Office/Section/ Department/Faculty/ name	The name under which the host department/faculty/institute/laboratory is registered.
Street	The street name.
Number	The street number.
Town	The town, in English (please avoid any district codes).
Postcode/Cedex	The postal code.
Country	[drop-down menu] Please select one country.
Phone	Please insert the full phone number including country and city/area code. Example +32-2-2991111.
Mobile	Please insert the full mobile number including country and city/area code. The mobile number is optional, but can be useful for contact regarding possible interview scheduling or last minute changes.

Other Contact Persons with access rights	
First name(s)	[pre-filled from 'Contacts' at Step 4]
Family name	[pre-filled from 'Contacts' at Step 4]
E-mail	[pre-filled from 'Contacts' at Step 4]
Phone	Editable. Please insert the full phone number including country and city/area code. Example +32-2-2991111.

3 – Budget (notes for information ONLY)

Financial information (in euros) – whole duration of the project	
Please ensure that all costs are given in whole Euros (integer), not thousands of Euros. Please ensure that the figures in this table match the total eligible costs and requested EU contribution in Part B (section 4.a Resources), where needed including the 25% indirect costs.	
Participant Number in this proposal	The PI's host institution of the proposal is automatically number one.
Organisation short name	Read-only based on the PIC data in the Beneficiary Register.
Organisation country	Read-only based on the PIC data in the Beneficiary Register.
Total Eligible Costs	The sum of direct costs (personnel and others), indirect costs of 25% and subcontracting.
Requested Grant	The total budget that you are requesting as the ERC grant (in Euros)

4 – Ethics (notes for information ONLY)

In H2020 the completion of a general Ethics table has become compulsory and part of the online administrative submission forms. The PI must indicate any ethics issue in this section 4 together with a proposal page number (referring to Part B). For correct indication of any ethics issue related to your proposal, please refer to Annex 2 to this document. Annex 2 will also give guidance on how to write the ethics self-assessment and give indication of any supporting documentation needed for the Ethics review procedure.

Areas excluded from funding under Horizon 2020 (Art. 19.3 of the H2020 Framework Programme)

(i) Research activity aiming at human cloning for reproductive purposes;
(ii) Research activity intended to modify the genetic heritage of human beings which could make such changes heritable (Research relating to cancer treatment of the gonads can be financed);
(iii) 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.

All Horizon 2020 funded research shall comply with the relevant national, EU and international ethics related rules and professional codes of conduct. Where necessary, the beneficiary(ies) shall provide the ERCEA with a written confirmation that it has received (a) favourable opinion(s) of the relevant ethics committee(s) and, if applicable, the regulatory approval(s) of the competent national or local authority(ies) in the country in which the research is to be carried out-. The copy of the official approval from the relevant national or local ethics committees must also be provided to the ERCEA.

Ethics Issues (extended table available in Annex 2)	
I confirm that I have taken into account all ethics issues described above and if any ethics issues apply, I have attached the required documents.	[Tickbox] - **The Ethics Issues Table has to be completed even if there are no issues (simply confirm that none of the ethics issues apply to the proposal).** If any of the ethics issues indicated in the Ethics Issues Table apply to your proposal, you **must** provide an ethics self-assessment following the instruction in Annex 2. For indication of additional supporting documentation needed, please see the extended table of ethics issues in Annex 2.

5 – Call specific questions (notes for information ONLY)

Eligibility	
I acknowledge that I am aware of the eligibility requirements for applying for this ERC call as specified in the ERC Work Programme 2015, and certify that, to the best of my knowledge my application is in compliance with all these requirements. I understand that my proposal may be declared ineligible at any point during the evaluation or granting process if it is found not to be compliant with these eligibility criteria.	[Yes] - Please confirm that you are eligible according to all requirements established in the ERC Work Programme 2015.

Data-Related Questions and Data Protection **Consent to any question below is entirely voluntary. A positive or negative answer will not affect the evaluation of your project proposal in any form and will not be communicated to the evaluators of your project**	
For communication purposes only, the ERC asks for your permission to publish your name, the proposal title, the proposal acronym, the panel, and host institution, should your proposal be retained for funding.	[Yes/No]
Some national and regional public research funding authorities run schemes to fund ERC applicants that score highly in the ERC's evaluation but which cannot be funded by the ERC due to its limited budget. In case your proposal could not be selected for funding by the ERC do you consent to allow the ERC to disclose the results of your evaluation (score and ranking range) together with your name, non-confidential proposal title and abstract, proposal acronym, host institution and your contact details to such authorities?	[Yes/No]
The ERC is sometimes contacted for lists of ERC funded researchers by institutions that are awarding prizes to excellent researchers. Do you consent to allow the ERC to disclose your name, non-confidential proposal title and abstract, proposal acronym, host institution and your contact details to such institutions?	[Yes/No]
The Scientific Council of the ERC has developed a monitoring and evaluation strategy in order to help it fulfil its obligations to establish the ERC's overall strategy and to monitor and quality control the programme's implementation from the scientific perspective. As provided by section 3.10 of the ERC Rules for Submission, a range of projects and studies may be initiated for purposes related to monitoring, study and evaluating the implementation of ERC actions. Do you consent to allow the ERC and third parties carrying out these projects and studies to process the content of your proposal including your personal data and the respective evaluation data? The privacy statement on grants[13] explains further how your personal data is secured.	[Yes/No]

1.1.2.2 Instructions for completing 'Part B' of the proposal

The proposal has to be presented in the form of the so-called (Part B) following the template provided in PPSS **, the use of the template is mandatory**. The electronic upload of the proposal Part B is done at Step 5 'Edit Proposal' and submitted via PPSS – see point 1.1.3 of this document.

[13] http://erc.europa.eu/sites/default/files/document/file/erc_sps_grants_02_2012_2.pdf

Important Notice: Please be aware that there is only one evaluation step. The "Part B" must contain all the information required to evaluate your proposal.

The information to be included in each of the sections as well as the maximum length of each section or its sub-sections, which needs to be respected strictly, is described below.

In fairness to all applicants, the page limits below will be applied strictly. Only the material that is presented within these limits will be evaluated (external experts will only be asked to read the material presented within the page limits, and will be under no obligation to read beyond them).

Each proposal page **shall** carry a **header** presenting the **PI's last name** and the **acronym of the proposal.**

The following parameters **shall** be respected for the layout:

Page Format	Font Type	Font Size	Line Spacing	Margins
A4	Times New Roman Arial or similar	At least 11	Single	2 cm side 1.5 bottom

The activities to be funded should draw substantially on the ERC-funded research project (whose ID number has to be indicated in PPSS 'Part 1. General Information'), but they are not aimed at extending the original research or predominantly concerned with overcoming technical obstacles. The grant will cover activities at the very early stage of turning research outputs into a commercial proposition, i.e. the initial steps of pre-competitive development of commercial potential.

Part B Section 1, 2, 3 and 4:

Please use the online template provided in the Participant Portal Submission Page for the call.

Section 1: The idea - Innovation potential (max. 2 pages)

This section is about describing the idea to be taken to proof of concept in a few words (abstract) and the innovation potential of the proposed idea. It will be used to assess the evaluation criterion #1: Excellence.

a. Succinct description of the idea to be taken to proof of concept

Write here an "abstract-like "description of your project, explaining what the idea is all about and what are the expected outcomes of the project. This description should be understandable for a non-specialist in your field.

b. Demonstration of Innovation Potential

Please explain how the proposed project will greatly help move the existing ERC research to the initial steps of a process leading to a commercial or social innovation.

Section 2 – Expected Impact (max. 2 pages):

This section is about describing the expected impact of the PoC project. Please identify which impact can be expected, and which benefits will the execution of the project bring to society and the economy. It will be used to assess the evaluation criterion #2: Impact

Please describe in detail:

a. Economic and/or societal benefits

b. Commercialisation process and /or any other exploitation process

c. Proposed plans for :

- Competitive analysis
- Testing, technical reports (where applicable)
- IPR position and strategy (where applicable)
- Industry/sector contacts (where applicable)

Please refer to the ERC Work Programme 2015 (ERC Proof of Concept Grant evaluation) for the explanation of these sub-criteria.

