

European Research Council

Executive Agency

Established by the European Commission



European Research Council (ERC)

Information for Applicants to the Proof of Concept Grants 2018 Call

Version 1.0 20 September 2017

Purpose of this document

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 2018 ¹, the revised 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)² (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.

Applicants can also consult the ERC-2018-PoC FAQs³, available on the Participant Portal.

Note: As with other parts of the EU's Horizon 2020 Framework Programme, National Contact Points (ERC NCPs) have been set up across Europe⁴ 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 at

https://ec.europa.eu/research/participants/portal/desktop/en/support/national_contact_points.html.

http://ec.europa.eu/research/participants/portal/desktop/en/support/faq.html#c,faqs=categoryMachineName/t/pp_roles_and_righ ts/0/1/1/category&categoryMachineName/t/pp_roles_and_righ ts/0/1/1/category&categoryMachineName/t/p_submission_eval/0/1/1/category&categoryMachineName/t/ethics_research_integrity/0/1/1 /category&categoryMachineName/t/grants/0/1/1/category&categoryMachineName/t/ethics_research_integrity/0/1/1 /category&categoryMachineName/t/grants/0/1/1/category&categoryMachineName/t/eu_research_policy/0/1/1/category&programmeList/t/H2020/0/1/1/program me&programmeList/t/3rd_health_programme/0/1/1/programme&programmeList/t/asylum_migration_and_integration_fund/0/1/1/programme&programmeList/t/consumer_programme/0/1/1/programme&programmeList/t/COSME/0/1/1/programme&programmeList/t/creative_europe_programme/0/1/1/programme&programmeList/t/resamus_programmeList/t/internal_security_fund_borders/0/1/1/programme&programmeList/t/internal_security_fund_police/0/1/1/programme&programmeList/t/pilot_projects_preparatory_actions/0/1/1/programme&programmeList/t/promotion_of_agricul tural_products/0/1/1/programme&programmeList/t/research_fund_for_coal_and_steel/0/1/1/programme&programmeList/t/internal_security_fund_poreducts/0/1/1/programme&programmeList/t/research_fund_for_coal_and_steel/0/1/1/programme&programmeList/t/internal_security_fund_poreducts/0/1/1/programme&programmeList/t/research_fund_for_coal_and_steel/0/1/1/programme&programmeList/t/internal_security_fund_poreducts/0/1/1/programme&programmeList/t/research_fund_for_coal_and_steel/0/1/1/programme&programmeList/t/internal_security_fund_poreducts/0/1/1/programme&programmeList/t/research_fund_for_coal_and_steel/0/1/programme&programmeList/t/internal_security_fund_poreducts/0/1/1/programme&programmeList/t/internal_security_fund_poreducts/0/1/programme&programmeList/t/research_fund_for_coal_and_steel/0/1/programme&programmeList/t/internal_security_fund_poreducts/0/1/programme&programmeList/t/internal_security_fund_poreducts/0/1/programme&programmeList/t/internal_s

¹ European Commission C(2017)5307 of 2 July 2017.

² C(2015)4975 of 23 July 2015.

³ ERC-2018-PoC FAQs:

⁴ 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 2018 call

The IT submission system has changed from pdf to html 5. Please take the necessary time to make sure the IT configuration works properly.

New paragraph on "No contact with Peer Reviewers" rule during the evaluation process in line with the section 3.2 of the new ERC Rules for Submission document.

Info on similar proposals submitted in the past (in "General information" section), now restricted to proposals previously submitted only to ERC (in "Call specific question").

Changes in Part B:

Section 1 - a. The idea – Excellence in Innovation potential now should develop two (2) aspects:

a.1 the problem and

a.2 the solution;

Section 2 – Expected Impact: new structure

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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 2018

The ERC Work Programme 2018⁵ 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 or societal 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, Advanced and Synergy) of any nationality who intends to conduct their Proof of Concept activity in any EU Member State⁶ or Associated Country⁷.

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

http://ec.europa.eu/research/participants/data/ref/h2020/wp/2018 2020/erc/h2020-wp18-erc_en.pdf

⁵ ERC Work Programme 2018:

⁶ 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.

Please consult the link for the list of <u>Associated Countries</u>. Please also check the <u>online manual</u> for up-to-date information on the current position for Associated Countries.

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 State⁶ or Associated Country⁷.

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 (12 months project + 6 month integrated extension)**. 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 costs⁸.

Specific Eligibility Criteria

| | Proof of Concept Grant |
|----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Canaifia Eliaikilitu | The PI must be an ERC frontier research grant holder that is either ongoing or where the duration of the project fixed in the ERC Grant Agreement has ended less than 12 month before 1 January 2018. |
| Specific Eligibility Criteria | 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 State⁶ or Associated Country⁷ as a legal entity created under national law, or it may be an International European Interest Organisation (such as CERN, EMBL, etc.), the European Commission's Joint

⁸ In H2020 it is not possible to ask lower percentages for the indirect costs. The eligible direct costs exclude 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.

Research Centre (JRC) or any other entity created under EU law. Any type of legal entity, public or private, including universities, research organisations and undertakings can host Principal Investigators and their teams. The ERC welcomes applications from Principal Investigators hosted by private for-profit research centres, including industrial laboratories.

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 may be ruled ineligible and not considered for evaluation.

The PI can submit the PoC proposal with a different Host Institution than the one where the ERC Frontier Research Grant is being currently implemented, providing that this other HI complies with the eligibility criteria as stipulated in the ERC 2018 Work Programme.

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 may result in rejection of the proposals concerned from evaluation or from the grant preparation in accordance with section 3.11 of the ERC Rules for Submission. Plagiarism detection software may be used to analyse proposals submitted to the ERC.

No Contact with Peer Reviewers

Please, note that in accordance with section 3.2 of the <u>ERC Rules for Submission</u>, any direct or indirect contact about the peer review evaluation of an ERC call between an applicant legal entity or a PI submitting a proposal on behalf of an applicant legal entity, and any independent expert involved in the peer review evaluation under the same call, in view of attempting to influence the evaluation process, is strictly forbidden. Such contact can constitute an exclusion situation and, if this situation is established in accordance with Article 106 of the Financial Regulation, will result in the decision of the ERCEA to reject the proposal concerned from the call in question.

Restrictions on submissions of proposals

The restrictions for submission under the <u>ERC Work Programme 2018</u> are set out below. The Scientific Council may decide in the light of experience that different restrictions will apply in subsequent years.

