ISN PROGRAMS

ISN Programs

Clinical Research Program

Practical Details for Applicants

2016 edition

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The Clinical Research Program has 2 separate application rounds a year. The respective deadlines for submitting complete applications with all supporting documents are ***May 1*** and ***October 1***.

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Three types of studies are funded under the Clinical Research Program:

Screening and intervention studies

These studies identify individuals at high risk for or with chronic kidney disease by screening programs. They should be complemented by patient follow-up programs through medical management including health education, lifestyle modification and pharmacological treatment in order to reduce end-stage kidney and cardiovascular disease and mortality.

Clinical local research studies addressing specific local needs

These are small clinical research projects aimed to address specific needs at the local regional/country level. Projects should be related to acute and chronic kidney disease.

Acute Kidney Injury studies

Projects that focus on clinical aspects of Acute Kidney Injury (AKI) in low and middle income countries – especially studies on epidemiology, risk factors, prevention and treatment and that align with key priorities of the 0by25 ISN human rights initiative.

Step 1 - *Making sure you are eligible*

There are several eligibility criteria for proposals. These include:

- The project must be conducted in a low- or middle-income country (LMIC; based on World Bank criteria).
- Projects are normally led or co-led by an investigator from an LMIC. Projects for which one or more investigators are PI is based in a high income country must demonstrate meaningful involvement for investigators in the LMIC (project conception and design; important roles in publications and presentations), and that the project will build research capacity in the LMIC.
- Priority will be given to countries that are the least developed (according to World Bank ranking), but have a reasonable infrastructure to allow the implementation of the project
- Project should be complementary to, or in alignment with, the national or institutional health strategy or mission
- Applications should be from nationally recognized institutions
- The project leader and co-applicants must be ISN members (either an individual member or a Joint group).
- The project should focus on t the identified research priorities described in the call for

applications.

- All applications must be approved before submission by ISN's Regional Coordinators, who survey the activities of the prevention programs on a regional level. For more details on how to contact your Regional Coordinator, please see below
- Applications addressing specific local needs must be accompanied by a letter of support specifying regional need. Prospective applicants should check with the Regional Coordinator prior to preparing their application.
- The proposal must provide detailed rationale, aims, and methodology
- A detailed budget is required
- The project must be feasible within the time and budget proposed. If the project's budget exceeds the maximum ISN funding of US $20,000, the proposal must explain how the project can be accomplished (i.e. co-funding from another source; scaling back the project etc.).
- Applications must be submitted before the established deadlines announced in this Call of Proposals

Step 2 - *How To Apply And The Procedure To Follow*

Proposals must be submitted by the Applicant to the Regional Coordinators of the ISN Clinical Research Program. There are eight Regional Coordinators worldwide, who are appointed to coordinate prevention activities in countries belonging to a certain ISN Regional Committee region.

The list of regional coordinators is available on our website:
http://www.theisn.org/programs/clinical-research-program?showall=&start=1

Applicants are encouraged to make resubmission inquiries (to gauge the suitability of topics; or for advice on preparing a competitive application) to the Regional Coordinator assigned to his/her specific region or country. Once the application is finalized, it should be submitted via the **ONLINE APPLICATION TOOL** of the ISN Clinical Research Program: http://cr.theisn.org Applicants should **upload a letter signed by the Regional Coordinator** stating the approval of the proposal.