Important: Point c) states where applicable, this does not mean you should skip these points if not applicable. In this case, please explain why it does not apply to the project (is it out of scope? has it already been achieved?) in order for the evaluators to understand why this issue is not addressed in the frame of the Proof of Concept project.

Section 3: The proof of concept plan (max 2 pages)

It will be used to assess the evaluation criterion #3: Quality and efficiency of the implementation.

This section is about describing the planning of the proposed activities, the project-management plan and the team that will conduct the activities. You should demonstrate the relevance of the approach chosen for establishing the technical and commercial feasibility of the project.

a. Plan of the activities

b. Project-management plan

c. Description of the team

Section 4: The budget (max 1 page + costing table)

This section is about describing the resources needed for the project. You should demonstrate that the requested budget is necessary for the implementation of the proposed activities and properly justified.

a. Resources:

It is strongly recommended to use the budget table template included in Part B to facilitate the assessment of resources by the panels. (See Box 3 and 4 for guidance on eligible- and non-eligible direct and indirect costs as well as the different cost categories). Please use whole Euro integers only when preparing the budget table.

b. Justification (description of the budget)

Describe the necessary resources and specify any existing resources that will contribute to the project. It is advisable to include a short technical description of the equipment requested, a justification of its need as well as the intensity of its planned use. Please note that a properly and correctly compiled budget with a sufficiently detailed and reasoned justification is necessary to facilitate the evaluation on criterion #3.

Subcontracts may only cover the execution of a limited part of the project and recourse to the award of subcontracts must be duly justified having regard to the nature of the project and what is

necessary for its implementation. Hence in the case of subcontracting please include the tasks and budget for each subcontract as well as a brief justification for this.

Attention is also drawn to the specificities of the conditions which apply to subcontracting in terms of the award of the contract and implementation. It is therefore noted that in certain specific contexts it may be appropriate to consider what the most suitable modality to include the costs for third parties may be.

Supporting Documentation

Any additional annexes, including, the host institution support letter should be provided and uploaded as separate pdf documents. These annexes do not count towards the maximum page limit for Part B.

Box 3 Eligible and non-eligible direct and indirect costs

Direct eligible costs are those which support all the research, management, training and dissemination activities necessary for the conduct of the project, such as:

- Personnel Costs;
- Costs for subcontracting
- Other direct costs such as :
  - ✓ Contracting (see page 96-97 of the ERC annotated model grant agreement);
  - ✓ Travel costs and related subsistence allowances;
  - ✓ The depreciation costs for equipment;
  - ✓ Costs for other goods and services [consumables and supplies; dissemination/publication costs (page charges and related fees for publication of results including for Open Access), IPR costs, costs of the Certificates on the Financial statements]
  - ✓ Direct costing for Large Research Infrastructures

Indirect eligible costs are those which cannot be identified as directly attributable to the project, but which are incurred in direct relationship with the project's direct eligible costs, such as:

- Costs related to general administration and management;
- Costs of office or laboratory space, including rent or depreciation of buildings and equipment, and related expenditure such as water, heating, electricity;
- Maintenance, insurance and safety costs;
- Communication expenses, network connection charges, postal charges and office supplies;
- Common office equipment such as PCs, laptops, office software;
- Miscellaneous recurring consumables.

Non-eligible costs cannot be reimbursed through the ERC grant, in particular:

- Costs related to return on capital;
- Debt and debt service charges;
- Provisions for possible future losses or debts;
- Interest owed;
- Doubtful debts;
- Currency exchange losses;
- Excessive or reckless expenditure;
- Costs reimbursed under another EU grant
- Deductible VAT ;

More detailed information and guidance on the financial issues is provided in the Horizon 2020 Reference Documents and in the ERC Annotated Model Grant Agreement.

Box 4 Use of third party resources and/or third parties involved in the action

The Host Institution and the other organisations involved in the action (if any) must normally have the technical and financial resources needed to allow the Principal Investigator to carry out his/her activities. As an exception, the Host Institution and the additional participants may use in-kind contributions provided by third parties or call upon subcontractors or linked third parties to carry out work under the action.
Seconding personnel, contributing equipment, infrastructure or other assets are the most usual forms of in-kind contributions (= resources) provided by third parties.
Subcontracting is instead the most common form by which a third party is typically asked to carry out directly some action's tasks. In some cases, often related to the organisational structure of the Host Institution, affiliated entities ("linked third parties") are involved to carry out some tasks too.
Part B2 of the proposal must indicate the resources obtained from third parties or the task to be subcontracted and an estimation of the costs.
More detailed information and guidance on the role and involvement of the various types of 3rd parties is provided in the ERC Annotated Model Grant Agreement under articles 11, 12, 13 and 14

The specific case of Subcontracting

A subcontractor is a third party which has entered into an agreement on business conditions with one or more participants, in order to carry out part of the work of the project without the direct supervision of the participant and without a relationship of subordination.

Where it is necessary for the participants to subcontract certain elements of the work to be carried out, the following conditions must be fulfilled:

- subcontracts may only cover the execution of a limited part of the project;
- recourse to the award of subcontracts must be duly justified in Part B of the proposal having regard to the nature of the project and what is necessary for its implementation;
- recourse to the award of subcontract by a participant may not affect the rights and obligations of the participants regarding background and foreground;
- Part B of the proposal must indicate the task to be subcontracted and an estimation of the costs;

The beneficiary must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, it must avoid any conflict of interests.

Framework contracts between a participant and a subcontractor, entered into prior to the beginning of the project that are according to the participant’s usual management principles may also be accepted.

1.1.2.3 Supporting Documentation

A scanned copy of the following supporting documentation needs to be submitted with the proposal by uploading electronically in PPSS in PDF format:

- The host institution (applicant legal entity) must confirm its association with and its support to the project and the Principal Investigator. As part of the application the institution must provide a binding statement that the conditions of independence are already fulfilled or will be provided to the Principal Investigator if the application is successful. The host institution support letter (template available on PPSS, or please see Annex 1 to this document) needs to be originally signed, stamped and dated by the institution's legal representative. Proposals that do not include this institutional statement may be declared ineligible.
- Any additional supporting documents which may be required following the indications provided in this document (i.e. ethical self-assessment and supporting documentation for the ethics review procedure).

Copies of official documents can be submitted in any of the EU official languages. Document(s) in any other language must be provided together with a certified translation into English.

Please provide only the documents requested above. Unless specified in the call, any hyperlinks to other documents, embedded material, and any other documents (company brochures, supporting documentation, reports, audio, video, multimedia etc.) will be disregarded.

Check if the proposal is complete for the evaluation

Incomplete proposals (where parts or sections of the proposal and/or the host institution's commitment statement are missing) may be declared ineligible and will not be evaluated[14]. The proposal must be submitted **before the relevant deadline of the call.**

Where there is a doubt on the eligibility of a proposal, the evaluation may proceed pending a decision by an eligibility review committee. If it becomes clear before, during or after the evaluation phase, that one or more of the eligibility criteria has not been met, the proposal is declared ineligible and is withdrawn from any further examination.

[14] See also section 2.4 'eligibility check' in the ERC Rules for Submission and the ERC Work Programme 2015.

Box 5 Checklist – Is your proposal complete?

For the submission of a complete proposal to the Proof of Concept Grant Call, the following components have to be prepared:

The Administrative 'Proposal submission forms': to be completed online in PPSS

- on-line forms pre-registration and sections 1, 2, 3, 4 and 5

The Proposal (Part B) and all supporting documentation should be uploaded and submitted via PPSS as PDF files. Make sure all file names contain the 'Proposal Short Name', such as PartB_[Proposal-Short-Name].pdf

The Project Proposal (Part B):

- **Section 1 – The idea-Innovation Potential**
- **Section 2 – Expected Impact**
- **Section 3 – The proof of concept plan**
- **Section 4 – The budget**

The Supplementary Documents:

- The supporting statement from the host institution: originally signed, stamped and dated by the host institution's legal representative (see Annex 1).
- If applicable, the ethics self-assessment explaining how the ethics issues will be treated (see Annex 2 to this document on how to write the ethics self-assessment and on the need for supporting documentation).