The year of an ERC call for proposals refers to the Work Programme under which the call was made and can be established by its call identifier. A 2018 ERC call for proposals is therefore one that was made under the Work Programme 2018 and will have 2018 in the call identifier (for example ERC-2018-PoC). Ineligible or withdrawn proposals do not count against any of the following restrictions (please consult the ERC Rules for Submission, section 2.2).

Principal Investigators may submit <u>only one</u> proposal under <u>Work Programme 2018</u>. If multiple submissions are made at different cut-off dates under the <u>Work Programme 2018</u>, only the first eligible proposal will be considered.

A Principal Investigator whose proposal was rejected on the grounds of a breach of research integrity in the calls for proposals under Work Programmes 2016 or 2017 may not submit a proposal to the calls for proposals made under Work Programme 2018.

More than one Proof of Concept Grant may be awarded per ERC funded frontier research project, but only one Proof of Concept project may be running at any one time for the same ERC frontier research project.

Preparing and submitting an ERC Proof of Concept Grant application⁹

ERC grant applications can be submitted only in response to a 'call for proposals'. Calls announced in the ERC Work Programme 2018 are published on the ERC website¹⁰, the Research and Innovation Participant Portal¹¹, and in the Official Journal of the European Union¹².

It is a continuous call with three deadlines; an applicant may submit <u>only one</u> application per call. Ineligible and withdrawn proposals do not count against this limit.

The provisional timing of evaluation will be updated on a regular basis on the ERC website.

The submission deadlines foreseen are:

ERC-2018-PoC-1: 16th January 2018, 17.00 (Brussels local time)

ERC-2018-PoC-2: 18th April 2018, 17.00 (Brussels local time)

ERC-2018-PoC-11th September 2018, 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 Portal¹¹ where any modifications of the submission deadlines are indicated.

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

⁹ 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, the ERCEA will provide a version of the proposal translated using computer-aided technology. An English translation of the abstract must be included in the proposal.

http://erc.europa.eu/

http://eur-lex.europa.eu/JOIndex.do?ihmlang=en

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' (Part A)
 - 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 applied.

1.1.2 How to complete the grant application

1.1.2.1 Instructions for completing the online administrative Proposal Submission Forms 13

Proposals must be submitted electronically via the web-based Participant Portal Submission Service (PPSS)¹⁴. 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 (Part A) are an integral part of the proposal and are divided in 5 Sections:

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

Section 2 - Participants & contacts - Administrative data of participating organisations contains information about the PI and the PI's host institution¹⁵.

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 checklist (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.

The H2020 Online Manual (http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applyingfor-funding/submit-proposals en.htm) describes the standard process of proposal submission. The 'IT HOW TO'

¹³ The Service Specific Privacy Statement (SSPS) on the protection of personal data related to the processing operations of applicants' and beneficiaries' data: proposal evaluation, grant management and follow-up in H2020 is available through the following link: http://ec.europa.eu/research/participants/data/support/legal_notice/h2020ssps-grants_en.pdf

Applicants are reminded not to provide irrelevant and excessive data (mainly with regards to health data).

14 For General user guidance please refer to the <u>User Guide of the Submission Service</u>.

wiki site provides an online IT manual with screenshots.

15 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. <u>The precise</u> guestions 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. For any difficulty encountered, please, contact the PPSS Service Desk in due time before the call deadline by using the Research Enquiry Service:

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. You may also contact the SEP helpdesk on +32 (2) 29 92222 to receive immediate assistance on any issue with the submission system.

1 – General information (notes for information ONLY)

* Failure to respond to the mandatory fields below will block the submission.

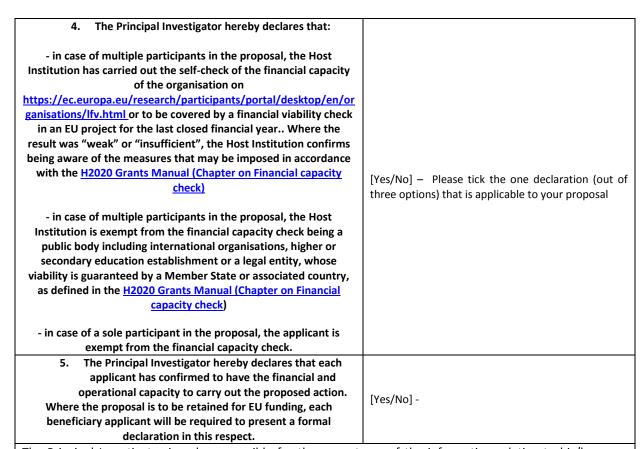
| Торіс | [pre-filled] - ERC Proof of Concept Grant - ERC-2018-PoC Chosen upfront on the participant portal call page ERC-PoC-2018. |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Call identifier | [pre-filled] - Call for proposals for ERC Proof of Concept Grant 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-2018-PoC. |
| Type of Action | [pre-filled] - Proof of Concept Grant [ERC-POC] Definition for 'type of action', ERC-PoC. |
| Deadline ID | [pre-filled] - ERC-2018-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 symbols or special characters please, except underscore, space, hyphen or dot). |
| 1 | The same acronym should appear on each page of the proposal. |

| Proposal Title (max. 200 char.) (non- confidential information)* | The title should be <u>no longer than 200 characters</u> and should be understandable to the non-specialist in your field. Note that for technical reasons, the following characters are not accepted in the Proposal Title and will be removed: <> " & 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. |
|---------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Duration in Months* | The estimated duration of the project in full months (0-18 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. |

| 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) |
|-----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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. |
| Panel under which the original ERC grant was funded | This is the reference number to the panel that funded the parent project linked to the submitted PoC. This panel can be found in the Grant Agreement or, alternatively, on our website http://erc.europa.eu under the "Funded Projects" link |

| 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. |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Abstract (min.100/ max. 2000 char. with spaces) (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 (see also Data-Related Questions 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. |

| | Declarations | |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| 1. | The Principal Investigator declares to have the written consent of all participants on their participation and on the content of this proposal, as well as any researcher mentioned in the proposal as participating in the project (either as other PI, team member or collaborator).* | [Yes/No] Tick the box for 'yes' |
| 2. | The Principal Investigator declares that the information contained in this proposal is correct and complete. | [Yes/No] Tick the box for 'yes' |
| 3. | The Principal Investigator declares that all parts of this proposal comply 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] Tick the box for 'yes' |



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 is to be retained for EU funding, the Host Institution and each beneficiary applicant will be required to present a formal declaration in this respect.

