



ISN GO Research & Prevention Committee

*Non-communicable Chronic Disease Prevention Programs
in Developing Countries*

**Guidelines for Applicants
responding to the Call for Proposals**

The ISN Research Committee Prevention Program

1. Background

Chronic non-communicable diseases are now of pandemic proportions and the major cause of morbidity and mortality worldwide, both in developed and developing world. Of these, chronic kidney disease, diabetes, hypertension and cardiovascular disease all contribute to the global burden of chronic diseases which are expected to increase rapidly in the next two decades particularly in developing countries. Here chronic diseases are replacing acute and communicable diseases as the dominant health problem, and are now the principle cause of disability and death and the use of health resources. Among non-communicable disease, chronic kidney disease, apparently neglected by health organizations, is actually playing a central role and represents a key element within the network of major chronic diseases. For instance, chronic kidney disease is a major risk factor for cardiovascular mortality, and kidney disease is a major complication of diabetes. Indeed, it is increasingly recognized that the burden of chronic kidney disease is not only limited to its eventual requirement for renal replacement therapy but it also has major impact on public health. Patients with reduced kidney function represent a population not only at risk for progression of kidney disease and development of ESRD, but also at an even greater risk for cardiovascular disease. Moreover, traditional cardiovascular risk factors, such as diabetes and hypertension are also associated with chronic kidney disease.

Although the evidence for the pandemic non-communicable chronic diseases is irrefutable, there is a paucity of programs to detect, manage, and prevent them especially with a global approach. To tackle chronic diseases, especially chronic kidney, diabetic and cardiovascular disease, the International Society of Nephrology (ISN) has developed a global program for early detection and management particularly in developing countries. Its Research Committee has now prepared the present Call for Proposals to foster Applications on non-communicable chronic disease prevention programs to be performed in emerging countries.

2. What is the KHDC program?

The Research Committee of the International Society of Nephrology has developed a global early detection and intervention program for emerging countries that would be implemented according to the particular needs, organization facilities and economic imperatives of the given country. KHDC is the acronym of the program for detection and management of

Chronic Kidney Disease, Hypertension, Diabetes and Cardiovascular Disease. This program has been developed as a global template which involves a screening and management phase and data assessment. It is, however, flexible, and acceptance will be on a competitive basis taking into account the ability of the local team to adapt the program to their local circumstances and needs. The overall aim is to encourage local capacity to enable further expansion within the country and region. ISN cannot provide funds for all prevention programs, particularly for those that require very substantial and long term commitment, which may exceed the ISN Research Committee's financial resources. Nevertheless, within the limited resources available the ISN Research Committee is expected to provide partial financial support for a few selected applications awarded on a competitive basis. It will also help with training of personnel, developing local expertise and with fund raising. Overall the emphasis is on a model to promote and foster autonomous prevention programs in regions where they are most needed.

3. Purpose of the program

The KHDC program serves as a framework for a range of broad activities aimed toward:

- Helping doctors, health care workers, institutions and governments in developing countries to establish local “prevention” programs for chronic kidney disease, hypertension, diabetes and cardiovascular disease
- Increasing public and government awareness of the pandemic chronic non-communicable diseases and their consequences.

The program provides support for three main types of activities:

- i. Screening. Identify the individuals with chronic kidney disease, hypertension, diabetes and cardiovascular disease by community-based or selective screening programs
- ii. Prevention. Promote medical management including health education, lifestyle modification and pharmacological treatment in order to reduce end stage kidney and cardiovascular disease and mortality
- iii. Research. Perform small research projects aimed to address specific needs at local regional/country level related to chronic kidney disease.

4. Eligibility criteria for proposals

There are several eligibility criteria for proposals. These include::

- The project must be conducted in the developing world

- Countries will be favored 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 coordinator must be an ISN member
- The project should focus on prevention and management of chronic non-communicable diseases and their risk factors
- The proposal must provide detailed rationale, aims, and methodology
- The project must be realistic in term of feasibility, with mechanism for monitoring well defined outcomes
- A detailed budget is required
- Sufficient evidence must be presented that the project can become self sustaining of the project on long-term, even after the end of ISN support
- Applications must be submitted within the established deadlines announced in this call of proposals

5. How to apply and the procedure to follow

Proposals must be submitted by the Applicant to the Regional Coordinators of the ISN Research Committee Prevention Program. There are seven Regional coordinators worldwide, namely:

- Dick de Zeeuw (Groeningen, The Netherlands), <d.de.zeeuw@med.umcg.nl>
(Eastern Central Europe: Russia, Community Independent States)
- Meguid El Nahas (Sheffield, UK), <M.El-Nahas@sheffield.ac.uk>
(Middle East, Arabic region, North Africa/Mediterranean region)
- Ricardo Correa-Rotter (Mexico City, Mexico), <correarotter@prodigy.net.mx>
(Latin America)
- Saraladevi Naicker (Johannesburg, South Africa), <naickersd@medicine.wits.ac.za>
(Africa)

- Muthu Mani (Chennai, India), <muthukrishnamani@gmail.com>
(South Asia: India, Pakistan, Bangladesh, Nepal, Bhutan, Sri-Lanka)