Please ensure that all forms and supplementary documents are uploaded correctly in PPSS before the final submission. It is strongly recommended to double-check by downloading them and verifying their completeness. If all components are not present and complete in the final submission your proposal risks to be declared ineligible.

1.1.3 How to submit the grant application

General user guidance
The User Guide of the Submission Service is available online at
http://ec.europa.eu/research/participants/data/support/sep_usermanual.pdf.

The H2020 Online Manual (http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/submit-proposals_en.htm) describes the standard process of proposal submission. The 'IT HOW TO' wiki site provides an online IT manual with screenshots.

Proposals must be submitted electronically using the electronic submission system of the web-based Participant Portal (PPSS)[15]. Access to the electronic submission system is available from the call page (after selecting a topic, click on the 'Submission Service' button, and a type of action of a call) of the Research and Innovation Participant Portal[16].

An Internet browser and version 9 (or above) of the Adobe reader are needed and is set up as your default PDF handler. Make sure Adobe Reader plug-in is enabled on your browser (all previous reader installations must be removed). Please note that some internet browsers and/or Operating Systems (OS) may not be supported by the PPSS. To check the requirements, click on: https://ec.europa.eu/research/participants/submission/manage/diagnostics or the 'User guide of the submission service', also available from the 'Submission Service'.

Step 1: 'ECAS registration' - Getting a user ID with the Commission
To be able to submit a proposal, you must first register an ECAS account. Getting a user ID with the **European Commission Authentication Service** (**ECAS**) is mandatory in order to login to the Participant Portal and to be able to use the different functions of the Portal, including the proposal submission. Each time you access the proposal for editing, this user ID is requested. The same user ID is used for all later interactions with the ERCEA, including notification of the results of the evaluation[17].

Step 2: 'Access the proposal submission system'
Access to the system is provided from the topic's page after selecting the 'Submission Service' and choosing the required action type. The system requires a login on the Portal with your ECAS ID.

Step 3: 'Create a draft proposal' (pre-registration)
At this step, you fill in pre-registration data for the proposal. These details will be used by the ERCEA in order to plan the evaluation. You will not have access to this page again once it is completed and you have progressed to Step 4, but certain data can be modified at a later stage. **Be careful to choose the correct PIC-number for your host institution AND to type the correct e-mail address of the PI at this step. We recommend that you as a PI create the draft proposal. This is to ensure that you have the right to manage the access rights to your proposal at Step 4.**

- When registering, please select the type of contact person you are: Principal Investigator, Main Host Institution Contact, or Contact person. **This will have an influence on the subsequent steps.** The person who creates the proposal becomes the 'primary coordinator contact' for the proposal (as used on the Participant Portal) and will determine the access rights of other people to the proposal data.

[15] In duly justified exceptional circumstances the ERCEA may authorise submission on paper.
[16] http://ec.europa.eu/research/participants/portal/page/home
[17] Further details are available here: https://webgate.ec.europa.eu/cas/eim/external/help.cgi

- Acronym: This is used to identify your proposal efficiently in the call. It should be no more than 20 characters (use standard alphabet and numbers only; no symbols or special characters, except underscore, space, hyphen or dot).
- Short summary: The short summary describes briefly the purpose of the proposal with a maximum of 2000 characters. You may decide not to provide the full summary, but a list of keywords of the proposal will help the services in the planning of the evaluation. The 'short summary' information is copied to the 'Abstract' field in the online administrative form section 1, where it can be modified (see step 5).

Please note that the list of participants will also be part of the pre-registration data.

At this step, the host institution **must be identified with a Participant Identification Code (PIC)**. **Failure to do so blocks the preparation and the submission of the proposal!** The PIC is a unique 9 digit number that helps the ERCEA identify a participant (organisation). It is used in all grant-related interactions between the organisation and the ERCEA (or with the European Commission in other actions of Horizon 2020). Once an organisation is registered (in the Beneficiary Register, which is hosted in the Participant Portal), it eliminates redundant requests for information.

If a PIC is not yet available for an organisation, it can be obtained by registering the organisation in the Beneficiary Register. A PIC is then given, which can then be used in PPSS[18].
If your host institution has already participated in a 7th Framework Programme proposal, it is likely that you already have a PIC number. You can check this on the Beneficiary Register Page, where additional information on how to register is also available: http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html

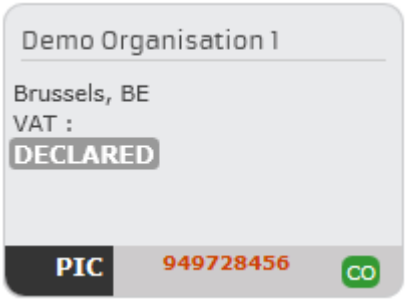
You are strongly advised to register your proposal well in advance of the call deadline to verify if the PIC is available for your host institution. If it is not, you then have sufficient time to register and contact your host institution or the PPSS Service Desk if needed at DIGIT-EFP7-SEP-SUPPORT@ec.europa.eu or (+32 (2) 29 92222).

After entering the PIC, certain sections of the online proposal submission forms are filled in automatically. The objective of the PIC is to identify the organisation and validation of the information will happen at a later stage, if the proposal is retained for funding.

Note:
- If an organisation has a participant identification code (PIC), it may be likely that it has a person in charge of the administrative questions with the European Commission (the legal entity appointed representative – LEAR[19]). Identifying this person inside your organisation may help you in the proposal submission process. The LEAR can modify the data related to the PIC if needed.

[18] This self-registration will lead to a request by the Validation Service to the organisation to provide supporting documents and to nominate a Legal Entity Authorised Representative (LEAR). However, this PIC code does not need to be validated for proposal submission. If your proposal is selected, this additional information and validation will be completed at a later stage before a grant agreement can be signed.
[19] The LEAR is a person nominated in each legal entity participating in FP7/H2020. This person is the contact for the ERCEA related to all questions on legal status. He/she has access to the on-line database of legal entities with a possibility to view the data stored on his/her entity and to initiate updates and corrections to these data. After the validation of the entity has been finalised, the contact person/authorised representative named in the Research and Innovation Participant Portal receives the PIC number. Once the LEAR is validated, he/she manages the modifications of the entity-related information in the Research and Innovation Participant Portal and distributes the PIC number within his/her organisation, which can be used in all proposals submission and negotiations.

- How to contact the LEAR? Go to the Beneficiary Register page, click 'Search', define the PIC and click on the green CO (contact organisation) button.



Once Steps 1 to 3 are completed, the draft proposal is created in PPSS. You will receive an email informing you that you have successfully created a draft proposal.

You can continue to Step 4 or return later to edit this draft proposal. This is done by following the steps below:

1. Go to the Participant Portal http://ec.europa.eu/research/participants/portal/page/home
2. Click on the login button and provide your ECAS username and password
3. Click on the 'My Proposals' tab
4. Depending on the status of the proposal, you jump to either Step 5 'Edit draft' or Step 6 'View submitted'.

Step 4 'Manage Your Related Parties and access rights'

Here you see the name and details of the host institution (always participant number '1') and the name of the person who created the draft proposal. At this step, you can:

- **add the main host institution contact person name or the PI (if not done yet) and e-mail**
- **add additional organisations** ('Add partners'), and
- **give access to other contact persons** (full access or read-only access)

Organisations must be identified by their nine-digit PIC numbers. A search function is provided in the system to facilitate the search for partners (if any).

When giving access rights to **contact persons**, the e-mail address of the person serves as the main identifier. You must define the level of access rights for each contact person:

- **full access** (Principal Investigator level of rights is named 'Coordinator contact' in PPSS - The Coordinator contact/PI has the right to edit all parts of the proposal, upload documents, submit, and withdraw the proposal) or **read-only rights** (Team member) are supported.
- For each contact person the **role within the project** must be defined: usually Principal Investigator or main host institution contact in ERC actions.

Please also be aware that **only one person should work on the forms at any given time**. In case of a save conflict the last save wins, which means that you risk overwriting changes made by other contact persons if you are working in parallel. We therefore recommend that you **give 'read-only' access** to your partners and collaborators (contacts) unless it is absolutely necessary to grant full access.

