



The EU Framework Programme  
for Research and Innovation

# HORIZON 2020



## ERC Rules for Submission and Evaluation

Version 1.0  
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## History of changes

Version	Date	Change	Page
1.0	15.04.2014	<ul style="list-style-type: none"><li>▪ Footnotes 1, 2,3,4 and 5 were updated in line with adopted legal basis and publication references of 20.12.2013</li><li>▪ New footnote 16 referring to possible font size, page size, line spacing and margin limitations for the proposal, as provided by the relevant Information documents for the Call</li><li>▪ Slight reformulation of the last paragraph of section 3.9 on the means of redress</li></ul>	3 7 20



Brussels, 15.04.2014  
Commission Decision C(2014)2454  
ANNEX 1

**ANNEX**

**EUROPEAN RESEARCH COUNCIL**

**Rules for the submission of proposals and the related evaluation, selection and award procedures relevant to the Specific Programme of Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)**

*to the*

**Commission Decision**

**on the European Research Council rules for submission of proposals, and the related evaluation, selection and award procedures relevant to the Specific Programme of Horizon 2020**

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## 1. CONTEXT, SCOPE AND DEFINITION OF TERMS

The European Research Council (ERC) is established by the European Commission<sup>1</sup> under the provisions of the Specific Programme of Horizon 2020 - the Framework Programme for Research and Innovation (“H2020 Specific Programme”)<sup>2</sup> as the means for implementing the priority of Horizon 2020, ‘Excellent Science’.

The ERC consists of a Scientific Council and a dedicated implementation structure set up by the European Commission as the European Research Council Executive Agency<sup>3</sup>; it is accountable to the Commission and operates under conditions of autonomy and integrity, guaranteed by the Commission.

The following definition of terms applies to this document:

“ERCEA” refers to the European Research Council Executive Agency.

“Regulation Horizon 2020” refers to the 'Framework Programme for Research and Innovation (2014-2020)'<sup>4</sup>.

“Rules for Participation” refers to the 'Rules for the participation and dissemination in 'Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)'<sup>5</sup>.

“Financial Regulation” refers to Regulation (EU, Euratom) No 966/2012 of 25 October 2012 on 'the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002'<sup>6</sup>.

“Rules of Application” refers to the Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union<sup>7</sup>.

The purpose of this document is to set out the rules applying to the submission and peer review evaluation of proposals, and to the award of grants to successful applicants. The rules set fundamental parameters which are designed to ensure that the procedures leading up to the award of grants are rigorous, fair, effective and

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<sup>1</sup>Commission Decision C(2013)8915, OJ C 373, 20.12.2013, p.23

<sup>2</sup> Council Decision 2013/743/EU, of 3 December 2013, establishing the specific programme implementing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC and 2006/975/EC, OJ L 347, 20.12.2013, p.965.

<sup>3</sup>Commission Implementing Decision 2013/779/EU, of 17 December 2013, setting up the European Research Council Executive Agency (ERCEA) and repealing Decision 2008/37/EC, OJ L 346, 20.12.2013, p.58.

<sup>4</sup>Regulation (EU) n.1291/2013 of the European Parliament and the Council, of 11 December 2013, establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) and repealing Decision N.1982/2006/EC, OJ L 347, 20.12.2013, p.104.

<sup>5</sup>Regulation (EU) n.1290/2013 of the European Parliament and the Council, of 11 December 2013, laying down the rules for participation and dissemination in 'Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) and repealing Regulation (EC) N.1906/2006, OJ L 347, 20.12.2013, p.81.

<sup>6</sup>OJ L298, 26.10.2012, p. 1.

<sup>7</sup>OJ L 362, 31.12.2012, p.1.

appropriate. They have been defined in association with the ERC Scientific Council, the latter being responsible, inter alia, for establishing the work programme for the implementation of the ERC activities ('ERC work programme'), the peer review evaluation methods and procedures applying to proposal peer review evaluation under the H2020 Specific Programme and for identifying the independent experts assisting in such peer review evaluation. They are adopted by the Commission in accordance with the H2020 Specific Programme.

Section 2 describes the key principles applying to the process. The procedures for the submission of proposals and their handling, including the verification of eligibility criteria, are also described under this section.

Section 3 describes the peer review evaluation, including the way in which independent experts are selected and contracted, and the way peer review evaluation is organised. It describes also the way in which appeals and complaints are handled, and the reporting of the peer review evaluation.

Section 4 describes the preparation and award of grants.

## 1. INTRODUCTION

Applications for financial support under Horizon 2020 are generally made in the form of proposals submitted to the ERC, following calls for proposals ("calls")<sup>8</sup>. Calls consist of the publication of the relevant documentation, including the work programme and associated documents. Proposals set out details of the planned work, the teams that will carry it out, and the budget required.

The ERCEA appoints independent experts (hereafter "experts") to carry a "scientific evaluation" of proposals to identify those whose quality is sufficiently high for possible funding.

The ERCEA contacts the Principal Investigator (PI) – a specified individual with scientific responsibility for the project – and the applicant legal entity of proposals that successfully pass the evaluation stage, and for which there is budget available, with a view to the preparation of the grant agreement.

If this preparatory phase is successfully concluded, a grant agreement providing for a European Union financial contribution is concluded with the applicant legal entity. These rules rest on a number of well-established principles:

- **Excellence.** Projects selected for funding must demonstrate a high scientific and/or technical quality<sup>9</sup>.
- **Transparency.** Funding and award decisions must be based on clearly described rules and procedures, and applicant legal entities and principal

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<sup>8</sup>With the possible exception of coordination and support actions referred to in Article 11.2 of the Rules for Participation, and actions to be carried out by legal entities identified in the WP when the actions do not fall under the scope of a call for proposals..

<sup>9</sup> Based on the criteria set out in the Rules for Participation.

investigators should receive adequate feedback on the outcome of the peer review evaluation of their proposals<sup>10</sup>.

- **Fairness and impartiality.** All proposals shall be treated equally. They must be evaluated impartially on their merits, irrespective of their origin or the identity of the submitting entity, the principal investigator or any team member.
- **Confidentiality.** All proposals and related data, knowledge and documents communicated to the ERCEA must be treated in confidence<sup>11</sup>.
- **Efficiency and speed.** Peer review evaluation, preparation and award of grants should be as rapid as possible, in accordance with the requirements set out in the legislation<sup>12</sup>, while maintaining the quality of the peer review evaluation.
- **Ethics considerations.** Any proposal which contravenes ethical principles<sup>13</sup> may be excluded from the peer review evaluation, selection and award procedure at any time.
- **Research integrity considerations.** The breach of research integrity rules may result in the exclusion of a proposal at any time.

The work programmes may set out specific conditions for participation or lay down further details of the application of the award criteria, which will be reflected in the call for proposals.

The call may spell out in more detail the way in which these rules and procedures will be implemented and, where options are presented, which are to be followed.

