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ERA-EDTA RESEARCH PROGRAMME GENERAL RULES

I. Background.

ERA-EDTA was established in 1964 to promote and support renal research in Europe and Countries bordering Europe and the Mediterranean Sea.

In 2009 the ERA-EDTA launched the first Call of the Research Grant Programme, a new initiative to support scientific exchange and collaboration among European Research Institutions and Clinical Nephrology Centres with the aim of promoting the visibility of the scientific European potential in research in nephrology by performing concerted investigations.

II. ERA-EDTA research programme.

Two main types of Projects can apply for financial support. Please note that other financial supports may be necessary for ambitious projects, however if the ERA-EDTA Research Programme grant is given, the project will always appear under the ERA-EDTA logo.

The ERA-EDTA Research Programme will be settled to contribute to the establishment of high-level European networks of Research in Nephrology including:

1. Translational Research Projects;

2. Clinical Research Projects (Collaborative Clinical Trials (CT) or Observational Studies (OS)).

The Council also has the right to launch focused calls.

III. Translational Research Projects' aim.

To contribute to the establishment of networks of high-level research centres throughout Europe aiming at developing translational research in the major fields of interest of the renal community. They should include both basic and health care-driven research centres. Multinational Composition of the Network is required. In case of large Networks it will be

possible that a single country can have more than one research group but it can never exceed 20% of the total composition of the Network. The composition of the Network should be balanced thus including strong and consolidated research groups (60-75%), as well as emerging research groups (25-40%), as defined in Appendix 1 (see below).

The network will propose a coordinated research project (defined in Appendix 1 – see below) in which the need, role and responsibilities of each group should be clearly defined. The Network should have a Principal Investigator and Coordinator responsible for the whole Project. It can also have one or more Sub coordinators.

The Network applying should clearly demonstrate that it can constitute a feasible and real coordinated Network able to deal with the type of research submitted.

A combined budget for funding the projects, including Public and/or Private (Foundation, Associations, Societies) Research Institutions, Universities or Other Research Related Bodies will be allowed. In any case, even if other funding is granted, the entire project will be under the ERA-EDTA logo.

IV. Clinical Research Projects (Collaborative Clinical Trials (CT) or Observational Studies (OS)).

1. Aim.

To create a Network of Nephrology Centres willing to perform non-industry supported clinical trials (CT), with potential benefits for many patients in Europe as well as all over the world. To contribute performing CTs by enrolling patients from different Countries in Europe thus establishing a true active clinical trial network among European Centres of Clinical Nephrology.

To facilitate the interaction among Nephrological Centres and the production of common results of relevance in the field of treatment of renal disease.

To show the expertise of European Clinical Nephrology Centres in CT.

Also in this case the project must have a Principal Investigator who is responsible for the Project.

So that any CT project submitted to this programme can be taken into consideration, it must comply with the EU regulations regarding this matter: (EU) No. 536/2014 of April 16, 2014, Regulations of the European Parliament and of the Council regarding clinical trials on medicinal products for human use.

2. How to apply.

A public call is done periodically according to the Council's decision (the frequency will depend on the funds available).

The call is advertised in the web and by e-mail to ERA-EDTA Members (categories A and B) and the proposals should be presented using a specific form. The online application form will be posted on the web-site in a specific designated area once the deadline is determined.

a. Translational research projects will be selected on the basis of adequacy, high quality, level of coordination and complementation, and other add-on values such as those combining both basic and clinical-epidemiological research and Eastern-Western European collaborative Projects;

b. Clinical research projects will include Observational Studies, as well as Collaborative Clinical Trials (CT). The call is open to spontaneous CT in Europe, which can be cosponsored by the industry but not industry driven. CT can be newly designed or been already approved by a national ethics committee, but still striving to gather a sufficient number of patients.

In order to be evaluated the project must have a few entry requirements:

a. The main applicant must be a current ERA-EDTA full member (categories A and B);

b. The project must be entirely developed within the borders of the ERA-EDTA geographical area (Europe, countries bordering Europe and the Mediterranean Sea);

c. The project must have a duration of at least two years and no more than four years;

d. The project must involve institutions from at least two different countries (obviously, part of the ERA-EDTA geographical area);

e. Each main applicant can only submit one pre-proposal per call;

f. The amount requested cannot exceed the maximum sum available for the Call;

g. All the people involved in the project must send a written statement (e-mail/letter) confirming that they support/endorse and/or will be active in this project.

By applying, please consider that at the time of submission of the project the SAB is in charge of verifying the feasibility of the project itself. For this purpose, and when this is necessary, SAB must receive all the approvals and documentations regarding the feasibility of the project, together with the application.