According to Article 131 of the Financial Regulation of 25 October 2012 on the financial rules applicable to the general budget of the Union (Official Journal L 298 of 26.10.2012, p. 1) and Article 145 of its Rules of Application (Official Journal L 362, 31.12.2012, p.1) applicants found guilty of misrepresentation may be subject to administrative and financial penalties under certain conditions.

Personal data protection

The assessment of your grant application will involve the collection and processing of personal data (such as your name, address and CV), which will be performed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Unless indicated otherwise, your replies to the questions in this form and any personal data requested are required to assess your grant application in accordance with the specifications of the call for proposals and will be processed solely for that purpose. Details concerning the purposes and means of the processing of your personal data as well as information on how to exercise your rights are available in the privacy statement. Applicants may lodge a complaint about the processing of their personal data with the European Data Protection Supervisor at any time.

Your personal data may be registered in the Early Detection and Exclusion system of the European Commission (EDES), the new system established by the Commission to reinforce the protection of the Union's financial interests and to ensure sound financial management, in accordance with the provisions of articles 105a and 108 of the revised EU Financial Regulation (FR) (Regulation (EU, EURATOM) 2015/1929 of the European Parliament and of the Council of 28 October 2015 amending

Regulation (EU, EURATOM) No 966/2012) and articles 143 - 144 of the corresponding Rules of Application (RAP) (COMMISSION DELEGATED REGULATION (EU) 2015/2462 of 30 October 2015 amending Delegated Regulation (EU) No 1268/2012) for more information see the Privacy statement for the EDES Database.

2 – Participants & contacts: 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] 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 . 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 S | tatus of your organisation |
| - | | the research and innovation programmes as registered and/or |
| | | of the European Commission. Read more about legal statuses. |
| Research and Innovation | n legal statuses: | |
| Legal perso | on | [pre-filled] |
| Public body | | [pre-filled] |
| Non-profi | it | [pre-filled] |
| International organisation | | [pre-filled] |
| International organisation of European Interest | | [pre-filled] |
| Secondary or Highe | r education | |
| establishme | | [pre-filled] |
| Research organisation | | (pre-filled] |

| Entreprise Data: | The enterprise data of the organisation is taken from the Beneficiary Register. Changes to the self-declared or self-assessed SME data can be performed by the self-registrant or by the LEAR (Legal Entity Appointed Representative) in the Beneficiary Register. |
|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Small and Medium-sized Enterprises (SMEs): - SME self-declared status - SME self-assessment - SME validation sme | [pre-filled] |
| | |
| Nace code | NACE code gives information about the main activity of the organisation. The code was selected at the time of registration of the organisation data. Administrative data for statistical purposes. [pre-filled] |

| Department(s) carrying out the proposed work | | |
|---------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| The information serves mainly statistical purposes. For determining the eligibility of the proposal, the official address | | |
| of the organisation is tal | ken into account | |
| Department Name | Please indicate the address of the main department/institute/ unit (max. 3) 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, if necessary. | |
| Street | Please enter the street name and number where the department/faculty/institute/laboratory is located. | |
| 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 (PI)

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 for any ERC specific question, please, contact the ERCEA using the following e-mail address: <u>ERC-PoC-APPLICANTS@ec.europa.eu</u>.

The name and e-mail of the contact persons including the Principal Investigator and the Host Institution contact are **read-only** in the administrative form (available on Step 5 of the application). Only additional details of the contact persons can be edited here. **To give access rights and contact details of contact persons**, please save and close the form, and **go back to Step 4** of the submission wizard and save the changes. By reopening the form the data will be updated based on the Step 4 information. **Please, note that the e-mail provisions the access rights and therefore it cannot be changed here. The name of a contact person can be edited at Step 4. In order to be able to submit your proposal after saving changes made in Step 4 (Parties), you have to re-open the administrative form ('Edit forms' button), revise the changes, validate and save the form. Failure to do so will prevent you from submitting your proposal.**

Further details are available in the <u>Submission Service User Manual</u>.

| Principal Investigator | | |
|------------------------|-------------------------------------------------------------------------------------------------------------------|--|
| ORCID | If you have a ORCID number please enter it here (an example is 0000-0002-1825-0097) | |
| Researcher ID | If you have a Researcher ID number (e.g. Researcher ID, ORCID) please enter it here. (An example is A-4031-2008). | |
| Other ID: | If you have a different researcher identifier number, 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 /Male* | This information is required for statistical and mailing purposes. Please tick Male or Female 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. |
| Place 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 | The street name and 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 +3: 2-2991111. | | | | |
| Phone2 / Mobile | Please insert the full mobile number (or second phone number) including country are city/area code. Example +32-2-2991111. The mobile phone number is optional, but it strongly recommended to insert it since this may be used to reach the PI for specific issues. | | | | |
| 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 the Host Institution contact persons are **read-only** in the administrative form (available at Step 5 of the application); only additional details can be edited here. To give access rights and contact details of your Host Institution, please save and close the form, then go back to **Step 4 of the submission wizard, add the details** at **Step 4 of the submission wizard** and save the changes (see instructions above, under the section of the PI). **Please note that submission is blocked without a Main Contact Person and e-mail address for the Host Institution.**

In order to be able to submit your proposal after saving changes made in Step 4 (Parties), you have to re-open the administrative form ('Edit forms' button), revise the changes, validate and save the form. Failure to do so will prevent you from submitting your proposal.

| Contact address of the Host Institution and contact person. All contact persons of the participant are listed here | | | | | | |
|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|--|
| based on the information given at Step 4. Data in blue is read-only. | | | | | | |
| Organisation legal name | [pre-filled from 'Contacts' at Step 4] | | | | | |
| First name(s) | [pre-filled from 'Contacts' at Step 4] | | | | | |
| Last 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 | | | | | |
| Department/ Office/Section/ /Faculty/ name | The name under which the host department/faculty/institute/laboratory is registered. | | | | | |
| Street | The street name and number. | | | | | |
| Town | The town, in English (please avoid any district codes). | | | | | |
| Postcode | The postal code. | | | | | |
| Constant | [drop-down menu] | | | | | |
| Country | Please select one country. | | | | | |
| Phone | Please insert the full phone number including country and city/area code. Example +32 2-2991111. | | | | | |
| Phone2 / Mobile | Please insert the full mobile number (or second phone number) including country and city/area code. The mobile number is optional. | | | | | |

| Other Contact Persons with access rights (full or read only) | | | |
|--------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|--|--|
| First name(s) | [pre-filled from 'Contacts' at Step 4] | | |
| Last 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

This simplified budget table summarises the total estimated eligible cost and the requested EU contribution, as they are also presented in the proposal (Part B, section 4, a. Resources). 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.