## 2. SUBMISSION

### 2.1 *Calls for proposals*

The content and timing of calls are set out in the ERC work programme. Notifications of calls for proposals are published in the Official Journal of the European Union. The ERC Work Programme and information documents relevant for the call are published on Commission website(s), as well as on the ERC website. The hyperlink to the electronic proposal submission service is available via the Commission website(s). These websites provide access to all the necessary information for those wishing to apply to calls. Contact details are provided for National Contact Points, and the

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<sup>10</sup> During the entire procedure, applicants may be asked to clarify obvious clerical errors, in accordance with Article 96.2 of the Financial Regulation.

<sup>11</sup> In this context, the term "confidentiality" should not be taken as equating to the security classification "EU CONFIDENTIAL". The procedures related to "EU CONFIDENTIAL" documents apply only to information and material the unauthorised disclosure of which would harm the essential interests of the EU of one of its Member States (Commission provisions on security (2001/844/EC, ECSC, Euratom).

<sup>12</sup> Article 20 of the Rules for Participation.

<sup>13</sup> Article 13(3) of the Rules for Participation.

Commission's Horizon 2020 Enquiry service. A dedicated help desk is available to deal with issues relating to the electronic submission of proposals.

Calls for frontier research projects may specify a single indicative budget for the entire call or separate indicative budgets for specific areas of research that will be evaluated by separate panels of independent experts.

Calls, or parts of calls, are considered 'open' for the submission of proposals for the period between the dates specified in the ERC Work Programme, and the related deadlines.

Each call, or part of a call, will also specify whether it has a single-stage or two-stage submission and/or a single-step or two-step peer review evaluation procedure. In the case of a two-stage submission, only those applicants whose proposals were positively evaluated in a first stage are invited to submit complete proposals in a second stage, as per the procedure specified in the call<sup>14</sup>.

For each call, the authorising officer appoints a 'call coordinator' to act as a contact point for practical questions and to plan and organise the proposal reception and evaluation process.

## *2.2 Submission of proposals*

Due to the bottom-up approach of the ERC frontier research actions, the ERC expects a large number of proposals in all fields of research. With a view to smooth planning of the evaluation and the planned time limits for informing applicants of the outcome of evaluations, each call requires applicants to go through a pre-registration stage.

Applicants will be informed exactly which information they need to provide, e.g. keywords, choice of panels, the identity codes of their organisations and summary information about the proposal. All this information will be accessed by the ERCEA services before the call deadline. Applicants will be duly informed by a disclaimer that this data will be accessed by the ERCEA services and will be given opportunity to refuse the access to personal data and to the summary information about the proposal.

Proposals and pre-registrations are submitted electronically via the electronic submission system operated by the Commission services (currently available on the Research and Innovation Participant Portal) in accordance with the provisions of the ERC work programme. Proposals for 'frontier' research actions may – pursuant to the provisions of the ERC work programme - involve one or more Principal Investigator(s). Proposals are submitted by the PI (or by a contact person on behalf of the PI) empowered by the applicant legal entity (host institution), to which the grant

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<sup>14</sup> In accordance with Article 15.5 of the Rules for Participation the Commission shall take into account the possibility of a two stage submission procedure provided in the provisions of the Financial Regulation and the Rules of Application, where appropriate and consistent with the objectives of the call.



may be awarded<sup>15</sup>. The PI must make the necessary declarations (including those confirming the explicit consent of all participants on their participation and the content of the proposal, the correctness and completeness of the information contained in the proposal and the compliance with ethical principles). Throughout the submission and peer review evaluation process the PI is the main channel for communication between the ERCEA and the applicant legal entity.

The preparation and uploading of all the proposal data and the declaration of applicant's agreement must take place prior to the attempt to submit the proposal. Before submitting the proposal, the applicant legal entity must also be registered in the Beneficiary Register on the Participant Portal and a LEAR (Legal Entity Appointed Representative) must be appointed in accordance with the relevant section on 'Register in the Beneficiary Register' of the Horizon 2020 Grants Manual. The application shall likewise include the declaration that the applicant has the financial and operational capacity to carry out the proposed action.

The electronic submission system will carry out a number of basic verification checks, for completeness of the proposal, internal data consistency, absence of virus infection, file types, size limitations, etc. These checks do not replace the formal eligibility checks and cannot assure that the contents of these files correspond to the requirements of the call.

Only upon completion of these checks as well as completion of the declarations required by the electronic submission system will the electronic submission system allow the proposal to be submitted.

In accordance with the ERC Work Programme, the submission system may automatically check page limits<sup>16</sup> in specific parts of the proposal, and if necessary issue warnings before final submission. In the case of a submitted proposal exceeding the specified limits, the system may insert a clear "watermark" on the excess pages or perform another action provided for in the ERC Work Programme. A proposal exceeding the page limits will not be blocked by the submission system.

The ERCEA has no access to the proposal until the call deadline has passed.

Submission is deemed to occur when the PI has received an email confirming successful submission, as specified in section 2.3, and not at any point prior to this.

Proposals not submitted before the specified deadline in accordance to the above procedure will not be regarded as having been received by the ERCEA. Applicants who failed to submit a proposal, and who believe that such a failure was due to a fault in the submission system, may immediately complain by email (at an address specified in the submission system) explaining the circumstances of their case,

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<sup>15</sup>Exceptionally, the PI may himself/herself act as the applicant legal entity, if he/she is acting in the capacity of the legal entity in his/her own right.

<sup>16</sup> These include any additional font size, page size, line spacing, and margins limitations provided by the information documents for the Call.

attaching a copy of the proposal. Such cases may be examined by the eligibility review committee (see section 2.5), taking into account the log of operations running up to the deadline. The PI will be notified without undue delay of the result of this examination. If it is found that a fault did indeed lie with the Commission's system, the system will be reopened for a limited period, for those affected allowing for submission of proposal as attached to the complaint. If a fault in the submission system is identified during a submission process by the Commission services, the call deadline may be extended.

The proposals submitted via the electronic submission system are entered into databases after the call closure. Versions of proposals sent on paper, or any other additional information affecting their content, removable electronic storage (e.g. CD-ROM), by e-mail or by fax will not be regarded as having been received by the ERCEA<sup>17</sup>.

To withdraw a proposal before the relevant call deadline, the electronic submission platform of the Commission should be used. These withdrawn proposals will not be considered subsequently for peer review evaluation or for selection, nor count against possible re-application restrictions<sup>18</sup>. For a proposal to be withdrawn after the call deadline, and for the application not to count against possible future re-applications restrictions, a written request<sup>19</sup> for withdrawal must be received by the Agency at the latest on the day preceding the panel meeting where a final position on the outcome of the evaluation of that proposal is established.

If more than one version of the same proposal<sup>20</sup> 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.