For the Principal Investigator and the host institution contact person full details will be required later in the administrative forms (section 2). **Please be aware that you MUST enter the details of the PI and the main host institution contact person at step 4, since these fields are not-editable in step 5 in the forms.** You may at any point return to Step 4 of the submission to add or delete any contact person or to change the access rights. Remember to save your data before leaving Step 4.
You may also add the LEAR as a contact person (e.g. as a team member with read-only rights) to the proposal at Step 4 of the application.

Once the coordinator saves the changes, an **automatic invitation** is sent to all contacts' e-mail addresses. The invited persons can **access the proposal** after logging in to the Participant Portal – with the ECAS account linked to the given e-mail address – under the '**My Proposals**' tab.

Step 5: 'Edit Proposal'

This step is the core of the submission process, as from this step, you can **edit the administrative** proposal submission forms, view the history, print the draft proposal, download templates, upload files and submit the proposal by clicking on the relevant buttons.

By clicking the 'Edit form' button at Step 5 of the submission wizard, users can fill in the administrative forms of the proposal.

The ERC actions have specific administrative forms. The specificities lay mainly in the budget table, in the call specific questions and in the list of declarations.

Guidance on how to fill in the administrative online form is provided directly in the form as ghost text for the single entries or as additional help text hidden behind question-marks  . Some parts of the form will be prefilled based on the data entered at pre-registration or in the Beneficiary Register.

Please use the functionality '**Validate form**' button to check the validity and completeness of your data. Any warning or error will be listed at the end of the validated form.

Further information on the preparation of the application (Administrative forms and Part B) is given in points 1.1.2.1 and 1.1.2.2 of this document.

- **For Part B you must only use PDF ('portable document format'). Other file formats will not be accepted by the system.** Irrespective of any page limits specified in this document, there is an **overall limit of 10 Mbytes to the size of each uploaded document (Part B, and supporting documentation).** However, it is advised to limit the size of Parts B to 2 Mbytes each.
- Unless specified in the call, embedded material and any other documents (company brochures, scientific papers, reports, audio, video, multimedia, etc.) sent electronically or by post, will be disregarded.
- There are also restrictions to the name given to the Part B files: use alphanumeric characters; special characters and spaces must be avoided.

> *You are advised to clean your document before converting it to PDF (e.g. accept all tracked changes, delete notes).*

Check that your conversion software has successfully converted <u>all</u> the pages of your original document (e.g. there is no problem with page limits).

Check that your conversion software has not cut down landscape format pages to fit them into portrait format. Check that captions and labels have not been lost from your diagrams.

Please note that the ERCEA prints out proposals in black and white on plain A4 paper. The printable zone on the print engine is bounded by 1.5 cm right, left, top bottom. No scaling is applied to make the page 'fit' the window. Printing is done at 300 dots per inch.

- **Completing the Proposal submission forms in the PPSS and uploading all the necessary files (mandatory: Part B and host institution support letter, and** – if applicable – optional annexes Ethical Self-assessment and supporting documentation for ethics issues) **does <u>not</u> yet mean that your proposal is submitted.** Once there is a consolidated version of the proposal, **the 'SUBMIT' button must be pressed**. The system performs a limited automatic validation of the proposal. A list of any problems such as missing data, wrong file format or excessive file size will then appear on the screen. You may submit your proposal with warnings, but **submission is blocked until all errors are corrected.** However, these checks do not replace the formal eligibility checks described in point of this document and cannot guarantee that the contents of these files respond to the requirements of the call. When corrected, you must then repeat the above steps to achieve submission.

IMPORTANT: If the submission sequence described above is not followed, the ERCEA considers that no proposal has been submitted.

- When the proposal is successfully submitted, the system will proceed to Step 6 where a message that indicates that the proposal has been received is displayed. The system also sends a submission confirmation e-mail to you, with the summary data of the submitted proposal. The mail can end up in the spam folder or be blocked by the anti-spam system of your organisation. This automatic message is not the official acknowledgement of receipt.

<u>Step 6: 'Submit'</u>

Reaching this step means that the proposal is submitted (i.e. sent to the ERCEA for evaluation). It does not mean that the proposal is valid, complete and eligible in all respects. Within a few minutes of submission your proposal will be available for download with an e-receipt in the PPSS system.

In Step 6 you can:

- *Download the proposal*. You are advised to download the proposal once submitted to check that it has been correctly sent. The downloaded proposal with an e-receipt is digitally signed and time stamped. The e-receipt is also the Acknowledgement of receipt.
- *Re-edit the proposal*, going back to Step 5. **You may continue to modify the proposal and submit revised versions overwriting the previous one right up until the deadline.** The sequence above must be repeated each time.

- *Withdraw/delete the proposal before the call deadline.* If the proposal is deleted or withdrawn, it is not considered for evaluation. (Note: your proposal draft is not deleted from the server and this withdrawal action can be reversed, but only before the deadline, by simply submitting it again).

Once submitted, it is recommended to verify the proposal and its content by downloading all the submitted files. We strongly advise that you submit a first version of your proposal at least 24 hours in advance of the call deadline.

Warning: Please note that in the last hours prior to call closure, the download option of checking your submitted proposal may be disabled due to a high pressure on the system. In this case we will inform the applicants via the Call Page on the Participant Portal (under 'call summary') that the function has been disabled:
http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/calls/erc-2015-stg.html#tab1 **.**

If the e-receipt and download option have been disabled, you may review your submitted proposal by going back to step 5 to check the data in the administrative forms and click on 'View History' to verify which attachments have been uploaded.

- Proposals must be **submitted before the deadline** specified in the call for proposals[20].
- PPSS will be closed for a relevant call at its call deadline. After this moment, it will be impossible to access PPSS for the relevant call.

Early registration and submission in PPSS is strongly recommended and should be done as early as possible in advance of the call deadline. Applicants, who wait until shortly before the close of the call to start uploading their proposal, take a serious risk that the uploading will not be concluded in time and thus the 'SUBMIT' button will not be active anymore in order to conclude the submission process.

[20] In the unlikely event of a failure of the PPSS service due to a breakdown of the Commission server during the last 24 hours of a call, the deadline will be extended by a further 24 hours. This will be notified by e-mail to all applicants who had registered for this call by the time of the original deadline, and also by a notice on the call page on the Participant Portal: http://ec.europa.eu/research/participants/portal Such a failure is a rare and exceptional event; therefore do not assume that there will be an extension to this call. If you have difficulty in submitting your proposal, you should not assume that it is because of a problem with the Commission server, as this is rarely the case. For technical inquiries on the use of PPSS, please contact the Participant Portal IT Help Desk (**http://ec.europa.eu/research/participants/api/contact/index.html**). Please note that the ERCEA will not extend deadlines for system failures that are not its own responsibility. In all circumstances, you should aim to submit your proposal well before the deadline to have time to solve any problems.

Box 6: Proposal submission - important to know:

- Proposals sent by means other than PPSS will not be accepted[15].
- Up to the call deadline, it is possible to modify a proposal simply by submitting a new version. As long as the call has not yet closed, the new submission will overwrite the old one.
- **After the call deadline no update of the proposal will be accepted. Only the material that the proposal contains within the given page limits while respecting the indicated layout parameters will be evaluated.**
- Submission is deemed to occur only if the submission sequence described above has been followed and not when the applicant starts uploading the proposal.
- Proposals are kept under secure conditions at all times. When no longer needed, all copies are destroyed except those required for archiving and/or auditing purposes.
- In some rare occasions the proposal may be altered while in transit on the internet. To check that the uploaded proposal has been received unaltered, please download and verify all uploaded files.

If the submission is technically successful, the applicant receives an automatic computer-generated acknowledgement from PPSS. Acknowledgement of receipt is subsequently provided by e-mail after the call deadline.

Subsequent to submission, and only in exceptional cases, the ERCEA may contact the PI if this is necessary to clarify questions of eligibility, ethics issues, research integrity or to verify administrative or legal data contained in the proposal.