Please, ensure the table contains the correct total eligible cost and requested grant in whole Euro integers, not thousands of Euros.

| Participant Number in this proposal | The PI's host institution of the proposal is automatically number one. | | |
|-------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|
| Organisation short name | [pre-filled] Read-only based on the PIC data in the Beneficiary Register. | | |
| Organisation country | [pre-filled] Read-only based on the PIC data in the Beneficiary Register. | | |
| Total Eligible Costs/€ (including 25% indirect costs) | The total estimated eligible costs consist of the following cost categories (A+B+C) as listed in the template budget table of Part B: A - Total direct costs (Total personnel ¹⁶ and Total other direct costs), B - Indirect costs/overheads (0.25 of Total direct costs (A). Indirect costs are fixed to a flat rate of exactly 25%) C1 - Subcontracting costs (without overheads) C2 - Other direct costs with no overheads ¹⁷ (such as costs of resources made available by third parties which are not used on the premises of the beneficiary) | | |
| Requested Grant/€ | The total budget that you are requesting as the ERC grant (in Euros) | | |

http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference docs.html#h2020-mga-erc

¹⁶ There is no minimum level of commitment explicitly required for the PI of a PoC proposal. However, as the PI is responsible for managing the PoC project, the percentage of the Pl's working time spent on the action cannot be zero (although it could be less than 10%). It is essential that the cumulative amount of time declared by the PI on the PoC action and on the main StG/CoG/AdG/SyG grant (if still ongoing) does not exceed 100%.of the PI's total working time.

In principle, if the PI charges salary to the PoC action, the Host Institution must keep time records for the number of hours declared. Similarly, all team members for which personnel costs are being charged should keep time sheets of the hours worked on the project (see also Article 18.1 of the Annotated Model Grant Agreement http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/amga/h2020-amga_en.pdf)

H2020 ERC Model Grant Agreement - Articles 11 and 12 -

4 - Ethics issue table (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 that, if any ethics issues apply, I will complete the ethics self-assessment and attach the required documents.

[Tick box] - 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 <u>must</u> 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)

| Eligi | bility | | | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|--|
| I acknowledge that I am aware of the eligibility requirements for applying for this ERC call as specified in the ERC Work Programme 2018, 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 - Tickbox] - Please, confirm that all eligibility requirements established in the ERC Work Programme 2018 are complied with — Particular attention should be given to the section 'Eligibility Criteria' pp. 42-43 of the ERC 2018 Work Programme. Please, also refer to Annex 3 - Countries Associated to Horizon 2020 and Restrictions Applying to Some Legal Entities Established in Certain Third Countries. | | | | | |
| I confirm that the proposal that I am about to submit draws substantially on an existing or recently finished ERC funded frontier research grant | [Tickbox]Please explain the relation between the idea to be taken to proof of concept and the ERC frontier research project (StG, CoG, AdG or SyG) | | | | | |
| 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, in whatever form and medium, 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? This consent is entirely voluntary and refusal to give it will in no way affect the evaluation of your proposal. | [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? This consent is entirely voluntary and refusal to give it will in no way affect the evaluation of your proposal. | [Yes/No] | | | | | |
| For purposes related to monitoring, study and evaluating implementation of ERC actions, the ERC may need that submitted proposals and their respective evaluation data be processed by external parties. Any processing will be conducted in compliance with the requirements of Regulation 45/2001. | | | | | | |

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.

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 <u>shall</u> carry a <u>header</u> presenting the <u>PI's last name</u> and the <u>acronym of the</u> 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 cm top and 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 value creation process, i.e. the initial steps of pre-competitive development of innovation potential.

Part B - Sections 1, 2, 3 and 4:

Please, use the online word template provided in the Participant Portal Submission Page for the call. References do not count towards the page limits.

Section 1: The idea – Excellence in 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 in innovation potential.

- a. Succinct description of the idea to be taken to proof of concept
- a.1- The problem: Description of the problem or the need that the idea is aiming to solve or alleviate

a.2- The solution: Explanation of how the idea will solve or alleviate the problem or the need and the meaning that this will make. A clear value proposition should be included¹⁸.

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 nonspecialist in your field.

b. Demonstration of Innovation Potential

Please, give a detailed description of how the project outcomes will be innovative or distinctive. This should include a clear explanation of why the solution proposed is new, compared to what already exists.

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

This section is about describing the expected impact of the PoC project. It will be used to assess the evaluation criterion #2: Impact.

Please, describe in detail the following:

- a. Identification and description of any effect or benefit to the economy, society, culture, public policy/services.
- **b.** Outline of the value creation process (plans for the knowledge transfer, the commercialisation or any other process foreseen to generate the above listed benefit)

This should include proposed plans to:

- asses and validate the effectiveness of the project's outcomes (Testing, technical reports or any other form of validation to confirm that the solution is effective, efficient, sustainable, or *just)* (where applicable)
- clarify the IPR position and strategy¹⁹ or knowledge transfer strategy (where applicable)
- set up contacts with industrial partners, societal or cultural organisations, policy makers or any other potential users or sponsors of the projects' results (where applicable)

Please, refer to the ERC Work Programme 2018 (ERC Proof of Concept Grant evaluation) for the explanation of these sub-criteria.

Important: Point (b) 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.

¹⁸ Explain: 1) how the idea solves users' problems or improves their situation; 2) why potential users or sponsors should pay for this solution and not for other existing ones.

¹⁹ Any application for funding of IPR activities under the ERC Proof of Concept will not discharge beneficiaries from their prior obligations under their pre-existing ERC Grant Agreement in respect of protecting IPR capable of industrial or commercial application. If any foreground was potentially protectable in the pre-existing ERC project, beneficiaries had the legal obligation to seek for adequate and effective protection according to the Rules for Participation and the ERC Model Grant Agreement

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/societal feasibility of the project:

- a. Plan of the activities
- b. Project-management plan, including risk and contingency measures
- 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 (incl. project costs):

It is strongly recommended to use the budget table template included in Part B to facilitate the assessment of resources by the panel.

The project cost estimation should be as accurate as possible. Significant mathematical mistakes may reflect poorly on the credibility of the budget table and the proposal overall.

The evaluation panels assess the estimated costs carefully. The requested contribution should be in proportion to the actual needs to fulfil the objectives of the project.

The ERC funds up to 100% of the total eligible costs. In case the total costs differ from the requested grant, it should be specified in the proposal what exactly is funded from other sources.

Please, use whole Euro integers only when preparing the budget table.