Proposals are archived under secure conditions at all times. When no longer needed, all copies of proposals other than those required for archiving and/or auditing purposes shall be destroyed.

### *2.3 Reception by ERCEA*

The date and time of receipt of the submitted proposals are recorded. An email is sent to the PI and applicant legal entity at the moment of successful submission, and any subsequent submissions.

After the call closure, an e-receipt will be made available to the PI and applicant legal entity via the Participant Portal, containing:

- the full proposal including the proposal title, acronym and unique proposal identifier (proposal number);

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<sup>17</sup> In duly justified exceptional circumstances the ERCEA may authorize submission on paper.

<sup>18</sup> As set out in the ERC Work Programme.

<sup>19</sup> Further details on how to submit the request will be provided in the information documents for the call.

<sup>20</sup> Each version with the same proposal number.

- the call identifier to which the proposal was addressed;
- the date and time of receipt (i.e.the call deadline).

There is no further contact between the ERCEA services and applicants on their proposal until after completion of the evaluation, with the exception of the following cases:

- If the ERCEA services need to contact the PI and/or applicant legal entity if this is necessary to clarify matters such as eligibility<sup>21</sup>, ethics issues, research integrity or to verify administrative or legal data contained in the proposal.
- In response to any enquiries or complaints made by the PI and/or the applicant legal entity<sup>22</sup>.
- Proposals which are subject to interviews.

#### *2.4 Eligibility check*

Proposals must meet all the eligibility criteria laid down in the relevant ERC Work Programme in order to be evaluated.

If it becomes clear before, during or after the peer review 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. Where there is a doubt about a proposal's eligibility, the ERCEA services may proceed with the peer-review evaluation pending a final decision on eligibility. The fact that a proposal is evaluated in such circumstances does not constitute proof of its eligibility.

#### *2.5 Eligibility review committee*

If it is not clear whether a proposal is eligible and a more comprehensive review of the case is deemed necessary, an eligibility review committee may be convened. If the question can be resolved through an exchange of mails, a meeting may not be necessary.

This committee is made up of ERCEA staff, and where necessary, other Commission staff having the expertise as required in legal matters and information systems. The committee's role is to ensure a coherent legal interpretation of such cases and equal treatment of the applicant legal entities and PIs involved in the proposal.

It examines the proposal and the circumstances surrounding its submission and provides advice to help decide whether to reject it on eligibility grounds. The committee may decide to contact the PI and the applicant legal entity in order to clarify a particular issue.

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<sup>21</sup> Where, due to an obvious clerical error on the part of the applicant, the applicant omits to submit evidence or to make statements, the ERCEA services may ask the applicant to provide the missing information or clarify supporting documents so long as such information or clarifications do not substantially change the proposal.

<sup>22</sup> Article 17 of the Rules for Participation.

Those PIs and applicant legal entities whose proposals are found to be ineligible are informed of the grounds for such a decision and the means to address enquiries and complaints.

### **3. PEER REVIEW EVALUATION OF PROPOSALS**

#### *3.1 Role of independent experts*

The ERC relies on independent experts to ensure that only proposals of the highest quality are selected for funding.

An independent expert is an expert who is external to the ERC and the Commission<sup>23</sup>, is working in a personal capacity and, in performing his/her work, does not represent any organisation or scientific community.

For the purposes of the peer review evaluation, ERC independent experts (peer reviewers) may be requested to perform the following tasks related to the evaluation (with or without remuneration):

- As a chair-person of an ERC peer review evaluation panel(s), organising the work within their Panel, chairing Panel meetings, and attending a final consolidation meeting. Chair-persons may also perform individual evaluation of proposals, usually remotely, in preparation for the panel meetings.
- As a member of the ERC peer review evaluation panel(s), assisting in the preparation of Panel meetings, attending those meetings and contributing to the individual evaluation of proposals, usually remotely.
- Evaluating remotely or centrally individual proposals.

In addition, ERCEA may contract independent experts as observers in order to examine the peer review evaluation process from the point of view of its working and execution, as described in section 3.4.

Moreover, independent experts with the appropriate skills in ethics may be requested to carry out the ethics review process and the ethics monitoring of projects, as described in Annex A to these rules.

Furthermore, independent experts may also assist the ERC in assessing cases of breach of research integrity (scientific misconduct) during all stages of evaluation, granting and project implementation, as described in section 3.11.

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<sup>23</sup>Staff from relevant specialised EU agencies is regarded as external experts.

### 3.2 Contracting experts

The ERC Scientific Council is responsible for proposing independent experts for the peer review evaluation of frontier research projects<sup>24</sup> and for the monitoring of the implementation of frontier research actions pursuant to Articles 40.1 b) and 2 of the Rules for Participation. The ERC Scientific Council may rely on its members and on information provided by members/chairs of peer review evaluation Panel(s)<sup>25</sup> or by the ERCEA<sup>26</sup> to identify the independent experts.

The responsible authorising officer will conclude a contract with the selected experts<sup>27</sup> based on the model approved<sup>28</sup> by the Commission, where the contractual conditions, including code of conduct, and provisions on conflicts of interest are set out in the expert model contract. Independent experts must have:

- appropriate skills and knowledge appropriate to the areas of activity in which they are asked to assist.
- high level of professional experience (public or private sector) in scientific research, scholarship, or scientific management.
- appropriate language skills required for the tasks to be carried out.

Other skills may also be required (e.g such as mentoring and educating young scientists, managing or evaluating projects; technology transfer and innovation; international cooperation in science and technology).

The ERCEA has also recourse to the database of experts resulting from calls for applications from individuals and calls addressed to relevant organizations according to Article 40 of the Rules for Participation.

Experts may come from countries other than the Member States or countries associated to Horizon 2020.

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<sup>24</sup>The selection by the Scientific Council is not required for concluding a contract with independent experts for the evaluation of proposals for actions other than frontier research (such as co-ordination and support actions) and with the ethics experts referred to in Annex A point (I) of these Rules.

<sup>25</sup> The panels' chairs are mandated by the Scientific Council to select experts for remote evaluation on the basis of the specific expertise required by each proposal.

<sup>26</sup> ERCEA may provide information to the Scientific Council on the performance of contracted experts and/or names of independent experts registered in the Commission's database according to Article 40 of the Rules for Participation.

<sup>27</sup> Prior to contracting remunerated experts, ERCEA will invite the selected experts to complete the formalities for registration as ERC experts in the database referred to in Article 40 of the Rules for Participation.

<sup>28</sup> Commission Decision C(2013) 8373, of 10 December 2013, on the model contracts for experts for Horizon 2020 – The Framework Programme for Research and Innovation of the European Union (2014-2020), Research and Training Programme of the European Atomic Energy Community (2014-2018) and the Research Fund for Coal and Steel Programme.

In assembling pools of experts, the ERCEA seeks to ensure the highest level of scientific and technical expertise, in areas appropriate to the call, considering also other criteria, such as:

- Gender balance<sup>29</sup>;
- Geographical diversity across the EU and associated countries, and reasonable inclusion of nationals of third countries.