V. Selection of the proposals.

The proposals will be scored by following three steps.

1. First step:

The pre-proposals will be submitted to a strict administrative check aimed at excluding all the projects that do not comply with the requirements mentioned above and again listed below:

a. the main applicant must be a current ERA-EDTA full member (categories A and B);

b. the entire project must be developed within the borders of the ERA-EDTA geographical area;

c. the project must have a duration of at least two years and no more than four years;

d. the project must involve institutions from at least two different countries (obviously, part of the ERA-EDTA geographical area);

e. each main applicant can submit only one pre-proposal;

f. the amount requested cannot exceed the maximum sum available for the Call;

g. approvals and documentation regarding the feasibility of the project must be properly submitted and valid;

h. all the people involved in the project must send a written statement (e-mail/letter) confirming that they support/endorse and/or will be active in this project.

Only the applications that fully comply with the above entry requirements will be forwarded to the SAB, the official ERA-EDTA body in charge of verifying the feasibility of the projects themselves and eventually proceed with the evaluation and score of the projects, that will be done in accordance to a pre-defined common score-system.

If there are any SAB Members involved in one or more of the submitted pre-proposals, they must abstain from the evaluation procedure. Still with this regard, after receiving the pre-proposals to be evaluated, each SAB Member has to fill in a Conflict of Interest (C.O.I.) form declaring his/her eventual C.O.I. in one or more of the submitted applications.

IMPORTANT: the minimum number of SAB members needed to evaluate the applications in the 1st step of the process is 6 (with a mix of basic and clinical scientist). If too many SAB Members with voting rights have a C.O.I. in one or more of the applications to be evaluated, the SAB Secretary-Coordinator and the Chair (provided that they have no C.O.I.) can be involved in the evaluation procedure. If there is still a lack of reviewers within SAB, external reviewers will have to be selected and involved in the evaluation procedure. The ERA-EDTA Council should be promptly informed if this last scenario must be applied for final approval.

The SAB is entitled to suggest modifications, deletions and implementations as well as to suggest a lowering of the original financial requests.

2. **Second step:**

The applicants whose projects pass the first step of the evaluation procedure have to decide whether or not to submit a final version of their proposal by filling in the appropriate "Final Application Form".

Only the SAB Members not involved in the projects retained for the second round can be involved in the selection of the external reviewers who will be in charge of the further evaluation.

3. **Third step:**

After the receipt of the scientific and technical evaluation done by the external reviewers, the Projects will be ranked by the SAB Members without conflict of interest and then submitted to the Council, that must decide which of them can be financially supported by ERA-EDTA for that specific Call.

If needed (doubts about feasibility, to decide among best ranked pre-selected projects, etc.…) the principal investigator may be asked to present the project "face to face" at a Council Meeting in order to receive more information for making the final decision.

If a project is not approved as presented and modifications are requested by the Council, the PI may be invited to re-submit a new proposal.

The new proposal will follow the same evaluation procedure as described above.

If the project is finally approved by Council, any eventual expenditure involved in this second procedure will be subtracted from the total amount that Council has approved to be given to the project itself.

VI. Evaluation of the results and progress of the proposal.

Normally the SAB will receive a report every six months of how the project is progressing (necessary to receive the next payment) as well as a final report at the end of the programme. The Council must be kept constantly informed of the progression of the approved projects: the SAB Co-Chair is in charge of preparing these reports for Council on behalf of the PIs.

Only in specific cases, and after a Council decision, will more frequent reports be necessary.

Report template to be sent every six months:

Final Report template: http://www.era-edta.org/privata/images/Final_Report_template_(RESEARCH_PROGRAMME).doc

The reports must be sent to: researchprogramme@era-edta.org

All the reports should include number and impact factor of publications, progress in shared publications and exchanged fellows during the action. The report of this proposal will be open for further 3 years after the end of the programme to include other posterior achievement of the programme itself.

All the publications should clearly state and acknowledge the ERA-EDTA support. Failure to properly acknowledge the ERA-EDTA support may cause the interruption of further payment installments and/or the P.I. (Principal Investigator) responsible for the project could be asked to refund part of the amounts already paid. The sentence approved by Council related to this matter is: "*This article (to be adapted accordingly) was written by (to be adapted accordingly) with the support of the ERA-EDTA (European Renal Association – European Dialysis and Transplant Association).*"

All kinds of positive achievements in the different centres involved in the Network, as a result of the supported programme, should be communicated to the ERA-EDTA (researchprogramme@era-edta.org).

The ERA-EDTA should receive due visibility when the results are presented or published (see also above).