Specify briefly your commitment to the project and how much time you are willing to devote to the proposed project. Please note that for Proof of Concept Grants, there is no minimum commitment percentage of the working time required to the PI. However, in the grant agreement, PIs must enter a minimum of their working time, as they are responsible for managing the ERC PoC project. It is essential that the cumulative percentage commitment that the PI spends on the ERC PoC action and on the main ERC StG/CoG/AdG/SyG Grant (if still ongoing) does not exceed 100%.

Describe the size and nature of the team, indicating, where appropriate, the key team members and their roles. The participation of team members engaged by another host institution should be justified in relation to the additional financial cost this may impose to the project. NB: Take into account the percentage of your dedicated time to run the ERC funded activity when calculating your personnel costs.

Specify any existing resources that will contribute to the project. Describe other necessary resources, such as infrastructure and equipment. 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. When estimating the costs for travel, please also consider participation of the PI and team members in conferences and dissemination events.

The terms and conditions laid down in the ERC Model Grant Agreement address how scientific publications must be made available through Open Access. Applicants should be aware that it will be

mandatory to provide Open Access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to results from ERC projects funded through this call. This includes long-text publications such as monographs and book chapters. Open Access can be ensured through green or gold Open Access-routes, and Open Access must in any case be ensured through a repository at the latest 6 months after publication (12 months for publications from the Social Sciences and Humanities). Please see Article 29.2 of the ERC Model Grant Agreement for more details, or contact ERC-OPEN-ACCESS@ec.europa.eu.

Costs for providing immediate Open Access to publications (article processing charges/book processing charges) are eligible and can be charged against the ERC grant if they are incurred during the lifetime of the project. When drafting the budget, it is highly advisable to consider the need to include such expenditure, and if that is the case, to make a realistic estimation of the amount needed. In addition, the ERC recommends that all funded researchers follow best practice by retaining files of research data produced and used, and are prepared to share these data with other researchers when not bound by copyright restrictions, confidentiality requirements, or contractual clauses.

Budget table (provided in the Part B form template): please, include the direct costs of the project plus a flat-rate financing of indirect costs calculated as 25% of the total eligible direct costs (excluding subcontracting) towards overheads. Furthermore, please, include a breakdown of the budget subdivided in personnel costs, travel, equipment, consumables, publication costs (including any costs related to Open Access), other direct costs, and any envisaged subcontracting costs.

For more detailed information on eligible- and non-eligible direct and indirect costs as well as the different cost categories, please consult the H2020 ERC Mono, Multi model Grant Agreement and the H2020 ERC Annotated Model Grant Agreement²⁰ at:

http://ec.europa.eu/research/participants/data/ref/h2020/mga/erc/h2020-mga-erc-pocmono en.pdf

http://ec.europa.eu/research/participants/data/ref/h2020/mga/erc/h2020-mga-erc-poc-multi_en.pdf

 $http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/amga/h2020-amga_en.pdf\\$

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.

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²⁰ Applicants should pay special attention to the new cost category 'Direct costing for Large Research Infrastructures'. This new cost category will only be applicable for PIs who are hosted by institutions with Large Research Infrastructures of a value of at least EUR 20 million and **only** after having received a positive ex-ante assessment from the Commission's services. This new cost category should only be used for costs to access large research infrastructures inside the premises of and owned by the participating organisations. Please refer to the <u>ERC Model Grant Agreement</u>, pgs. 92 to 102.

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.

1.1.2.3 Supporting Documentation

Any additional annexes, including the host institution support letter (and where relevant in case of ethical issues) should be provided and uploaded as separate pdf documents. These annexes do not count towards the maximum page limit for Part B.

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 printed on the paper with the official letterhead of the Host Institution, 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 evaluated²¹. 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.

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²¹ See also section 2.4 'Eligibility check' in the <u>ERC Rules for Submission</u> and in the sections "Proposal submission' and 'Proposal description' of the <u>ERC Work Programme 2018.</u>

Box 3 Checklist – Is your proposal complete?

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

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

- first pre-register;
- complete the <u>mandatory</u> details on the Principal Investigator and Main Host Institution Contact Person;
- complete the administrative forms (Part A sections 1, 2, 3, 4 and 5). Click on 'Validate Form' to check if there is any missing data.

The Proposal (Part B) and all supporting documentation should be uploaded and submitted via PPSS as PDF files. Make sure all file names²² contain the 'Proposal Short Name', such as PartB [Proposal-Short-Name].pdf

The Project Proposal (Part B):

- Section 1 The idea Excellence in Innovation Potential
- Section 2 The expected Impact
- Section 3 − The proof of concept plan
- Section 4 The budget

The Supplementary Documents:

- The supporting statement from the host institution: printed on the paper with the official letterhead of 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).
- Click on 'Validate' in the application to see any missing data of the form or the application.

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 (including all the sections in Part B and required supplementary documents) are not present in the final submission your proposal may be declared ineligible.

 $^{^{\}rm 22}$ Please note that filenames cannot exceed 75 characters including the file extension.

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 <u>'IT HOW TO'</u> 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)²³. Access to PPSS is available from the call page (after selecting a topic, and clicking on the 'Submission Service' button, and the type of action of a call) of the Research and Innovation Participant Portal²⁴.

Please, note that some internet browsers and/or Operating Systems (OS) may not be supported by PPSS. The electronic submission system of the European Commission is a web application, so you will need a working Internet connection to use it. Although the system has been tested with a set of typical reference configurations, it is not guaranteed that the system will be fully functional on your computer. The system provides a diagnostic window that will warn you about some possible incompatibilities.

To use the electronic submission system, ensure well before the deadline that your computer configuration complies with the mandatory system requirements. **NB:** <u>As requirements can change, please check them here:</u>

https://ec.europa.eu/research/participants/submission/manage/diagnostics, or the 'User guide of the submission service' also available from the 'Submission Service'.

Please, make sure you have the correct version of Adobe Reader installed and is set up as your default PDF handler. Most browsers have their own built-in PDF viewers. If your browser's built-in PDF viewer is not allowing you to properly open, view and edit the Administrative form in step 5, it is recommended that you disable your browser's PDF viewer and instead use the corresponding Adobe Reader plug-in. This way you will be able to open up, view and edit the form within the browser. As stated above, you can also complete the form offline and then save it to the Commission servers. In case you chose to work offline, please check immediately that the set-up allows you to save the data to the submission system.