Regular rotation of experts, consistent with the appropriate balance between continuity and renewal.

The names of the independent experts assigned to individual proposals are not made public. However, the list of independent experts used in a call will be published yearly on Commission websites, and the list of panel members will be published on the ERC website.

ERCEA may put in place a system to assess the performance of independent experts.

Statistics on gender, geographic distribution, rotation and, where appropriate, private public sector balance will be monitored and reported on an annual basis.

Any direct or indirect contact about the peer review evaluation of an ERC call between the PI and/or any team member and/or any person linked to the applicant legal entity submitting a proposal under the same call and any independent expert involved in that peer review evaluation is strictly forbidden. Any such contact may result in the decision of the ERCEA to exclude the proposal concerned from the call in question.

### *3.3 Exclusion of independent experts at the request of an applicant*

Applicants may be allowed by the ERC work programme to request via the submission system that up to three specific people be excluded from evaluating their proposal. In such cases, applicants may be asked to specify the reasons for their request<sup>30</sup>. Under such circumstances, if the person identified is an independent expert participating in the evaluation of the proposals for the call in question, he/she may be excluded from the evaluation of the proposal concerned, as long as the ERCEA remains in the position to have the proposal evaluated.

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<sup>29</sup> The European Union pursues a gender balance and equal opportunities policy in the field of research. See in this regard Commission Decision 2000/407/EC of 19 June 2000 "on gender balance within the committees and experts groups established by it".

<sup>30</sup> Reasons have to be based on clear grounds such as direct scientific rivalry, professional hostility, or similar situation which would impair or put in doubt the objectivity of the potential evaluator.

### *3.4 Independent observers*

Independent experts may be appointed as observers to examine the peer review evaluation process from the point of view of its working and execution. The remit of observers covers the entire peer review evaluation session, including any remote assessments. If proposals are subject to remote evaluation, observers have access to all communications between the ERCEA and the peer reviewers and may make contact with some or all peer reviewers to poll their opinions on the conduct of the peer review evaluation. Observers have access to any meetings that are part of the peer review evaluation session.

The task of the observers is to look at the operation of peer review evaluation sessions from the point of view of their working and not the outcome, unless the outcome of the peer review evaluations is a direct result of the operational aspects. For this reason, it is not necessary that the observers have expertise in the area of the proposals being evaluated. Indeed, it is considered advantageous to avoid having observers with too intimate a knowledge of the particular Research & Innovation area in order to avoid conflicts between their opinions on the outcome of the peer review evaluations and the functioning of the sessions. In any case, they will not express views on the proposals under examination. The role of the observers is to give independent advice on the conduct of the peer review evaluation sessions, ways in which the procedures could be improved and the way in which the independent experts apply the criteria. The observers verify that the procedures set out or referred to in these rules are adhered to and report to the programme management on ways in which the process could be improved.

The observers report their findings to the ERC. The observers are also encouraged to enter into informal discussions with the ERCEA officials involved in the peer review evaluation sessions and to make observations on any possible improvements that could be put into practice immediately. Any such suggestions will be recorded in the observer's final report.

The ERCEA will inform the programme committee of the selected observers' identity, their terms of reference and their findings, and may publish a summary of their reports.

The contractual conditions of observers, including tasks, code of conduct and provisions on conflict of interests are set out in the expert's contract.

### *3.5 Selection and award criteria*

All eligible proposals are evaluated by the ERC, assisted by experts where provided for, to assess their merit with respect to the selection and award criteria relevant for the call.

The criteria, including any proposal scoring and associated weights and thresholds, are set out in the ERC work programme, based on principles set out in the Rules for

Participation<sup>31</sup>. The information documents for the call may further explain how these criteria will be applied<sup>32</sup>.

Additional procedures may be applied for proposals with ethically sensitive issues (see Annex A).

### *3.6 Organisation of the peer review evaluation*

The ERC Scientific Council establishes the peer review evaluation methodology, which may vary in detail for different calls, and oversees the peer review evaluation process and establishes rules of procedure for ERC panels. The ERC Scientific Council may also delegate its members to be present during the panel meetings as observers. However, Scientific Council members shall not influence, under any circumstances, the outcome of the panel meeting they attend.

The peer review evaluation is organised on the basis of the principles set out in section 1 above, to ensure a consistent, rigorous, quality-based assessment of proposals against the criteria set out in the ERC work programme.

Where a call specifies a two-step evaluation procedure, only those proposals that pass the first step, based on the evaluation procedure set out for the first step in the ERC work programme, shall go forward to the second step<sup>33</sup>. If the call is oversubscribed, a limited set of criteria may be used in the first step of the evaluation.

In exceptional circumstances, and with the sole intention of facilitating the efficiency of the evaluation procedure, if an expert is unable to approve a report, the ERCEA services may do so on the expert's behalf, subject to the agreement of the expert.

#### *3.6.1 Peer review evaluation of frontier research projects*

The peer review evaluation is carried out by means of panels of independent scientists and scholars. Panels may be assisted by ERC peer reviewers, who perform the peer review evaluation fully or partially at their home or place of work ("remote evaluation"). Panels are established to span the spectrum of research areas covered by the call, each panel having responsibility for a particular set of research fields.

Panels operate, according to the rules of procedure for ERC panels mentioned above, under the chairmanship of a senior independent expert.

Any peer review evaluation may be organised in two subsequent steps. In such case, the outcome of the first step is the input for the second step. The sequence of events in a step is usually as follows:

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<sup>31</sup>Article 15 of the Rules for Participation.

<sup>32</sup>Proposals are normally evaluated against the criteria for the type of grant for which they are submitted. However, for instance in cases where the type of grant was chosen erroneously the ERCEA may decide to evaluate a proposal against the criteria of a different type of grant. This may only be done if it is clear that the proposal does not correspond, or corresponds poorly, to the originally chosen type of grant, and if a more appropriate type of grant is open in the call in question.

<sup>33</sup>In accordance with Article 204.2 of the Rules of Application.



Allocation of proposals to panels: Each proposal is allocated to a panel on the basis of the subject-matter of the proposal. Initial allocation will be based in principle on the indication provided by the applicant, the title and content of the proposal and/or information, possibly in the form of “keywords”, provided in the proposal. Proposals may be allocated to a different panel with the agreement of both panel chairs concerned.

Individual assessment: Proposals are examined against the relevant criteria by at least 3 peer reviewers<sup>34</sup>, qualified in the scientific and/or technological fields related to the proposal, who complete and approve individual assessment reports.

Comments provided by the experts must be consistent with any scores awarded. The comments recorded must give sufficient and clear reasons for the scores and, if appropriate, any recommendations for modifications to the proposal, should the proposal be retained for grant preparation.