1.1.3.1 Modifying or withdrawing a proposal

Up to the call deadline at step 6, it is possible to **modify a proposal simply by submitting a new version**. As long as the call has not yet closed, the new submission will overwrite the old one.

The last version of your proposal submitted before the deadline is the one which will be evaluated; no later version can be substituted and no earlier version can be recovered.

Once the deadline has passed, the ERCEA cannot accept any further additions, corrections or re-submissions. However a read-only access to the submitted proposal is granted in case the PI (or other contact persons) wishes to verify what has been submitted. **This possibility is available for 90 days after the call deadline.**

Proposals may be withdrawn before the call deadline at Step 6 using the 'Withdraw' button. These withdrawn proposals will not be considered subsequently for evaluation.

For a proposal to be withdrawn after the call deadline, a written request for withdrawal must be received by the Agency at the latest on the day preceding the panel meeting where a final position on the outcome of the evaluation of that proposal is established. The withdrawal of a proposal must be done by sending an e-mail to the call-specific mail-box (ERCEA-POC-APPLICANTS@EC.EUROPA.EU) including a signed scanned letter of withdrawal. The ERCEA will use the date of the e-mail as reference point when deciding if a withdrawal can be accepted. The applicant will receive an acknowledgement of receipt of the e-mail and the signed scanned letter to confirm the withdrawal.

If more than one version of the same proposal is submitted before the call deadline, only the most recent version is kept for evaluation. In the case of very similar proposals submitted by the same PI, the ERCEA services may ask the PI to withdraw one or more of the proposals concerned.

Please consult regularly the Research and Innovation Participant Portal call page for updated information

1.2 Evaluation and selection of grant proposals[21]

1.2.1 Eligibility Check

Proposals are first checked to ensure that all of the eligibility criteria are met.

A proposal must fulfil all of the following eligibility criteria:

- It must be submitted before the submission deadline.
- It must be complete, readable and printable (i.e. all of the requested forms, parts or sections of the proposal, and supporting documents must be completed and present).
- Its content must relate to the objectives of the ERC call, as defined in the ERC Work Programme 2015
- The relation between the idea to be taken to proof of concept and the ERC frontier research project (Starting, Consolidator, Advanced or Synergy) in question must be demonstrated.
- It must meet the eligibility requirements of the respective ERC grant as well as other criteria mentioned in the relevant call for proposals.

The eligibility is checked on the basis of the information given by the PI in the proposal and in section 5 of administrative 'Proposal Submission Forms'. Where there is a doubt on the eligibility of a proposal, the evaluation may proceed pending a final decision on an eligibility review committee. If it becomes clear before, during or after the evaluation phase, that one or more of the eligibility criteria has not been met (for example, due to incorrect or misleading information), the proposal will be declared ineligible and not considered any further.

1.2.2 Evaluation of proposals

The proof of concept is a grant awarded in relation to an existing ERC-funded project which has already been evaluated on the basis of excellence as the sole criterion. The proof of concept opportunity to be funded will have arisen from scientifically excellent ERC-funded research that has already been subject to rigorous peer review. The activities to be funded **must** draw substantially on the ERC-supported research, but they are not aimed at extending the original research or predominantly concerned with overcoming technical obstacles.

Per each deadline, a one-step submission and evaluation procedure will be used. The evaluation will be conducted by independent experts. These experts may work remotely and may if necessary meet

[21] See also the ERC Work Programme 2015.

as an evaluation panel on the application of the evaluation criteria for selection of proposals for proof of concept grant (as described in the ERC Work Programme 2015).
- Excellence (Innovation potential)
- Impact
- Quality and efficiency of the implementation (Quality of the proof of concept plan)

Independent experts will evaluate independently each eligible proposal on each of the three evaluation criteria on a "pass/fail" basis.

In order to be considered for funding, proposals will have to be awarded a pass mark by a majority of independent experts on each of the three evaluation criteria.

A proposal which fails one or more of the criteria will not be ranked and will not be funded.

If there is not enough budget to fund all the proposals which pass all three evaluation criteria, those proposals which pass all three evaluation criteria will be sorted by the number of pass marks awarded by independent experts to criterion 1 (Excellence- Innovation potential), then by the number of pass marks awarded to criterion 2 (Impact), then by the number of pass marks awarded to criterion 3 (Quality and efficiency of the implementation). Proposals will be funded in order of the ranking resulting from this 3-level sorting exercise until depletion of the available budget per evaluation round.

Rankings resulting from each of the three evaluation rounds following the three submission deadlines are to be considered independent.

1.2.3 Ethics Review

Please see the Annex A to the ERC Rules for Submission for a detailed description of the ERC Ethics Review procedure.

The ethics review process concerns all projects funded by the ERC in Horizon 2020. The applicants should pay particular attention to the ethical aspects of the proposed work and should submit all ethics documentation available for their proposal.

The process is aimed at ensuring that the Article 19 of Horizon 2020 Framework Programme, and Articles 13 and 14 of the Rules for Participation are implemented and, in particular, that all the research and innovation activities under Horizon 2020 comply with ethics principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.

The main areas that are addressed during the ethics review process include:

1. Human protection (including study participants and researchers)
2. Animal protection and welfare
3. Data protection and privacy
4. Environment protection
5. Participation of non-EU countries
6. Malevolent use of research results

When submitting their proposal, applicants must complete the Ethics Issues Table which is section 4 of the online proposal submission forms and submit an ethics self-assessment if they answer yes to

one or several questions in the Ethics Issues Table. Please see Annex 2 to this document for guidance to write an ethics self-assessment.

Further to the outcome of the ethics review process, the host institutions and the principal investigators receive an unsigned copy of the ethics report so as to preserve the anonymity of the experts.

Please include any supporting documentation, such as any authorisation you may already have. This will allow a more effective ethics clearance and an accelerated granting process if the proposal is retained for possible funding[22].

Please upload any related documents in PPSS Step 5 'Edit Proposal'.

PIs need to be aware that no grant agreement can be signed by ERCEA prior to a satisfactory conclusion of the ethics review procedure.

Those whose proposals are rejected because of ethics considerations are informed of the grounds for such a decision.

A dedicated website that aims to provide helpful information including ethics issues is available at: http://ec.europa.eu/research/participants/portal/desktop/en/funding/guide.html

1.2.5. Feedback to applicants

Official communications and feedback from the ERCEA to the PI and the host institution (applicant legal entity) will be done via the ECAS secured web-mail account accessible via the Participant Portal. If they have not yet registered an ECAS account, the PI or the applicant legal entity's contact person will receive an activation e-mail (at the address 'E-mail 1' provided in step 4 of the proposal submission) inviting them to activate their ECAS account. Following to this first activation the ECAS account will be maintained for following communications or feedback.

PIs and applicant legal entities are provided with feedback on the outcome of the evaluation in the form of an evaluation summary report. This indicates whether the proposal is retained for funding or not, and provides the passed/failed status for each of the three criteria, with corresponding comments given by the panel.

Please note that the comments by the individual experts may not necessarily be convergent – controversy and differences in opinion about the merits of a proposal are part of the 'evaluation method' and are legitimate.

1.2.5.1 Evaluation review procedure

Please see the section 3.9 of the ERC Rules for Submission for a detailed description of the assistance, inquiries and evaluation review procedures.

Upon reception of the feedback on the outcome of the evaluation with the evaluation summary report or with the results of the eligibility check, the PI and/or the PI's host institution (applicant legal entity) may wish to introduce a request for evaluation review, if there is an indication that there has been a shortcoming in the way a proposal has been evaluated, or that the results of the eligibility checks are incorrect. The evaluation review procedure is not meant to call into question the scientific

[22] A full description of the Ethics Review is provided in the ERC Rules for the submission of proposals and the related evaluation, selection and award procedures relevant to the H2020 Specific Programme.

judgement made by the experts; it will look procedural shortcomings and – in rare cases – into factual errors.

Such requests for evaluation review should be raised within 30 days of the date of dispatch of the feedback on the outcome of the evaluation, and should follow the instructions provided in the Feedback to applicants.