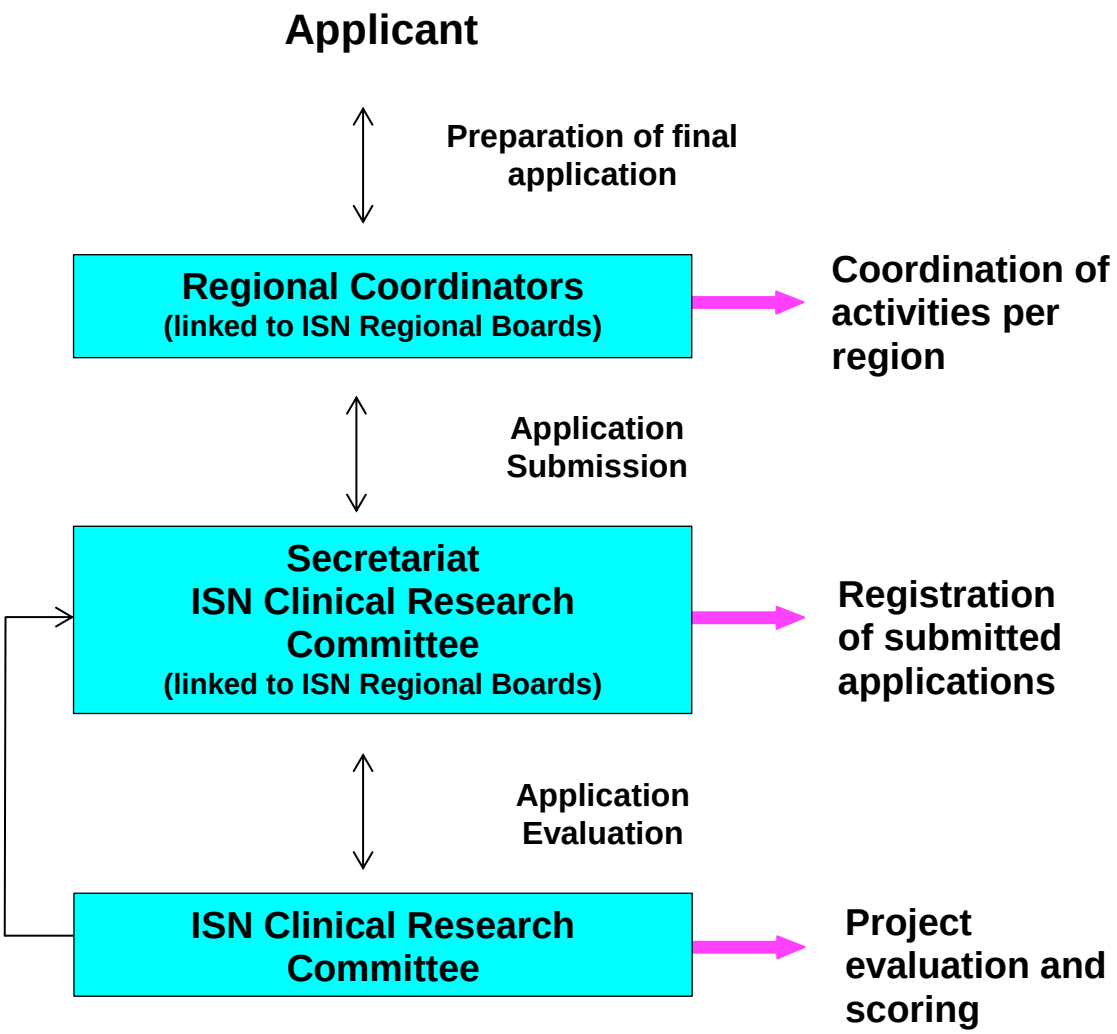
The project application must be prepared based on the Application template attached to these guidelines (Annex A). The applicant must apply in English. The application should be completed as carefully and as clearly as possible so that it can be assessed properly. The applicant should be precise and provide enough details to ensure the application is clear -- particularly as to how the aims of the project will be achieved; the benefit that will flow from it; whether the proposal

is novel, feasible and the budget justified; and the way in which it is relevant to the program's objectives. Hand-written applications will not be accepted. Submission of the proposal should use electronic files.

Step 3 - *Evaluation And Selection Procedures Of Applications*

Regional Coordinators will help applicants to prepare the final project before submission

The Secretariat registers the submitted proposals with an identification number and provides the Clinical Research Committee with a brief comment together with the applications for evaluation. Marcello Tonelli, Chair of Clinical Research Committee leads the Selection Committee. For each proposal, - Selection Committee members provide an individual evaluation through a scoring system that addresses specific items, namely the description of the scientific project, measurability of the objectives, the organization, the overall feasibility and the budget. At the discretion of the committee, the appropriate Regional Coordinator may be contacted for their opinion as to importance, feasibility, novelty etc. The chair of the Selection Committee summarizes the scores and, after further evaluation with the members, identifies the awarded project to the Secretariat of ISN Clinical Research Committee for registration. Notifications will be sent to both successful and unsuccessful applicants. Applicants not awarded will be provided with few comments that would be helpful in case the principal investigator would like to resubmit the proposal to the next available Call. The structure of the organization for submission, evaluation and selection of the applications is shown in the following figure.


Applicant
Preparation of final application
Regional Coordinators
(linked to ISN Regional Boards)
Coordination of activities per region
Application Submission
Secretariat
ISN Clinical Research Committee
(linked to ISN Regional Boards)
Registration of submitted applications
Application Evaluation
ISN Clinical Research Committee
Project evaluation and scoring

Step 4 - *Application Deadlines*

There are two rounds each year for submission of the proposals with the following deadlines (at 10 p.m., Central Europe Time): **May 1st** and **October 1st.t**

Announcement of the awarded projects will be by the Secretariat of ISN Clinical Research Committee in the course of August (for May submission) and in December (for October submission) respectively. Announcements of successful applications will be placed on the ISN web-site (www.theisn.org).