In the case of remote evaluation, the results are communicated to the ERCEA electronically. Each expert endorses electronically the completed ER. In so doing, the expert confirms finally that he or she has no conflict of interest with respect to the evaluation of that particular proposal.

If a proposal is considered to be out of scope by all individual experts, it will be declared ineligible, unless the ERCEA considers that a further consideration by experts is necessary.

Briefings of the panels: The ERCEA is responsible for briefing experts before each evaluation session. The standard briefing (adapted as necessary) should cover:

- the evaluation processes and procedures (including the criteria to be applied);
- the content of the research topics under consideration;
- the terms of the experts’ contract, including confidentiality, impartiality, concealment of conflict of interest, completion of tasks and approval of reports and the possible consequences of non-compliance;
- instructions to disregard any excess pages; and
- the need to evaluate proposals ‘as they are’, and the very limited scope for recommending improvements to highly scored proposals.

In remote evaluation, particular attention will be given to the briefing of experts , when specially adapted material may be needed (e.g. CD-ROMs, on-line

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<sup>34</sup>This may include members of Panels other than the Panel(s) to which the proposal is assigned or other peer reviewers. In case of oversubscription, it could be decided that proposals are examined by 2 peer reviewers.

presentations). Close contact is maintained with the individual experts to assist them on any query.

*Panel assessment:* Panels have the duty to examine consistently proposals falling within their area of competence<sup>35</sup> and to operate in a coherent manner with other panels, to ensure consistency of treatment of proposals across the range of panels and the scientific/technological areas open in the call.

The judgement of a panel on a proposal and its position in the ranked list is based on the individual assessments and discussion in the panel, and is arrived at by majority vote. The outcome of the panel assessment phase is a rank order list. In the final step of the peer review evaluation, the panel identifies those proposals which are recommended for funding if sufficient funds are available.

*Interviews:* If provided in the ERC work programme, the panel assessment may include interviews with the PI and/or the applicant legal entity. Any interview will be conducted by at least three panel members. Travel and subsistence costs incurred in relation to interviews may be reimbursed by the ERCEA<sup>36</sup>. Specific arrangements for interviews will be described in the information documents for the call. Interviews may be conducted at the location of the peer review evaluation panel meeting or, subject to technical feasibility, by electronic means (video link, teleconference or similar). Should a planned interview not be possible for reasons beyond the control of the ERCEA, the panel will have to take its decision based on the information made available to it.

### 3.6.2 *Two-stage submission procedure for frontier research projects*

The ERC work programme may specify that a two stage submission procedure applies. In such cases, the selection and award criteria applicable to each stage are set out in the ERC work programme. The precise methodology, to be established by the ERC Scientific Council, for the peer review evaluation at the first and second stage may differ (for example in the use of peer reviewers, and/or interviews of the PI). To uphold the principle of equal treatment, the panel may recommend - in accordance with the methodology established by the ERC Scientific Council - the exclusion from further evaluation for proposals submitted at the second stage which deviate substantially from the corresponding first-stage proposal.

Second stage applicants will be asked to declare that their proposal is consistent with their first stage submission.

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<sup>35</sup>This includes cross-panel or cross-domain interdisciplinary proposals which may be assigned for review to members of more than one Panel or additional peer reviewers.

<sup>36</sup> The reimbursement of travel expenses, dally allowance and accommodation allowance will be possible for Principal Investigators who have been invited by the ERCEA to attend an interview, as well as for anyone responsible for accompanying the PI when the PI is a disabled person. The relevant Commission Decision on the reimbursement rules of expenses incurred by people from outside the Commission invited to attend meetings in an expert capacity applies by analogy (Commission Decision C(2007) 5858).

### 3.6.3 *Evaluation of coordination and support actions and other type of actions*

The details on the evaluation procedure of coordination and support actions and of other type of actions will be set out in the ERC work programme and other relevant call documents.

For grants to identified beneficiaries, independent experts are only appointed if ERCEA deems it appropriate.

### 3.7 *Peer review evaluation results, selection and rejection of proposals*

Based on the outcome of the peer review evaluation the ERCEA draws up the final list(s) of proposals for possible funding.

This results in:

- A list of proposals which are of sufficiently high quality to be retained for possible funding (the *retained list*). If the call establishes indicative budgets for particular panels, domains, fields of research, etc., separate retained lists may be prepared for each such field.
- If the total recommended funding for retained proposals following peer review evaluation exceeds the budget available for the call, one (or - in the case of indicative budgets associated with separate panels, domains, research fields, etc. – more) reserve list(s) of proposals may be established. The number of proposals kept in reserve is determined by the ERCEA in view of budgetary considerations, and is based on the likelihood that such proposals may eventually receive funding due to eventualities such as withdrawals of proposals, or availability of additional budget.
- A list of proposals which are not retained for funding. This list includes those proposals found to be ineligible (whether before, during or after the peer review evaluation), proposals considered not to achieve the required threshold of quality, proposals which, because they fall below a certain ranking, cannot be funded because the available budget is insufficient, and proposals remaining from the reserve list, when the budget for a particular call has been used up.

The assessment of quality, and the recommended rank order for funding of proposals on the retained list, is based on the peer review evaluation of the proposal against all relevant criteria. However, whenever a call specifies a two-step peer review evaluation procedure and thus where a proposal is judged not to achieve a quality threshold set for a particular evaluation criterion in the call, the proposal may be recommended for rejection during the course of the peer review evaluation, without necessarily assessing it further against other applicable criteria.

The ERC Scientific Council confirm the final ranked list of proposals recommended for funding by the peer review evaluation.

Any proposal that contravenes ethical principles or which does not fulfil the conditions set out in the H2020 Specific Programme, the ERC work programme or in the call shall not be selected<sup>37</sup>. Proposals may be also rejected on ethics grounds following the procedures in Annex A. Any such rejection letter will provide details for addressing enquiries and complaints.

Any applicant PI or applicant legal entity to an indirect action under the H2020 Specific Programme who has committed an irregularity<sup>38</sup> or has incurred in misrepresentation of data or information included in the proposal<sup>39</sup> may be excluded from the selection procedure at any time, with due regard being given to the principle of proportionality.

### *3.8 Feedback to applicants*

Following the peer review evaluation, the ERCEA provides feedback through an “information letter” to the PI and the applicant legal entity. The aim is to inform applicants of the result of the “scientific evaluation” by experts, and for the successful proposals, to initiate the “grant preparation” phase as described in Section 4. All communication and feedback from the ERCEA to the PI and the applicant legal entity is done electronically. The Calls for proposals indicate the expected date of feedback about the outcome of the evaluation.

Those whose proposals that are found to be ineligible will be informed of the grounds for such a decision and of the means to address enquiries and complaints.

a) Following the peer review evaluation of first-step in a two-step peer review evaluation:

Those whose proposals are not retained for the next step for budgetary or quality reasons receive feedback on the peer review evaluation in the form of an Evaluation Report (ER).