Requests must be:

- related to the evaluation process, or eligibility checks, for the call and grants in question;
- set out using the on-line form via the above-mentioned web-based mailing system, including a clear description of the grounds for complaint;
- received within the time limit specified on the information letter;
- sent by the PI and/or the PI's host institution (as the applicant legal entity).

An initial reply will be sent to complainants no later than three weeks after the deadline for evaluation review requests. This initial reply will indicate when a definitive reply will be provided.

An evaluation review committee of the ERCEA may be convened to examine the evaluation process for the case in question. The evaluation review committee will bring together staff of the ERCEA with the requisite scientific/technical and legal expertise. The committee's role is to ensure a coherent interpretation of requests, and equal treatment of applicants. The evaluation review committee itself, however, does not re-evaluate the proposal. Depending on the nature of the complaint, the committee may review the evaluation report, the individual comments and examine the CVs of the experts. In the light of its review, the committee will recommend a course of action to the ERCEA. If there is clear evidence of a shortcoming that could affect the eventual funding decision, it is possible that all or part of the proposal will be re-evaluated. Unless there is clear evidence of a shortcoming there will be no follow-up or re-evaluation.

Please note:

- A re-evaluation will only be carried out if there is evidence of a shortcoming that affects the quality assessment of a proposal. This means, for example, that a problem relating to one evaluation criterion will not lead to a re-evaluation if a proposal has failed anyway on the other criteria.
- The evaluation score following any re-evaluation will be regarded as definitive. It may be lower than the original score.
- Only one request for evaluation review per proposal will be considered by the committee.
- All requests for evaluation review will be treated in confidence.

2: Annexes

Annex 1: COMMITMENT OF THE HOST INSTITUTION[23, 24]

(to be printed on the official letterhead of the host institution)
Commitment of the host institution
The <<please fill in here the name of the legal entity that is associated to the proposal and may host the principal investigator and the project in case the application is successful>>, which is the applicant legal entity, confirms its intention to sign a supplementary agreement with
<<please fill in here the name of the principal investigator>>

in which the obligations listed below will be addressed should the proposal entitled <<acronym>> : <<title of the proposal>> be retained.

Performance obligations of the applicant legal entity that will become the beneficiary of the grant agreement, should the proposal be retained and the preparation of the grant agreement be successfully concluded:

The applicant legal entity commits itself to engage the principal investigator for the duration of the grant to:

a) ensure that the work will be performed under the guidance of the principal investigator.
b) carry out the work to be performed, as it will be identified in Annex I of the ERC Grant Agreement, taking into consideration the specific role of the principal investigator.

For the host institution (applicant legal entity):
Name and Function
…… ; …….
Email and Signature of legal representative
…… ; …….
Stamp of the host institution (applicant legal entity)
IMPORTANT NOTE: All the above mentioned items are mandatory and shall be included in
the commitment of the host institution.

[23] A scanned copy of the signed statement should be uploaded electronically via the Participant Portal Submission Service in PDF format.

[24] This statement (on letterhead paper) shall be signed by the institution's legal representative and stating his/her name, function, email address and stamp of the institution.

ANNEX 2: SPECIFIC GUIDANCE RELATED TO ETHICS

Ethics Self-Assessment

Overview

The aim of the ethics self-assessment is to provide guidance for discussion of the ethics issues involved in the proposal and of how they will be dealt with.

- How do you **introduce**, at the outset, **the ethical perspective in your research**?

Please provide a **description of the ethics issues** associated to your proposal, making sure you cover all topics flagged in the ethics issues table. Please **specify** as well **any authorisation or permission** you already have **for the proposed work** and **include copies** (the ethics self-assessment and the copies do not count towards the page limit of your proposal). All documents must be submitted in an official EU language or the original document together with a certified translation in English or another official EU language. Please list the documents provided with their expiry date. In case such documents are not available yet, please provide an approximate timing for their submission.
For a detailed list of required information and documents related to each ethics issue, see the table listed in this annex 'Information and documents to be provided by the applicants'.

Human embryos/foetus

Please make sure that you describe adequately why the use of human embryos/foetus is needed, the ethics issues associated to it and how you plan to deal with them and to conform to national legislation.

Please note that research on **human stem cells**, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding shall be granted for research activities that are prohibited in all the Member States. No activity shall be funded in a Member State where such activity is forbidden.

Any proposal for research on **human embryonic stem cells** shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethics approvals that will be provided. As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member States involved[25].

If your proposal involves the use of Human embryos/foetus, including human embryonic stem cells (hESC), please provide the following information:

- Confirm that the proposal does not include research activities which destroy embryos including for the procurement of stem cells;

[25] Regulation of the European Parliament and of the Council laying down the rules for the participation and dissemination in 'Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)
Regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)

- Confirm that you have taken into account the legislation, regulations, ethics rules and/or codes of conduct in place in the country(ies) where the research is to take place, including the procedures for obtaining informed consent;
- Describe the origin of the Human embryos/foetus/hESC;
- Describe the measures taken to protect personal data, including genetic data, and privacy;
- Describe the nature of financial inducements, if any.

If already available at this stage, please submit the national/local ethics approvals, information sheets and informed consent forms to cover the research on Human embryos/foetus, including human embryonic stem cells (hESC).

Humans

This category refers to **any type of research involving empirical work with human beings, regardless of the scientific domain**. Common to all fields, the main ethics issues concern the respect for persons and for human dignity, the just distribution of research's benefits and burden, the social value and the rights and interests of research participants, the need to ensure participants' free informed consent (with particular attention to vulnerable categories of individuals such as children, patients, discriminated people, minorities, persons unable to give consent, etc.). Research methodologies should not result in discriminatory practices or unfair treatment.
When children and other persons unable to give consent are directly involved, their assent (besides parents or legal guardians' consent) should be elicited when feasible[26].

With regard to proposals in the field of **social sciences and humanities**, their peculiarity for what concerns ethics issues and requirements should be taken into consideration. Please specify what type of work with humans is involved (ex: interviews, observation, experiments with volunteers, and whether those include physical interventions), and discuss the ethical implications of the chosen methodologies. For instance, describe the sampling methods or recruitment procedures and discuss whether they may result in discriminatory practices. Assess whether the research topics or methodologies may entail any psychological, social, legal or other type of harm to participants. If due to the research context or methodology, standard written informed consent procedures are not applicable or advisable, please explain how you will ensure consent in a more appropriate way. The involvement of persons having personal or hierarchical links with the investigators should be avoided, or else the procedure to ensure real free and informed consent should be described (including students being awarded academic credits for participating in research projects).

For guidance on how to deal with ethics issues in social research, see also:
http://ec.europa.eu/research/participants/data/ref/fp7/89867/social-sciences-humanities_en.pdf

With regard to **medical studies**, the *Declaration of Helsinki*[27] sets the ethics framework for research, specifying the main principles for medical research (e.g. protection of life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects, protocols' design, role of research ethics committees, informed consent procedures, etc).
Moreover, projects funded under the EU research framework programmes have to comply with the principles enshrined in the *Council of Europe Convention on human rights and biomedicine* – known as the Bioethics Convention (Oviedo). Its main purpose is to protect individuals against exploitation

[26] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use – see article 4 and 5.
[27] WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

arising out of treatment or research and it contains several detailed provisions on informed consent[28].
Regarding clinical trials, they must comply with the EU Directive on Clinical Trials[29]. Its purpose is to rationalise the procedure involving documentation and administration required for conducting clinical trials, and to ensure that patients are afforded the same protection in all EU Member States. On 17 July 2012, the Commission adopted a "*Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use (and repealing Directive 2001/20/EC)*, which is expected to enter into force in 2016, and should also be taken into account.

Please explain how your research will take into account the relevant ethical framework.

Human cells/tissues

Human cells and tissues used in the research should either be commercially available (please indicate the source) or, in case you produce them or they originate from another laboratory, you should demonstrate that their production is ethically authorized. If cells or tissues derive from clinical practice (e.g. operations), please make sure that donors have provided their informed consent to their use for research.
If your research implies use of human cells/tissues collected in the framework of another research project, please provide the adequate authorisations to secondary use.
Please specify if any material from existing biobanks will be used. Please specify if your project has the aim or effect to set up a biobank.