Step 5 - *Requirement Of Awarded Projects*

The Applicant of the awarded project should provide the Secretariat of the ISN Clinical Research Committee with the brief but detailed report of ongoing activities, results and outcomes every six months. On this basis, a decision whether to continue financial support of the specific project for another year will be made. A report of the activities related to a given project should be furnished by the project coordinator at the annual meeting of the ISN Clinical Research Committee. Results/outcomes of all awarded projects will be reviewed periodically by the ISN Council. The Principal Investigator should acknowledge the support of ISN Clinical Research Program Committee in any publications derived from the awarded project. A copy of the published paper(s) or abstract(s) presented to national/international Meetings dealing with the project should be sent to the Secretariat of Clinical Research Committee.

Step 6 - *Financial Allocation Provided In Support Of The Call For Proposals*

There is no specific amount of funding allocated for each request for applications. These amounts will be established every year by the ISN Council according to the global resources available. The maximum fund available for a particular grant is US $20,000. However, ISN reserves the right to award less than this amount based on the results of peer review. Given the limited resources, the grant is not intended to cover all the proposed budget of a given awarded project but merely to provide significant start up support. Nevertheless, the ISN Clinical Research Committee will work together with the Institutions receiving awards to enhance the funding by approaching local and international health providers, professional bodies, international foundations, as well as pharmaceutical companies. Since some projects are expected to be more than 1 year in duration, the ISN grant could be confirmed for the

subsequent year if a second year of funding is requested, if the conditions outlined in section 8 above are fulfilled and if funding is available. However, to foster self- sustainability of each program, eventually assuring long term independence, from the second year the ISN grant will be progressively reduced. The ISN Clinical Research Committee will be responsible for balancing the need to fund new projects every year, maintain the minimum necessary support for ongoing programs and limiting total funding to remain within available resources as approved by the Council.

Step 7 - *Budget guidelines*

The applicant should limit his/her budget request to a maximum to fit the resources available by the Call. This threshold will be established every year by the ISN-Program Clinical Research Committee according to the annual fund assigned to the Committee by the ISN Council. As mentioned above the amount requested from ISN for each proposal should not exceed US $20,000. Projects with total budgets that exceed $20,000 can be submitted for consideration providing that there is a clear and feasible plan to obtain the additional funds from other sources. Applications that make vague statements about how the shortfall will be obtained are unlikely to be funded. ISN research grants may not be used to support the salary of investigators, but only for project support. Nevertheless, the ISN Clinical Research Committee is aware that the human resources (project coordinator, doctors, network administrators, nurses and technicians) may have to take part-time or full-time leave from their institutions to participate to the prevention project. In this case, the proposed budget may include also payment for such people just related to the time of their involvement in the project. This should be clearly specified in the budget by the applicant. However, the ISN Clinical Research Committee encourages the applicant's institution to consider these prevention or research programs as part of routine clinical practice and community service and to make any effort to continue the economic support of its employers (doctors, nurses, technicians, health workers) during any time period spent on the project as full time staff.

Step 8 - *Duration of proposed project*

There is no specific time limitation for projects. However, ISN advises that programs that include a clinical management component provide no less than 5 years follow-up to ensure proper evaluation of hard endpoints. For small research projects, the minimum duration is 12 months and the projected time should not exceed 36 months.

Step 9 - *Ethical committee approval and informed consent*

ISN recognizes the limitation of human study committees in developing countries. Nevertheless, the ISN Clinical Research Committee requires that the applications - which involve human studies - be reviewed and approved by whatever the local equivalent of a human subject committee is. Should this local committee not be available, the applicant must state that the ISN and the Review Committee will work to insure that all research and data collection is conducted consistent with established guidelines for human studies, including informed consent and privacy protection. Therefore, the application must include an informed consent document in the patient language with a statement that the data collected will insure the privacy rights of individual subjects.

ANNEX A – Application Template

ISN CLINICAL RESEARCH PROPOSAL

Section A: ***General Project Information (1 page)***

1. **Country/Region**:
2. **Project title**:
3. **Name and address of the coordinating Institution (Applicant)**

Legal name:

Address:

Head of the Institute/Department:

4. **Name of the principal investigator/ local coordinator of the project**

Name:

Position:

Contact Address

Email:

Phone no:

Fax no:

5. **Co-Investigators/ Collaborators**

Name

Role in project

6. **Name of the Regional Coordinator who was consulted about the project:**

7. **Duration of the project:**

Section B: Concept summary (maximum 0.5 pages):

What (intervention/exposure, outcome) will this project study, why (rationale), in whom (population), how (what design will be used), over how long (duration) and what impact will it have (significance)?