Only in case of problems, or for new projects, upon invitation done by the ERA-EDTA Secretary-Treasurer on behalf of the ERA-EDTA President and thus the Council, the Principal Investigator of these granted projects will be invited to participate in the Autumn Council meeting to give a report on the project (both scientific as well as financial). In general, however, it will be the SAB Chair and/or Co-Chair that will make these presentations to Council on behalf of the Principal Investigator of all granted projects. These will normally be done at the Autumn/Fall Council Meeting.

Together with a scientific report, also a financial one must be presented every six months: only if the allocated amounts already paid have proven to be used and the project is on schedule according to the initial proposal, will the future installments be regularly paid. If this is not the case then a new financial time-table will have to be prepared by the main applicant of the project and submitted to the SAB and then to the Council, that is the body responsible for then formally approving the changes.

IMPORTANT: If a project does not start within 12 months after the PI has received the official confirmation of acceptance on behalf of the ERA-EDTA Council, the ERA-EDTA Council can decide to withdraw the funding already granted.

VII. Semestral (six monthly) and final reports evaluation procedure.

1. Scientific evaluation.

The SAB Chair, Co-Chair and Secretary-Coordinator are in charge of evaluating and thus approving or rejecting the semestral and final reports, as far as the scientific aspects are concerned. Exceptionally, if deemed necessary, they can also involve additional SAB Members in this procedure. The evaluation will include verifications of the fulfillment of the milestones as described in the proposal.

2. Financial evaluation.

The ERA-EDTA Operative Headquarters, SAB Secretariat, will be in charge of receiving the reports and verifying the correctness of the amounts related to the ERA-EDTA grant money already paid, as well as all the expenses reported.

If the report is approved both from a scientific as well as a financial point of view, and the milestones described in the application reached, the SAB Secretariat will send the report to all the Council Members for approval by email. Once this is done the PI and all the other SAB Members will be informed accordingly by the SAB Secretariat. The final approval or rejection of the semestral and final reports must be explicitly written in the minutes of the following Council Meeting.

Only after the Council's approval will the Administration Dept. proceed with the payment of further installment or the final payment, if applicable.

If there is something wrong/not clear in the scientific and/or financial part of these reports, the applicant will be asked to submit further details. Only after the problem is checked and resolved, the SAB Secretariat will forward the report to the Council, as described above, for its official approval/rejection.

IMPORTANT - If a semestral report is rejected or not submitted in due time, the ERA-EDTA Council can decide to withdraw the funding already granted.

VIII. Duration of the project.

The normal duration of the projects must be between 2 and 4 years. A time-line of the progress of the project, including milestones reached, must be submitted with the scientific and financial semestral reports to allow a proper evaluation of the outcome of the project itself. Normally projects are expected to end after the granted period.

However, if special circumstances necessitate an extension of the project duration, this can be done by the PI by sending a specific request to SAB. Provided the SAB Chair, Co-Chair and Secretary-Coordinator accept the extension, it can then be granted by Council. Note that this extension is expected to be cost-neutral.

IX. ERA-EDTA research programme appendix 1: definitions.

Clinical-epidemiological research: In this type of research patients are the main subject of the proposal and a strong epidemiological component is needed.

Translational research: This type of research can be done in isolated molecules, cells, animals or patients but it is aimed at understanding the molecular and cellular basis of the disease, with the compromise of establishing a potential therapeutic benefit for patients.

Research group: This is represented by a team of investigators of different levels and functions, generally led by one group leader and doing research on one or more lines of research, whether or not with an applied orientation. This team generally has other elements of cohesion such as laboratory space, other sources of funding and, most important of all, a proven common experience in research, reflected by a common scientific output: publications, patents, grants, etc.

Consolidated research group: This alludes to a research group led by one or more IPs with more than 10 years of continuous scientific output. It should reflect a significant contribution to a field in terms of widely referenced publications, whose impact is beyond doubt, not only regarding metrics but also public recognition of the scientific community. The size of this type of group is typically between 8-15 members.

Emerging group: This alludes to a research group, generally led by one IP who has started its independent position within the last 5 years. It should reflect contributions of high quality even if not necessarily numerous. The significance of the subject of research, momentum and potential should be generally agreed by investigators of the same area. The size of the group is typically 4-6 members.

IPs leading these groups do not have and are not expected to have high Hirsch indexes.

Coordinate research project: In this type of projects, the participation of several independent teams is requested. The project should aim at the resolution of difficult problems with resources of high caliber and which cannot be undertaken by each individual group. The principles of complementarities in approaches and techniques, as well as of cohesion between consolidated and emerging groups should be a main point of the conception of the project.

Last approval by the ERA-EDTA Council done by email vote on February 13, 2019 (recorded in the minutes of the Council meeting held in London (U.K.), February 21-23, 2019).