Protection of personal data

Please explain how you will ensure privacy and confidentiality in personal data collection and processing, in accordance with EU legislation, in particular:
Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
However, the European legislation on data protection is evolving and the coming legislation should also be taken into consideration – (Reform of data protection legislation: http://ec.europa.eu/justice/data-protection/)

In case your research involves the collection/processing of **sensitive personal data** (health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction) or **genetic information**, please justify the need for their collection, discuss the possible ethics implications and how you will address them.
In case your research involves **tracking or observation** of participants, please state whether any video or photo will be used publicly and describe the methods you will use to guarantee the privacy of the participants.
In case you are planning to use **secondary data**, please specify if these originate from publicly available sources, or, if not, whether the data has been authorized for secondary use (by primary

[28] The article on the purpose and object of the Convention states that the Parties "shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine". The Convention also concerns equitable access to health care, professional standards, protection of genetic heritage and scientific research.
[29] Directive 2001/20/EC. The Clinical Trials Directive is concretised further by Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use.

owner of the data who must also confirm that the informed consent included the possibility of a secondary use of data).

In any case, please **describe** in details **the specificity of data collection, storage, protection, retention and destruction**. Please provide as well an authorisation from the University data protection controller or national data protection authority.

Animals

Animal welfare is a value of the Union (Article 13 of the TFEU). Animals have an intrinsic value which must be respected and they must be treated as sentient creatures. As a consequence, one of the main aims of the Directive 2010/63/EU is to improve the welfare of animals used in scientific procedures, taking into account that new scientific knowledge is available in respect of factors influencing animal welfare as well as the capacity of animals to sense and express pain, suffering, distress and lasting harm.
According to the Directive, it is compulsory to carry out ethical evaluation based on the principles of replacement, refinement, reduction (**3Rs principle**) and all breeders, suppliers, users and the experiments with animals must be authorised.
Therefore, in addition to provide authorisations if already available, please elaborate on **the need to use animals** and the justification to this; consider whether your project has been designed so that procedures involving animals are carried out in the most humane and environmentally sensitive manner possible; make sure that the 3Rs principle will be adequately implemented; reflect on appropriateness of veterinary care and husbandry, impact on animals in terms of pain and distress (mention the anaesthesia and euthanasia methods if any); perform a harm-benefit analysis.

Provide reference to **compliance with relevant EU and national legislation**, see in particular:
Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes

Non-EU countries

International research raises several concerns, especially when they take place in developing or emerging–economy countries where participants may be more vulnerable due to economic or political reasons, and a significant disparity of power may exist between researchers and research participant.
Thus, the researcher must ensure that he will **comply with the relevant EU legislation in addition to the legislation of the host country**. He should also comply with international reference documents, such as the Declaration of Helsinki.
The researcher should also make sure – if applicable – that the **benefits of the research are shared** with relevant local actors.

Therefore, if the Host institution of the project is located in an **associated country** Please check the H2020 Online Manual and click on 'International coorporation' for up-to-date information on this topic,or if the project includes research activities taking place in a **non-EU country**, the PI must provide a declaration that he will rigorously apply the ethical standards and guidelines of H2020, regardless of the country in which the research is carried out.

In case work is foreseen in *low or lower-middle income country(ies*) according to World Bank classification***, an authorization from local competent institutions (as appropriate) will be required.***

In case of **exportation of any materials outside a non-EU country** – including personal data - some additional documents are required, including an ethics approval, the local authorisation for export, and a Material Transfer Agreement.

In case of use of local resources ***(and especially*** animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples), please explain which resources are used, why and what measures are foreseen on this specific aspect for benefit sharing.

Finally, if the situation in the country may put individuals taking part in the research at risk, please provide details on the foreseen security measures, including insurance cover.
For further guidance, please see **http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm**

Environmental protection

Some types of research may imply a risk for the safety of the environment or of the staff involved. Examples include studies on pathogen agents and virus, or experiments that may lead to the release of dangerous substances or particles in the air/water/soil or in the human body.

If your research implies such risks, you are required to describe the foreseen security, health and safety measures, and their conformity with EU and national guidelines.

See: Directive 2000/54/EC (on the protection of workers from risks related to exposure to biological agents at work), Directives 2009/41/EC and 98/81/EC (on the contained use of genetically modified micro-organisms – GMMs, and European Commission Recommendation of 07/02/2008 on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research).

If your research takes place in a protected area, please take into consideration the relevant Directives, namely Directive 2008/56/ECof the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) – specifically its Annex III ; Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora ; Council directive 79/409 EEC on the conservation of wild birds

Dual use

Dual use specifically refers to technologies that can be used for both peaceful and military aims (See Regulation 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). The technologies might present a danger to participants, or to society as a whole, if they were improperly disseminated and must be correctly identified, mentioning as well if they are defensive or offensive.
In the bio-medical field, dual use refers for instance to research which may enhance the virulence of microorganisms causing diseases; diminish the immunity of the host; enhance the transmissibility of the pathogens (enhance the contagiousness); alter (enlarge) the host range of the pathogen; render a vaccine ineffective; confer resistance to life-saving antibiotics; prevent diagnosis of infection or detection of a pathogen; enable eventual weaponization, severity of disease/symptoms or mass casualty, see:
http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

In case your research may fall under the mentioned categories, please provide details on the project and on the measures that you foresee to prevent/address/mitigate the risks they might raise.

Misuse

In general, potential **misuse** of research may be defined as “research involving or generating materials, methods or knowledge that could be misused for unethical purposes”.
The main areas of concern regarding potential misuse are: research involving agents or equipment that could be directly misused for criminal or terrorist purposes; research which creates knowledge that could be used for criminal or terrorist purposes; research which can result in stigmatization and discrimination; application and development of surveillance technologies; data mining and profiling technologies.

Other ethics issues

If any other ethically relevant issues apply to your project, please describe them here and explain how you address them.

ETHICS ISSUES TABLE - CHECKLIST

Information and documents to be provided by the applicants

BOX 1: HUMAN EMBRYOS/FOETUS		Information to be provided	Documents to be provided
Does your research involve Human Embryonic Stem Cells (hESCs)?[i]			
If **YES:**	- Will they be directly derived from embryos within this project?	*Research cannot be funded.*	*Research cannot be funded.*
	- Are they previously established cells lines?	Origin and line of cells. Details on licensing and control measures by the competent authorities of the Member States involved.	Copies of relevant Ethics Approvals.
Does your research involve the use of human embryos?		Origin of embryos. Details on recruitment and informed consent procedures.	Copies of relevant Ethics Approvals. Informed Consent Forms. Information Sheets.
Does your research involve the use of human foetal tissues / cells?		Origin of human foetal tissues/cells. Details on informed consent procedures.	Copies of relevant Ethics Approvals. Informed Consent Forms. Information Sheets.

BOX 2: HUMANS		Information to be provided	Documents to be provided
Does your research involve human participants?		*Please provide information in one of the subcategories below:*	
If **YES:**	- Are they volunteers for social or human sciences research?	Details on recruitment and informed consent procedures.	Copies of relevant Ethics Approvals. Informed Consent Forms. Information Sheets.
	- Are they persons unable to give informed consent?	*Information above **plus:*** Details on the procedures used to ensure that there is no coercion on participants.	*Documents as above.*
	- Are they vulnerable individuals or groups?	Details on the type of vulnerability. Details on recruitment and informed consent procedures.	*Documents as above.*
	- Are they children/minors?	*Information above **plus:*** *Details on* the age range. Details on children/minors assent procedures. Describe the procedures to ensure welfare of child/minor.	*Documents as above.*
	- Are they patients?	Details on the nature of disease/condition/disability. Details on recruitment and informed consent procedures.	*Documents as above.*
	- Are they healthy volunteers for medical studies?	*Information above **plus:*** Details on incidental findings. policy.	Copies of relevant Ethics Approvals.
Does your research involve physical interventions on the study participants?			
If **YES:**	- Does it involve invasive techniques?	Risk assessment.	Copies of relevant Ethics Approvals.
	- Does it involve collection of biological samples?	Details on the type of samples to be collected. Details on procedures for collection of biological samples.	Copies of relevant Ethics Approvals.