Section C: ***Project description (maximum 6 pages, single spaced)***

1. **Specific aims of the program (approximately 0.5 pages):** What are the objectives of your project? Please provide 1-4 objectives; fewer is better. Each objective should be specific, measurable and linked to a hypothesis. See Appendix for examples.

2. **Background and rationale (approximately 1 page):** What is the previous work that has led you to contemplate this study? Why is this project important? Why is it important for the

investigator's country/region? Why is this work novel or how will it extends what has already been done? How will the results be used?

3. **Methods (approximately 2-3 pages):** Provide a detailed description of how the work will be done. Try to address the following as appropriate:

- **Primary and secondary outcomes:** What outcomes will you study? How will these outcomes be defined? Who will assess them and how?
- **Inclusion criteria/exclusion criteria**: who will be eligible and ineligible to participate, and why?
- **Confounders/covariates:** how will your account for the possibility of confounding and bias? If there are potential confounders, how will these be defined/measured and how will your account for them in analysis?
- **Recruitment/sampling method; sample size calculation:** how will you identify participants? How many participants do you need to make the study worthwhile and is this feasible?
- **Statistical methods:** how will you analyze the data? Do you have the skills to do the analysis yourself, or will you involve a statistician colleague?
- **Ethical considerations:** have you obtained/will you obtain ethics approval for this study? Are there any other ethical considerations to be addressed?
- **Knowledge translation:** who needs to know about the results of your study, and how will you ensure that they are aware of the findings once the study is finished?

4. **Research team (approximately 0.5 pages):** who are the members of your team, why are their qualifications/experience relevant for this study? What will each member of the team do? Does the team have the necessary skills and experience to do the work?

5. **Institutional environment (approximately 0.5 pages):** provide a few details about your institution, and why it is a suitable environment do this work. Does it have the necessary facilities/patient population to do the work?

6. **Significance (approximately 0.25 pages):** what do you expect to find, and how will this make a difference? What impact will it have scientifically, or to healthcare in your country/region? What are the next steps once this study is finished?

Section D: Timelines (Gantt chart)

Section E: Relevant references

Section F: Detailed budget in local currency and USD: What funds do you need and why? is the budget sufficient to complete the project? If not, where will additional funds come from? How did you estimate the costs?

Section G: Patient Information Sheet and Informed Consent Form

Appendix: Examples of Specific Aims

Devising appropriate specific aims is the most important part of formulating a research project. Although specific aims will fit on half a page (or less) it may take more than a dozen rounds of revision before they are finalized. Read and reread your specific aim, ensuring that they are specific and clear. Each aim should usually be followed by a hypothesis, although this may not be necessary for purely descriptive aims.

Example of a vague (inappropriate) specific aim:
Study whether ACE inhibitors improve outcomes in CKD patients.

Example of a better specific aim:
Use a two parallel group randomized trial to compare the effect of lisinopril 20mg daily with placebo for progression to dialysis-dependent kidney failure over 48 months in Martian adults with non-proteinuric polycystic kidney disease and baseline eGFR 30-59.9 ml/min/1.73 m^2.

Comment 1: there is a balance between specificity and clarity. For example, in the aim above, the terms "adult" and "non-proteinuric" are not defined. If these definitions are very important, they could be included in parentheses within the aim. If they are less important, they could be defined only in the methods. This requires a judgment and there may be no right or wrong answer.

Comment 2: ideally, specific aims will be followed by a hypothesis as below:

Use a two parallel group randomized trial to compare the effect of lisinopril 20mg daily with placebo for progression to dialysis-dependent kidney failure over 48 months in Martian adults with non-proteinuric polycystic kidney disease and baseline eGFR 30-59.9 ml/min/1.73 m^2. *We hypothesize that lisinopril will significantly reduce the rate of progression to kidney failure, compared with placebo.*

ANNEX B – Informed Consent

(Standard form)

Object:

Title of the project

I understood the purpose of the study as well as the potential benefits and risks of participating to the study. I had the opportunity to ask questions and my questions have been answered. I hereby give my Informed Consent to participate to this study. I have been given a copy of this Informed Consent Form.

I understand that, by signing this Informed Consent, I authorize access to my medical records to the monitor(s) and the auditors(s), and possibly to members of the Ethical Committees or Health Authorities, for verification of clinical study procedures and/or data.
I also realize that the information obtained from this study, including the results of all tests upon myself, will be held in both computerized and paper filing systems, although these will not identify me by name.

I understand that I am free to withdraw from the study:
- at any time
- without having to give a reason for withdrawing
- and without affecting my future medical care

Subject/Patient's signature: Date:
Patient's name:

I, the undersigned, have fully explained the relevant details of this study to the subject/patient named above to consent.

Doctor's signature:

Doctor's name:

A copy of the signed Informed Consent from must be given to the subject/patient