In case of difficulties with the browser and/or operating system including with the Adobe plug-inn needed to work online with the electronic submission form, we advise you to contact the PPSS Service Desk if needed at DIGIT-EFP7-SEP-SUPPORT@ec.europa.eu or directly by phone at +32 (2) 29 92222.

²⁴ http://ec.europa.eu/research/participants/portal/

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²³ In duly justified exceptional circumstances the ERCEA may authorise submission on paper.

Step 1: 'EU login registration' - Getting a user ID with the Commission

To be able to submit a proposal and, in general to login to the Participant Portal, you must first register an EU login account. 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 evaluation²⁵.

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 to login to the Portal with your EU login 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 (at step 5, when editing the administrative form). Be careful to choose the correct PIC-number for your host institution AND to type the correct e-mail address of the PI/or of another contact initiating the proposal 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. 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. 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.
- 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 (in English) 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 <u>must be identified with a Participant Identification Code (PIC)</u>. 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 <u>Beneficiary Register</u>, which is hosted in the Participant Portal²⁶), 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 PPSS²⁷.

http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/register-anorganisation/registration-of-organisation en.htm

²⁵ Further details are available here: http://ec.europa.eu/research/participants/portal/

²⁶ See H2020 Online Manual: Register in the Beneficiary Register:

²⁷ 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

If your host institution has already participated in an EU Research Framework Programme proposal, it is likely that you already have a PIC number. You can check this with the PIC search facility 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-<u>SUPPORT@ec.europa.eu</u> or (+32 (2) 29 92222).

After entering the PIC, certain sections (e.g. of section 2) of the online proposal submission forms are filled in automatically. The objective of the PIC is to identify the organisation. The 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 – LEAR²⁸). 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.

How to contact the LEAR? You can either (1) go to the Beneficiary Register page²⁹, click 'Search', define the PIC and click on the green CO (contact organisation) button or (2) click on the green 'Contact LEAR' button in the Host Institution box at Step 4





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 EU login username and password
- 3. Click on the 'My Proposals' tab

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.

²⁸ 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 grant preparation.

29 Beneficiary Register Page:

http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html

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 email
- give access to one or more 'Contact person'(s) (full access or read-only access) and
- add additional organisations ('Add partners').

Be careful to type the correct e-mail address of the PI and of the main contact person for the host institution at this step. Please note that if the Principal Investigator and the Main Host Institution Contact is the same person (because the PI is self-employed), you must use two different e-mail addresses as the system does not allow two identical e-mail addresses to be entered.

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). If you realise that you have made a mistake in selecting the organisation, you can use the 'Change Organisation' button.



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, be aware that **only one person should work on the forms at any given time**. If two persons work on the forms at the same time, in case of a save conflict, the last save wins; which means that you risk overwriting changes made by other contact person if you are working in parallel. It is therefore recommended that you **give 'read-only access'** to your partners and additional contact persons unless it is absolutely necessary to give them full access. However, please remember that the **Main Host Institution Contact has full access** – it is not possible to grant them 'read-only access'.

For the Principal Investigator and the Main Host Institution Contact Person full details will be required later in the administrative form (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; otherwise you will be prevented from submitting the proposal.

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 EU login 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 html 5 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 not 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 either as warning or error messages. You may submit your proposal with warnings, but submission is blocked until all errors are corrected. However, the automatic validation does not replace the formal eligibility checks described in point 1.2.1 of this document and cannot guarantee that the contents of these files respond to the requirements of the call. When any errors have been 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.

Step 6: 'Submit'

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:

- 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.
- 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.
- 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, <u>but only before the deadline</u>, 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 <u>Participant Portal</u> (under 'call summary') that the function has been disabled:

To access the call page ERC-2018-PoC go to 'Funding Opportunities' in the Participant Portal, click on Calls H2020 then select 'European Research Council' and then select the call you wish to view.

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 proposals³⁰.
- 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.

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³⁰ 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 4: Proposal submission - important to know:

- Proposals sent by means other than PPSS will not be accepted.
- 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 converted into a PDF file. Before uploading the file, please check that everything is correct. Additionally, please download and verify all uploaded files in due time before the submission deadline.
- In case of technical problems with PPSS please contact DIGIT-EFP7-SEP-SUPPORT@ec.europa.eu or get in touch with the SEP helpdesk directly on +32 (2) 29 92222 to receive immediate assistance.

If the submission is technically successful, the applicant receives an automatic computer-generated acknowledgement from PPSS.

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, 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 resubmissions. However <u>a read-only access to the submitted proposal</u> is granted in case the PI (or other contact persons) wishes to verify what has been submitted.

Proposals may be withdrawn before the call deadline at Step 6 using the 'Withdraw' button. A withdrawn proposal will not be considered subsequently for evaluation, nor count against possible re-application restrictions³¹.

For a proposal to be withdrawn after the call deadline, a written request for withdrawal must be received by the ERC Executive 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

³¹ As set out in the ERC Work Programme 2018 available at http://ec.europa.eu/research/participants/data/ref/h2020/wp/2018_2020/erc/h2020-wp18-erc_en.pdf

proposal must be done by sending an e-mail to the call-specific mail-box (erc-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 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 <u>Research and Innovation Participant Portal</u> call page for updated information.

1.2 Evaluation and selection of grant proposals³²

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:

- o It must be submitted before the submission deadline.
- o It must be <u>complete</u> (i.e. all of the requested forms, <u>parts or sections of the proposal</u>, and supporting documents must be completed and present).
- Its content must <u>relate to the objectives of the ERC call</u>, as defined in the <u>ERC Work</u>
 <u>Programme 2018</u>
- 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.
- o It must meet the <u>eligibility requirements</u> 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 by the 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 <u>must</u> draw substantially on

³² See also the <u>ERC Work Programme 2018:</u> http://ec.europa.eu/research/participants/data/ref/h2020/wp/2018 2020/erc/h2020-wp18-erc en.pdf.

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 single-stage submission and single-step evaluation procedure will be used. The evaluation will be conducted by independent experts. These experts may work remotely and may if necessary meet 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 2018).

- Excellence in 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.

1.2.3 Ethics Review

Please, see the Annex A to the <u>ERC Rules for Submission</u> 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 <u>Horizon 2020 Framework Programme</u>, and Articles 13 and 14 of the <u>Rules for Participation</u> 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 <u>Charter of Fundamental Rights of the European Union</u> and the <u>European Convention on Human Rights and its Supplementary Protocols</u>.

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 (as a separate annex) 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.

If the proposal is retained for funding, further to the outcome of the ethics review process, the host institutions and the principal investigators receive a copy of the ethics report - unsigned 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 funding³³.