For those proposals rejected after failing a quality threshold, the comments contained in the ER may only be complete for those criteria examined up to the point when the threshold was failed.

Those whose proposals are retained for the next step receive a notification, and may be invited to attend an interview.

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<sup>37</sup> Article 13(3) of the Rules for Participation.

<sup>38</sup> 'Irregularity' in the sense of Council Regulation (EC, Euratom) No. 2988/95; OJ L 312 23.12.1995, p.1

<sup>39</sup> Article 107.1 of the Financial Regulation.

b) Following the second step evaluation in a two-step peer review evaluation, and following the single peer review evaluation in the case of a single step evaluation:

Both the proposals above and below the quality threshold receive feedback on the peer review evaluation in the form of an evaluation report.

The ER provides the outcome of the peer review evaluation and contains the final panel score and ranking range, the panel comment and, as appropriate, the assessment of the individual criteria by the individual independent experts. For proposals on the retained list, where appropriate, the ER indicates any recommendation made on the maximum amount of funding to be awarded, and any other appropriate recommendations on the conduct of the project, and/or suggestions for improvements to the methodology and planning of the work.

For proposals raising ethics issues, feedback on the results of the ethics review process is communicated to the applicant in the form of an ethics report, which may include ethics requirements that may become contractual obligations.

Those whose proposals are rejected because of ethics and research integrity considerations are informed of the grounds for such a decision and the means to address enquiries and complaints.

The ERC will not change the ERs that form part of the panel report, except if necessary to improve readability or, exceptionally, to remove any factual errors or inappropriate comments, provided such errors or comments do not affect the evaluation results.

The information letter will contain indications of the means of redress available, including the evaluation review procedure.

### *3.9 Enquiries and complaints<sup>40</sup> and evaluation review<sup>41</sup> procedures*

The information documentation for the call will explain how applicants can seek assistance on any matter related to a call for proposals and subsequent procedures, and can file a complaint on any decision regarding the applicants' involvement in Horizon 2020. Contact details will be provided for both National Contact Points and a Commission help desk. A dedicated help desk will be provided for issues related to the electronic submission system.

The ERCEA provides information on the procedure that must be followed by PIs and/or applicant legal entities to address any enquiries or requests for evaluation review concerning the results of a particular evaluation in relation to any ERC call.

The letter referred to under section 3.8 will provide an address to be used for the PIs and/or applicant legal entities which consider that the evaluation of their proposal has

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<sup>40</sup> Article 17 of the Rules for Participation.

<sup>41</sup> Article 16 of the Rules for Participation.

not been carried out in accordance with the procedures set out in the Rules for Participation, the relevant work programme or call for proposals. The letter will specify a deadline for the receipt of any such complaints, which will be 30 days from the date of dispatch of the ERCEA's letter. As a minimum any question or request for evaluation review should contain the name of the call, the proposal number (if any), the title of the proposal, and a description of the alleged shortcomings. The method for submitting the complaint shall be described in the letter (e.g. via a dedicated web site).

An internal evaluation review committee may be convened to examine the cases that have been submitted by applicant legal entities and/or PIs in question, within the deadline mentioned above. Complaints that do not meet these conditions, or do not deal with the evaluation of a specific proposal, will not be considered. Applicants who submit requests other than via the dedicated web site will be requested to resubmit using that site.

The committee will bring together ERCEA staff with the requisite scientific/technical and legal expertise. The committee's role is to ensure a coherent legal interpretation of such requests and equal treatment of applicants. It provides specialist opinion of the implementation of the evaluation process on the basis of all the available information related to the proposal and its evaluation. It works independently. The committee itself, however, does not evaluate the proposal. If the committee considers that there has been a failing in the evaluation process that may have influenced the decision not to fund the proposal, it may suggest a further evaluation of all or part of the proposal by the independent experts. Depending on the nature of the complaint, the committee may review the CVs of the independent experts, their individual comments, and the evaluation report. 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 responsible for the call. Should the committee consider that there is evidence to support the complaint, it may suggest a partial or total re-evaluation of the proposal by independent experts or to uphold the initial outcome. The committee may make additional comments or recommendations.

The ERCEA services will inform complainants no later than three weeks of the deadline for evaluation review requests, of the date when a definitive reply will be provided. This definitive reply will be sent without undue delay.

The evaluation review procedure does not prevent the applicants from resorting to any other means of seeking redress such as applying to the Secretariat-General of the Commission for breach of the code of good administration (relations with the public), the European Ombudsman for 'maladministration' or the Court of Justice of the European Union for a decision affecting a person or legal entity. These channels are also available to applicants who wish to register a complaint after the deadline mentioned above.

### 3.10 *Reporting and information on the peer review evaluation process*

After each peer review evaluation, a report is prepared by the ERCEA services and made available to the ERC Scientific Council and the programme committee. The report gives statistical information on the proposals received (for example, number, priority themes covered, categories of applicant legal entities and budget requested), on the evaluation procedure and on the independent experts.

For communication purposes, the ERCEA may publish, after the end of the evaluation process and in any appropriate media, general information on the results of the peer review evaluation. Moreover, the ERCEA may publish information on the proposals recommended for funding as a result of the evaluation (or after step 2 in a two-step evaluation<sup>42</sup> and only for applicants who have agreed to the publication of these data<sup>43</sup>).

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 third parties<sup>44</sup>. Any processing will be conducted in compliance with the requirements of Regulation 45/2001. Applicants<sup>45</sup> are asked to give their free individual consent to the processing of proposals. They are not obliged to do so. Refusal to consent does not affect the evaluation process.

### 3.11 *Assessment of scientific misconduct*

In order to preserve research integrity, at all stages of the evaluation<sup>46</sup>, granting and implementation process, any alleged or suspected cases of scientific misconduct incurred by applicant Principal Investigators or by applicant legal entities shall be duly assessed. ERCEA in cooperation with the CoIME<sup>47</sup> will deal with the cases of detected misconduct in ERCEA. When necessary, ERCEA will rely for this purpose on duly qualified experts (see section 3.1).

Cases of scientific misconduct such as fabrication, falsification, plagiarism or misrepresentation of data that may arise during the evaluation or the granting process may result in exclusion of proposals from evaluation or from the grant preparation.

Severe cases of scientific misconduct in the implementation of the project may result in termination of the grant agreement.

ERCEA will put in place a procedure to assess alleged or suspected cases of scientific misconduct.

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<sup>42</sup>On the basis of the final list drawn by the ERCEA in accordance with section 3.7.

<sup>43</sup>This may include the names of PIs and applicant legal entities, the proposal title and acronym.

<sup>44</sup>Contractors, independent experts identified in Article 40 of the Rules for Participation, and/or beneficiaries of Coordination and Support Actions.

<sup>45</sup>The PIs and/or the host institutions.