BOX 3: HUMAN CELLS / TISSUES		Information to be provided	Documents to be provided
Does your research involve human cells or tissues? (*Other than from "Human Embryos/Foetus" i.e. BOX 1)*			
If **YES:**	- Are they available commercially?	Details on cell types and provider (company or other).	
	- Are they obtained within this project?	Details on cell types.	Copies of relevant Ethics Approvals.
	- Are they obtained within another project?	Details on cell types.	Authorisation by primary owner of cells/tissues (including references to ethics approval).
	- Are they deposited in a biobank?	Details on cell types.	Details on biobank and access to it.

BOX 4: PROTECTION OF PERSONAL DATA[ii]		Information to be provided	Documents to be provided
Does your research involve personal data collection and/or processing?			
If **YES:**	- Does it involve the collection and/or processing of sensitive personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	Details on protection of privacy/confidentiality. Details of procedures for data collection, storage, protection, retention, destruction or re-use. Explicit confirmation of compliance with national and EU legislation.	Copies of relevant Ethics Approvals for the collection of personal data. Informed Consent Forms. Information Sheets.
	- Does it involve processing of genetic information?	*Information as above.*	Copies of relevant Ethics Approvals for the processing of genetic information.
	- Does it involve tracking or observation of participants?	*Information as above **plus:*** Details on methods used for tracking or observing participants.	Copies of relevant Ethics Approvals for the collection of personal data.
Does your research involve further processing of previously collected personal data (secondary use)?		Details of the database used or to the source of data. Confirmation of open public access to the data or of authorisation for secondary use.	Document confirming open public access to the data (e.g. print screen from Website) or authorisation by primary owner of data Informed Consent Form (if applicable).

BOX 5: ANIMALS[iii]		Information to be provided	Documents to be provided
Does your research involve animals?		Confirmation of compliance with relevant EU and national legislation. Number of animals to be used, nature of the experiments, procedures, anticipated impact and how this will be minimised. Details on species and rationale for their use. Details on procedures to ensure animal welfare. Details on implementation of the 3Rs Principle.	Copies of all appropriate authorisations for the supply of animals and the project experiments. Copies of training certificates/ personal licences of the staff involved in animal experiments.
If **YES:**	- Are they vertebrates?	*Information as above.*	*Documents as above.*
	- Are they non-human primates?	*Information above **plus:*** Confirmation of compliance with Art. 8, 10, 28, 31, 32 (Directive 2010/63/EU). Discussion of specific ethics issues related to their use.	*Documents as above*. Personal history file (See art. 31 of Directive 2010/63/EU).
	- Are they genetically modified?[iv]	Confirmation of compliance with relevant EU and national legislation. Number of animals to be used, nature of the experiments, procedures, anticipated impact and how this will be minimised. Details on species and rationale for their use. Details on procedures to ensure animal welfare. Details on implementation of the 3Rs Principle.	Copies of all appropriate authorisations for the supply of animals and the project experiments. Copies of training certificates/ personal licences of the staff involved in animal experiments
	- Are they cloned farm animals?	*Information as above*	Copies of all appropriate authorisations for the supply of animals and the project experiments. Copies of training certificates/ personal licences

			of the staff involved in animal experiments. Copies of specific authorisation for cloning.
	- Are they endangered species?	*Information as above **plus:*** Confirmation of compliance with Art. 7 - Directive 2010/63/EU. Discussion of specific ethics issues related to their use.	Copies of all appropriate authorisations for the supply of animals and the project experiments. Copies of training certificates/ personal licences of the staff involved in animal experiments.

BOX 6: NON-EU COUNTRIES		Information to be provided	Documents to be provided
Does your research involve non-EU countries? *Countries:*(Maximum number of characters allowed: 1000) _____		Details on activities carried out in non-EU countries.	Signed declaration to confirm compliance with ethical standards and guidelines of H2020. Copies of relevant Ethics Approvals from EU country host and non-EU country (double ethics review, if possible).
Do you plan to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?		Details on type of local resources to be used and modalities for their use.	In case of human resources, copies of relevant Ethics Approvals, as above. In case of animals, plants, micro-organisms and associated traditional knowledge, document showing compliance with Convention on Biodiversity (e.g. access permit and benefit sharing agreement)
Do you plan to import any material, including personal data, from non-EU countries into the EU? *If you consider importing data, please fill in Box 4 on data protection too***.**		Details on type of materials or data to be imported.	As above (use of local resources) and: Material Transfer Agreement (MTA).
If **YES:**	- Specify material and countries involved (maximum number of characters allowed: 1000) _____		
Do you plan to export any material – including personal data –from the EU to non-EU countries? *If you consider exporting data, please fill in Box 4 on data protection too.*		Details on type of materials or data to be exported.	Authorisation for export from EU. Material Transfer Agreement (MTA).

If **YES**:	- Specify material and countries involved (maximum number of characters allowed: 1000) _____		
If your research involves low and/or lower middle income countries[30], are any benefit-sharing actions planned?		Details on benefit sharing measures. Details on responsiveness to local research needs. Details on procedures to facilitate effective capacity building.	As above (use of local resources) and narrative document describing benefit sharing, responsiveness to local research needs and capacity building.
Could the situation in the country put the individuals taking part in the research at risk?		Details on safety measures to be implemented, including training.	Insurance cover

BOX 7: ENVIRONMENTAL PROTECTION AND SAFETY[v vi vii]	Information to be provided	Documents to be provided
Does your research involve the use of elements that may cause harm to the environment, to animals or plants?	Confirmation of compliance with national/local guidelines/legislation Details on safety measures to be implemented.	Safety classification of laboratory. GMO authorisation, if applicable.
Does your research deal with endangered fauna and/or flora and/or protected areas?	Confirmation of compliance with international/national/local guidelines/legislation31	Specific approvals, if applicable.
Does your research involve the use of elements that may cause harm to humans,	Details on health and safety procedures.	University safety procedures.

[30] For a list of low and/or lower middle income countries, see: http://data.worldbank.org/about/country-classifications/country-and-lending-groups

31 See, in particular:
Directive 2008/56/EC; Council Directive 92/43/EEC; Council Directive 79/409/EEC
Council Regulation (EC) No 338/97.
Council Decision 93/626/EEC
Council Decision 2002/628/EC.

including research staff?	Confirmation of compliance with national/local guidelines/legislation	Safety classification of laboratory.

BOX 8: DUAL USEi' [viii]	Information to be provided	Documents to be provided
Does your research have the potential for military applications?		

BOX 9: MISUSE	Information to be provided	Documents to be provided
Does your research have the potential for malevolent/criminal/terrorist abuse?		

BOX 10: OTHER ETHICS ISSUES	Information to be provided	Documents to be provided
Are there any other ethics issues that should be taken into consideration? Please specify: (Maximum number of characters allowed: 1000) _____	Any relevant information.	Any relevant document.

[i] REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down the rules for the participation and dissemination in 'Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)

and
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)

[ii] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

[iii] DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2010 on the protection of animals used for scientific purposes
[iv] DIRECTIVE 2009/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 on the contained use of genetically modified micro-organisms and REGULATION (EC) No 1946/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 July 2003 on transboundary movements of genetically modified organisms – see specifically its articles 4 to 11 and its annexes III to V
[v] DIRECTIVE 2000/54/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 September 2000 - On the protection of workers from risks related to exposure to biological agents at work – see specifically its Chapter II and article 16

[vi] DIRECTIVE 2009/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 on the contained use of genetically modified micro-organisms – see specifically its annex IV
and
REGULATION (EC) No 1946/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 July 2003 on transboundary movements of genetically modified organisms - – see specifically its articles 4 to 11 and its annexes III to V
DIRECTIVE 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms
COUNCIL DECISION 2002/628/EC: of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety
COUNCIL DECISION 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity

[vii] DIRECTIVE 2008/56/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) – specifically its Annex III
COUNCIL DIRECTIVE 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora
Council directive 79/409 EEC on the conservation of wild birds and
Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein

[viii] 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
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