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

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

If a proposal is rejected because of ethics considerations, the applicant is informed of the grounds for such a decision and the means to address enquiries and complaints.

A dedicated website that aims to provide additional information including ethics issues is available at:

http://ec.europa.eu/research/participants/portal/desktop/en/funding/guide.htmlhttp://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.html

1.2.4. 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 EU login secured web-mail account accessible via the Participant Portal. If they have not yet registered an EU login 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 EU login account. Following to this first activation the EU login account will be maintained for following communications or feedback.

PIs and applicant legal entities are provided with feedback on the outcome of the evaluation through an information letter and an evaluation report. The evaluation report 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 of opinions about the merits of a scientific proposal are part of the scientific debate and are legitimate.

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³³ A full description of the Ethics Review is provided in the <u>ERC Rules for Submission</u>: http://ec.europa.eu/research/participants/data/ref/h2020/sql/erc/h2020-erc-se-rules-amended2_en.pdf

1.2.4.1 Evaluation review procedure

Please, see the section 3.9 of the <u>ERC Rules for Submission</u> 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 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 complaint against the ineligibility or 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. A complaint can be made if the PIs and/or applicant legal entities consider that the assessment of the eligibility and/or evaluation of their proposal has not been carried out in accordance with the procedures set out in the Rules for Participation, the relevant ERC Work Programme, call for proposals or the ERC Rules for Submission. The evaluation review procedure is not meant to call into question the judgement made by the peer review panel; it will look into procedural shortcomings and – in rare cases – into factual errors.

The information letter will provide an electronic address to be used for the PIs and/or applicant legal entities. The letter will specify a deadline for the receipt of any such complaints, which will be 30 days from the date of receiving the ERCEA's information letter.

Complaints must be:

- related to the evaluation review 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 Call information letter;
- sent by the PI and/or the PI's host institution (as the applicant legal entity).

An acknowledgement of receipt will be sent to complainants no later than two weeks after the deadline for submitting the complaint. This acknowledgment of receipt will indicate the estimated date of a definitive reply.

A redress committee of the ERCEA may be convened to examine the eligibility checks and review evaluation process for the case in question. The redress 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. During the evaluation review procedure, the 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. The committee will not call into question the scientific judgement of appropriately qualified panels of experts. In the light of its review, the committee will recommend a course of action to the Authorising Officer. 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 reevaluated. Unless there is clear evidence of a shortcoming there will be no follow-up or reevaluation.

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.

The above procedure does not prevent the applicants from resorting to any other means of seeking redress such as requesting a legal review of the procedural aspects of the evaluation (not the merits of your proposal) under Article 22 of Council Regulation 58/2003 (the request should be sent to RTD-FOR-APPEALS-UNDER-ART-22-OF-REG-58-2003@ec.europa.eu), or filing an action for annulment under Article 263 of the Treaty on the Functioning of the European Union (TFEU) before the Court of Justice of the European Union for a decision affecting a person or legal entity.

Applicants may choose which means of redress they wish to pursue³⁴. However, they should not take more than one formal action at a time. (Please, see section 3.9 of <u>ERC Rules for Submission</u> for further details).

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³⁴ Please be aware that, as per Article 22 of Regulation 58/2003, reaching a final decision on an Article 22 request may generally take more than 30 days. Therefore if you first file an Article 22 request you may not be able to submit afterwards an evaluation review request within the 30 days deadline.

2: Annexes

Annex 1: COMMITMENT OF THE HOST INSTITUTION 35, 36, 37

(Print on paper bearing the official letterhead of the host institution)

Commitment of the host institution for ERC 2018 PoC Call:

The <<ple>clease 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 host and engage the following 'principal investigator'

<<pre><<ple>clease fill in here the name of the principal investigator>>

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 H2020 ERC Grant Agreement (hereafter referred to as the Agreement), should the proposal be retained and the preparation of the Agreement be successfully concluded:

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

- a) implement the action, as it will be described in Annex 1 and in compliance with the provisions of the Agreement, and all legal obligations under applicable EU, international and national law;
- b) ensure that the work described in Annex 1 will be performed under the guidance of the principal investigator.

| roi the host histitution (applicant legal entity). |
|--------------------------------------------------------|
| Name and Function |
| ; |
| Email and Signature of legal representative |
| ; |
| Stamp of the host institution (applicant legal entity) |

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IMPORTANT NOTE: All the above mentioned items are mandatory and shall be included in the commitment of the host institution.

³⁵ A scanned copy of the signed statement should be uploaded electronically via the Participant Portal Submission Service in PDF format.

³⁶ 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.

³⁷ The statement of comprise of the institution.

The statement of commitment of the host institution refers to most obligations of the host institution, which are stated in the ERC Model Grant Agreement (MGA). The ERC MGA is available on the participant portal: http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-mga-erc

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.

This will allow a more effective ethics clearance and an accelerated granting process if the proposal is retained for possible funding.

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 involved³⁸.

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;

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)

- 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). Please note that the funding of hESC proposals requires an additional approval procedure at EU level in accordance with Articles 10 and 12 of Decision 2013/743/EU establishing the specific programme implementing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020).

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 feasible³⁹.

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*⁴⁰ 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.).

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WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

³⁹ <u>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.</u>

Moreover, projects funded under the EU research framework programmes have to comply with the principles enshrined in the <u>Council of Europe Convention on human rights and biomedicine</u> – known as the Bioethics Convention (Oviedo). Its main purpose is to protect individuals against exploitation arising out of treatment or research and it contains several detailed provisions on informed consent⁴¹.

Regarding clinical trials, they must comply with the EU Directive on Clinical Trials⁴². 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:

<u>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.</u>

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, including the informed consent provisions (if applicable).

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⁴¹ 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.

⁴² <u>Directive 2001/20/EC</u>. The Clinical Trials Directive is concretised further by <u>Commission Directive 2005/28/EC</u> of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use.

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 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.

Regarding the transfer of personal data from/to non-EU countries, please refer to the chapter 'Non-EU countries' below.

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: <u>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</u>.

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 <u>H2020 Online Manual</u> and click on 'International cooperation' 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/she 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 <u>low or lower-middle income country(ies)</u> according to OECD classification, an authorization from local competent institutions (as appropriate) will be required.

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

In addition to an authorisation from local competent institutions (as appropriate), 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.

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

If your research takes place in a protected area, please take into consideration the relevant Directives, namely <u>Directive 2008/56/EC</u> 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; <u>Council Directive 92/43/EEC</u> of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora; <u>Council Directive 79/409 EEC</u> on the conservation of wild birds.