<sup>46</sup> This can be triggered by the analysis performed during the scientific evaluation of the proposal, the project technical follow-up, whistleblowing or during the Ethics Review Procedure

<sup>47</sup> ERC Standing Committee on Conflict of Interest, Scientific Misconduct and Ethical Issues.

#### **4. AWARD DECISION AND PREPARATION OF GRANT AGREEMENTS**

The grants are awarded to the applicant legal entities by the responsible authorising officer, within the available budget, on the basis of the final ranked list as drawn by the ERCEA in accordance with Section 3.7, by means of a formal grant agreement.

The grant agreements are concluded with the applicant legal entities subject to the internal financial and legal procedures<sup>48</sup> and the verification of the requisites mentioned in this section.

The grant preparation in the ERC frontier research actions involves no negotiation of scientific/technical substance. A grant is subsequently awarded to the applicant legal entity on the basis of the proposal submitted and the funding recommended following the peer review evaluation, and subject to the agreement of the applicant legal entity with the PI, where applicable.

If it proves impossible to reach agreement with the PI and the applicant legal entity or if one or both of them have not signed any required supplementary agreement within a reasonable deadline that may be imposed, grant preparations may be terminated.

All administrative information should have been included already at proposal stage. During the preparation of the grant agreement, in addition to any points raised in the ER, the PI and the applicant legal entity may receive requests for further administrative, legal, technical and financial information necessary for the preparation of a grant agreement. The ERCEA services may request minor adaptations, in line with the results of the evaluations, possibly including modifications to the budget. The ERCEA services will justify all requested changes.

In these cases, the ERCEA services will give a deadline for applicants to reply. Modifications beyond the ERCEA's requests will not be accepted. In the absence of a reply in due time, the authorising officer may terminate the grant preparation phase for that proposal, and invite the next highest ranked proposal in the reserve list for grant preparations. In exceptional cases, when duly justified and requested by the applicant, the authorising officer may extend the deadline to reply.

The administrative and legal aspects during grant preparation would cover, in particular, the verification of the existence and legal status of the applicant legal entities<sup>49</sup>, review of any optional provisions in the grant agreement, or conditions required for the project, and other aspects relating to the development of the final grant agreement (including date of start of project, timing of reports and other legal

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<sup>48</sup>Including, if necessary, the completion of the procedure for consulting the programme committee provided for in the Specific Programme.

<sup>49</sup> See the relevant section on 'Legal Entity Validation – Eligibility check' in the Horizon 2020 Grants Manual.



requirements). The financial aspects would cover the establishment of the EU contribution, the amount of the pre-financing, the estimated breakdown of budget and Union financial contribution per participant, and the assessment of their financial capacity<sup>50</sup>, if required.

Equally, if during this phase the ERCEA services discover that the declarations made by applicants are false, the authorising officer may terminate grant preparations and invite the next highest ranked proposal in the reserve list for grant preparations.

The removal or substitution of a legal entity before the signature of the grant agreement will be permitted in duly justified cases.

Grants may not be awarded to potential participants who are, at the time of a grant award procedure, in one of the situations referred to in Articles 106 and 107 of the Financial Regulation (relating, for example, to bankruptcy, convictions, grave professional misconduct, social security obligations, other illegal activities, previous break of contract, conflicts of interest, misrepresentation).

Any potential participant who has committed an irregularity in the implementation of any other action under a Union or Euratom Programme may be excluded from the selection procedure at any time, with due regard being given to the principle of proportionality. Any proposal that contravenes ethical principles or which does not fulfil the conditions set out in the work programme or in the call for proposals shall not be selected.

Any arrangements for ethical issues (see Annex A) are clarified and addressed, if necessary.

Grant Preparation of proposals from the reserve list may begin once it is clear that sufficient budget has become available to fund one or more of these projects. Subject to budget availability, grant preparation should begin with the highest ranked proposals and should continue in descending order.

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<sup>50</sup> See the relevant section on 'Financial Capacity check' in the Horizon 2020 Grants Manual.

## 2. ANNEX A: ETHICS REVIEW PROCESS

### A. Objective

The ethics review process procedure 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 must submit an "ethics-ready" proposal.

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

The ethics review process consists of:

1. Three steps take place before the conclusion of grant preparation:
  - i) An Ethics Pre-Screening
  - ii) An Ethics Screening
  - iii) An Ethics Assessment
2. A fourth step takes place, after the signature of the grant agreement, during the life-time of the selected projects:
  - iv) The Ethics Monitoring

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

Further to the outcome of the ethics review process, the beneficiaries and the principal investigators receive an unsigned copy of the ethics report so as to preserve the anonymity of the experts. The ERCEA will provide details on the means to address enquiries and complaints.

### B. The Applicants' ethics self-assessment

When submitting their proposal, applicants must submit an ethics self-assessment. In this context they will:

- i) Complete an ethics issues table.
- ii) Describe how the proposal meets the national legal and ethical requirements of the country(ies) where the tasks raising ethical issues will be performed. In this context,

the applicants should provide a copy of any obtained ethics committee opinion or notification or regulatory approval<sup>51</sup> of any competent national or local authority as required by national legislation. The applicants will attest that these documents cover the activities planned in the context of their project. As regards legally required notifications to data protection authorities, a copy of the acknowledgment of receipt from the authority or the registered mail receipt shall be attached to the proposal.

If these documents are not available when submitting the proposal, the applicants must declare that, in case their project is selected for funding, they will communicate them to the ERCEA services, prior to the commencement of the relevant part of the research and indicate the timeframe for applying for opinion and/or for approval by any relevant authority at national level (such as the data protection authority, the clinical trials authority etc.).

When these documents are specifically obtained for the proposal, they will contain an explicit reference to the title of the proposal.

The ethics review process is carried out by the ERCEA dedicated ethics team with the help of independent experts who conduct their meetings in English. Consequently, in order to facilitate the analysis of the proposal and avoid unnecessary delays the applicants are requested to provide an English summary of the ethics opinions and related approvals/notifications, when these documents are not in English.

iii) Discuss in detail how the ethics issues identified in the ethics issues table, will be addressed, in particular in relation to:

- the research objectives per se (e.g. study of vulnerable populations, dual use, etc.).
- the research methodology (e.g. clinical trials, involvement of children and related consent procedures, protection of data collected etc.) and the design of the research project from an ethics viewpoint.
- the potential impact of the research (e.g. questions related to dual use, environmental damages, population stigmatisation, political or financial retaliation, benefit sharing, malevolent use, etc.) and how the ethics requirements set out in the work programme will be fulfilled.

## **C. The ethics review process**

### **C.1. Ethics Pre-Screening**

All proposals recommended for funding will undergo an Ethics Pre-Screening performed by the ERCEA ethics team where the proposals which can be cleared for granting are identified. All the proposals where potential ethical issues have been identified have to undergo an Ethics Screening. This process is based on the proposal, the "ethics issues table" and where applicable, the "ethics self-assessment" as submitted by the applicants. When additional information is needed the ERCEA ethics team may require additional information or documents in order to clear the proposal at the pre-screening level.