Malevolent use of research results

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 weaponisation, 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.

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

| | 1. HUMAN EMBRYOS/FOETUSES | 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 yo cells? | ur research involve the use of human foetal tissues / | Origin of human foetal tissues/cells. Details on informed consent procedures. | Copies of relevant Ethics Approvals. Informed Consent Forms. Information Sheets. |

| | 2. HUMANS | Information to be provided | Documents to be provided |
|---------|-----------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------|
| Does yo | ur research involve human participants? | Please provide information in one of the subcategories below: | |
| | | | |
| | And the continue of the social and boundary sciences | Details on years it ment and informed consent procedures | Coning of valouant Ethics Approvals |
| 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 : | Documents as above. |
| | | Details on the procedures used to ensure that there is no coercion on participants. | |
| | - Are they vulnerable individuals or groups? | Details on the type of vulnerability. | Documents as above. |
| | | Details on recruitment and informed consent procedures. | |
| | - Are they children/minors? | Information above plus : | Documents as above. |
| | | Details on the age range. | |
| | | Details on children/minors assent procedures. | |
| | | Describe the procedures to ensure welfare of child/minor. | |
| | - Are they patients? | Details on the nature of disease/condition/disability. | Documents as above. |
| | | Details on recruitment and informed consent procedures. | |
| | - Are they healthy volunteers for medical studies? | Information above plus : | Copies of relevant Ethics Approvals. |
| | | Details on incidental findings. policy. | |
| | our research involve physical interventions on the articipants? | | |
| 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. | Copies of relevant Ethics Approvals. |
| | | Details on procedures for collection of biological samples. | |

| | 3. HUMAN CELLS / TISSUES | Information to be provided | Documents to be provided |
|-----------------------------------------------------------|---------------------------------------------|--------------------------------------------------------|-------------------------------------------------|
| Does your research involve human cells or tissues? (Other | | | |
| than froi | m 'Human Embryos/Foetuses' i.e. section 1) | | |
| | - Are they available commercially? | Details on cell types and provider (company or other). | |
| If YES: | - 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. |

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

| | 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. | Copies of all appropriate authorisations for the supply of animals and the project experiments. |
| | | Number of animals to be used, nature of the experiments, procedures, anticipated impact and how this will be minimised. | Copies of training certificates/ personal licences of the staff involved in animal experiments. |
| | | Details on species and rationale for their use. | |
| | | Details on procedures to ensure animal welfare. | |
| | | Details on implementation of the 3Rs Principle. | |
| If YES: | - Are they vertebrates? | Information as above. | Documents as above. |
| | - Are they non-human primates? | Information above plus : | Documents as above. |
| | | Confirmation of compliance with Art. 8, 10, 28, 31, 32 (Directive 2010/63/EU). | Personal history file |
| | | Discussion of specific ethics issues related to their use. | (See art. 31 of Directive 2010/63/EU). |
| | - Are they genetically modified? ^{iv} | Confirmation of compliance with relevant EU and national legislation. | Copies of all appropriate authorisations for the supply of animals and the project experiments. |
| | | Number of animals to be used, nature of the experiments, procedures, anticipated impact and how this will be minimised. | Copies of training certificates/ personal licences of the staff involved in animal experiments |
| | | Details on species and rationale for their use. | |
| | | Details on procedures to ensure animal welfare. | |
| | | Details on implementation of the 3Rs Principle. | |
| | - 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: | Copies of all appropriate authorisations for the supply of animals and the project experiments. |
| | Confirmation of compliance with Art. 7 - Directive 2010/63/EU. | |
| | | Copies of training certificates/ personal licences |
| | Discussion of specific ethics issues related to their use. | of the staff involved in animal experiments. |

| | 6. THIRD COUNTRIES | Information to be provided | Documents to be provided |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | Details on activities carried out in non-EU countries. | Signed declaration to confirm compliance with ethical standards and guidelines of H2020. |
| If YES: | - Specify the countries involved (maximum number of characters allowed: 1000) | | Copies of relevant Ethics Approvals from EU country host and non-EU country (double ethics review, if possible). |
| sampl | u plan to use local resources (e.g. animal and/or human tissue es, genetic material, live animals, human remains, materials of ical 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) |
| counti | u plan to import any material, including personal data, from non-EU ries into the EU? consider importing data, please fill in section 4 on data protection. ports concerning human cells or tissues, please fill in section 3. | 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 | u plan to export any material, including personal data, from the EU to | Details on type of materials or data to be | Authorisation for export from EU. |

| non-El | U countries? | exported. | Material Transfer Agreement (MTA). |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| | consider exporting data, please fill in section 4 on data protection. ports concerning human cells or tissues, please fill in section 3. - Specify material and countries involved (maximum number of characters allowed: 1000) | | |
| If your research involves low and/or lower middle income countries 43, are benefit-sharing measures 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. |
| II | the situation in the country put the individuals taking part in the ch at risk? | Details on safety measures to be implemented, including training. | Insurance cover |

| 7. ENVIRONMENT & HEALTH 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 | Safety classification of laboratory. |
| For research involving animal experiments, please fill in also section 5. | Details on safety measures to be implemented. | 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/legislation 44 | Specific approvals, if applicable. |
| For research involving human participants, please fill in also box 2. | | |

⁴³ For a list of low and/or lower middle income countries, see: http://www.oecd.org/development/stats/49483614.pdf
44 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.

| Does your research involve the use of elements that may cause harm to | Details on health and safety procedures. | University safety procedures. |
|-----------------------------------------------------------------------|------------------------------------------------|--------------------------------------|
| humans, including research staff? | | |
| | Confirmation of compliance with national/local | Safety classification of laboratory. |
| | guidelines/legislation | |

| 8. DUAL USEi ^{, viii} | Information to be provided | Documents to be provided |
|------------------------------------------------------------------|----------------------------|------------------------------------------------------------------------------------|
| Does your research have the potential for military applications? | | Narrative document describing the potential dual use implications of the research. |
| | | |

| 9. MISUSE | Information to be provided | Documents to be provided |
|-------------------------------------------------------------------------|----------------------------|------------------------------------------------------------------------------------|
| Does your research have the potential for malevolent/criminal/terrorist | | Narrative document describing the potential dual use implications of the research. |
| abuse? | | dual use implications of the research. |

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

I confirm that I have taken into account all ethics issues described above and that, if any ethics issues apply, I will complete the ethics self-assessment and attach the required documents.

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

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

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

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

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

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

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 by 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

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

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

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