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<sup>51</sup> Approvals or notifications are necessary in certain cases which include research that relates to the relevant European and National legislation such as clinical trials, data protection and privacy, animal welfare, dual use etc.

## **C.2. Ethics Screening**

The Ethics Screening is carried out soon after the scientific evaluation and concerns only proposals shortlisted for funding, and where the identified ethical issues could not be cleared at the Ethics Pre-Screening. Each proposal will be screened by at least three independent ethics experts or the ERCEA, focusing on the elements described in section B above.

Proposals involving the use of Human Embryonic Stems Cells (hESCs) automatically undergo an Ethics Assessment.

The possible outcomes of the Ethics Pre-Screening and Screening are:

1. The proposal is "ethics-ready" and therefore receives ethics clearance.

The ethical issues are not significant or are well addressed and the preparation of the grant agreement can be finalised. A clearance note is produced to finalise the process.

2. Conditional clearance

The screeners formulate requirements which will become contractual obligations. These requirements constitute the condition to be fulfilled and, on this basis, the preparation of the grant agreement can be finalised. Whenever considered appropriate by the screeners or the ERCEA, the proposals falling in this category will undergo an Ethics Check (see section F below). The ethics screeners should suggest the most suitable time frame for such procedure (e.g. prior to the start of the relevant research work).

The documents and information provided to the ERCEA in response to the requirements will be reviewed by experts or ERCEA services who will have the possibility of formulating new requirements. Such an iterative process ends when the project receives ethics clearance from the ERCEA.

3. The Proposal must proceed to Ethics Assessment

For a limited number of proposals (e.g. severe intervention on humans, lack of appropriate ethics framework in the country where the research will be performed, etc.) the screening panel can recommend an Ethics Assessment prior to the signature of the grant agreement and, if appropriate, list the additional information that the applicants should provide prior to the Ethics Assessment.

An ethics report listing requirements is produced and transmitted to the applicant.

## **C.3. Ethics Assessment**

The Ethics Assessment is an in-depth analysis of the ethical issues performed on the proposals recommended for funding and flagged by the ethics screening experts, or on the proposals for which the ERCEA considers it appropriate. It is systematically performed on all proposals involving the use of hESCs.

The Ethics Assessment is carried out by a panel consisting of at least three independent ethics experts who focus on the elements described in section B above. The Ethics Assessment takes into account, when available, the analysis done during the Ethics Screening as well as the information provided by the applicants in response to the Ethics Screening.

The possible outcomes of the Assessment are:

1. The Proposal is "ethics-ready" and therefore receives ethics clearance.

The applicants have provided the necessary elements to adequately address the identified ethical issues and the preparation of the grant agreement can be finalised. A clearance note is produced to finalise the process.

2. Conditional clearance

The assessment panel formulate requirements which either constitute the condition to be fulfilled before the signature of the grant agreement or will become contractual obligations. The reviewers may also recommend that an Ethics Check is performed (see section F below) during the lifetime of the project and suggest the most suitable time frame (e.g. prior to the start of the relevant research work).

The documents and information provided to the ERCEA, prior or after the project start, in response to the requirements, will be reviewed by ethics experts or ERCEA services who will have the possibility of formulating new requirements. Such an iterative process ends when the project receive ethics clearance from the ERCEA services.

3. The Proposal must proceed to Second Ethics Assessment

The reviewers consider that the elements submitted to the Ethics Assessment do not constitute a sufficient basis to provide an opinion and request a Second Ethics Assessment, indicating the weaknesses to be addressed and the information to be provided. The signature of the grant is postponed up until the results of the Second Ethics Assessment.

An ethics report listing requirements is produced and transmitted to the applicant.

#### **D. Preparation of the grant agreement**

The outcome of the ethics review (Ethics Pre-Screening, Screening or Assessment) is taken into account during the grant preparation. This is reflected in the Annex I of the grant agreement, where the work to be performed is described. A proposal that does not comply with the ethics review requirements or is in breach of ethical principles or relevant legislation will be rejected.

The funding of proposals involving the hESCs will require the examination procedure foreseen in Article 5 of Regulation (EU) N°182/2011<sup>52</sup>, and the Commission shall adopt the decision on the approval of the funding.

#### **E. Ethics Monitoring**

The objective of Ethics Monitoring is to provide a reasonable assurance that the research complies with the ethics principles throughout the duration of the grant, also for the authorising officer.

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<sup>52</sup> Regulation (EU) No 182/2011 of the European Parliament and the Council, of 16.02.2011, laying down the rules and general principles concerning mechanism for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.02.2011, p.13—18).

The Monitoring may result in an amendment to the Grant Agreement (namely, in a modification of the Annex I, where the work to be performed is described).

The ERCEA will conduct the Ethics Monitoring, where necessary, with the assistance of independent experts (see section I of this Annex and section 3.2 of these Rules). The outcome of the Ethics Monitoring is the Ethics Monitoring Clearance.

#### **F. Ethics checks and audits**

Following the conclusion of the ethics review process, or at the initiative of the Commission services, an Ethics Check can be undertaken. Similarly, further to an Ethics Check or at the Commission services initiative, if there has been a substantial breach of ethical principles or relevant legislation, an Ethics Audit can be launched following the provisions and procedures laid down in the Grant Agreement.

The mentioned Ethics Checks and Audits will be conducted by the Commission services in accordance with the “Horizon 2020 Grants Manual”.

#### **G. Ethics advisors and Ethics boards**

During any of the ethics review steps and on the basis of the ethics reports, or at its own initiative, the ERCEA may ask the beneficiaries to appoint an independent ethics advisor or ethics board that may notably be requested to report to ERCEA on compliance with the requirements included in the ethics reports.

#### **H. Research carried out outside the EU**

When some or all of the research activities are carried out outside the EU, the applicants must confirm that the proposed research is compatible with the Union and International legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols, and could have been legally conducted in one of the EU Member States. This confirmation will be checked during the ethics review process by the ethics experts. In cases where the applicants confirm that there are no appropriate local, national or international ethics structures to give a positive opinion for the proposed research, a specific ethics review, organised by the European Commission, will be the binding opinion for the specific project.

#### **I. Ethics experts**

The independent ethics experts, involved in the ethics reviews process are selected on the basis of their skills, expertise and knowledge in the specific field(s) of the proposed research, as stated in article 3.2 of these Rules. The experts involved are bound by the requirements in the expert contract concerning conflict of interest and confidentiality.

#### **J. Implementation**

The Ethics Pre-Screening, Screening, Assessment and Monitoring are organised by the ERCEA dedicated ethics team, except for the Ethics Assessment of special cases agreed by DG RTD.