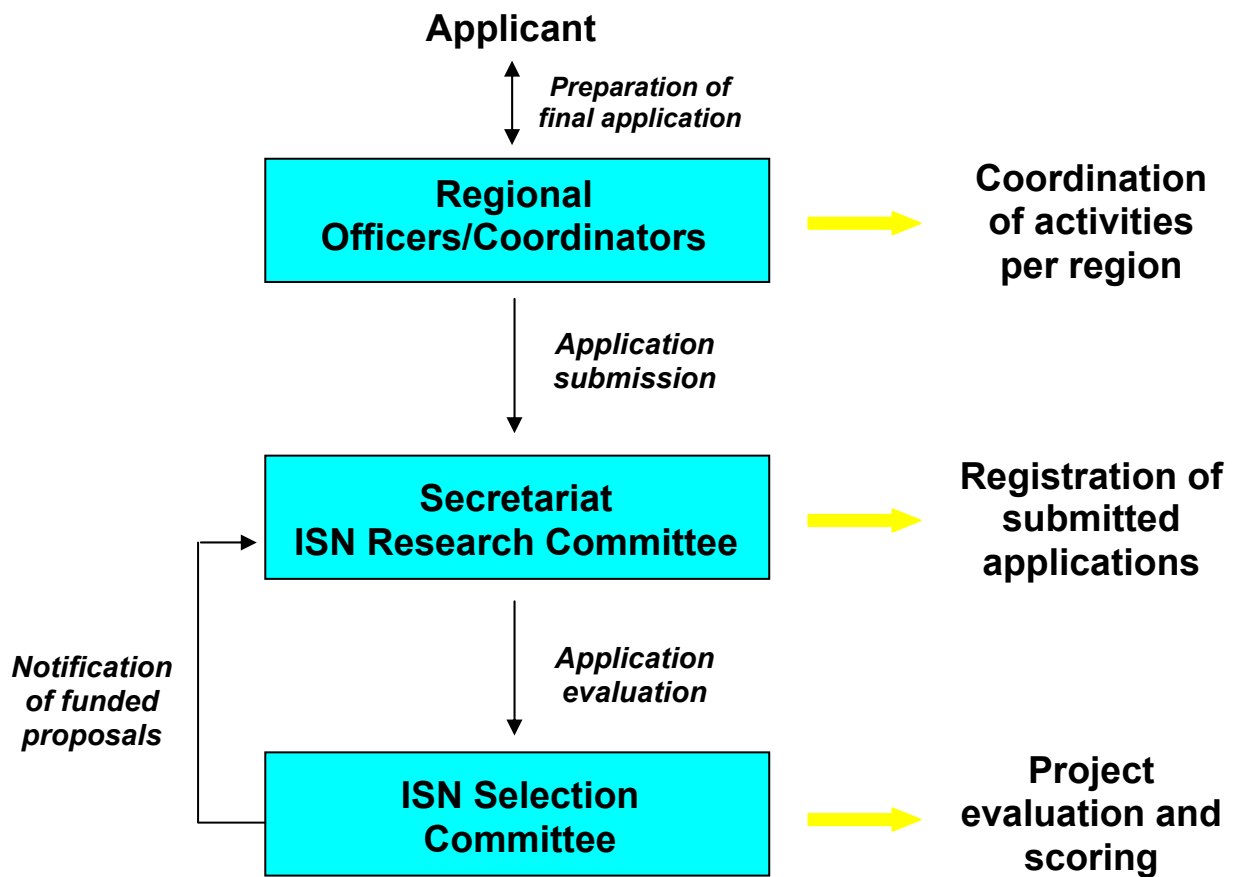
- Philip Li (Hong Kong, China), <philipli@cuhk.edu.hk>
(East/South East Asia: China, North Korea, Mongolia, Thailand, Malaysia, Vietnam, Cambodia, Laos, Myanmar)

- David Harris (Sydney, Australia), <david.harris@sydney.edu.au>
(Indonesia, Philippines, Pacific Islands, Australia)

The applicant should send the proposal to the Regional Coordinator assigned to his/her specific region or country. The project must be prepared based on the Application template annexed 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 and the way in which it is relevant to the program's objectives. Hand-written application will not be accepted. Submission of the proposal should be in an electronic versions.

6. Evaluation and selection procedures of applications

ISN funds must be spent on programs that have clear definition, measurable objectives and results, and a justified budget request breakdown. This has required the definition of a formal organization for ISN prevention program review and selection on a competitive basis. The structure of the organization is shown in the following figure:



According to this organization, the Regional Officer/Coordinator (which will coordinate the activities related to the prevention program at the regional level) will be contacted by the Applicant, and together they will judge whether the proposal fits the local needs and if it is feasible. He/she will help applicants to prepare the final project before submission to the Secretariat of the ISN Research Committee, based at the Clinical Research Center for Rare Disease ‘Aldo e Cele Decco’ of the Mario Negri Institute for Pharmacological Research, Bergamo, Italy (gremuzzi@marionegri.it). The Secretariat registers the submitted proposals with an identification number and provides the ISN Selection Committee with a brief comment together with the application for evaluation. The ISN Selection Committee is a group of people representative of all geographic areas where the project can potentially be established. William Couser, past President of ISN and Head of ISN-GO, is the chairman of the Selection Committee. Each member of the Selection Committee provides 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. The chairman of the Selection Committee summarizes the scores and, after further evaluation with the members, identifies the awarded project to the Secretariat of ISN

Research Committee for registration. Notifications will be sent to both successful and unsuccessful applicants through their Regional Coordinators. There is a Board (located to the Secretariat) that will provide oversight for the overall program.

7. Application deadlines

There are two rounds each year for submission of the proposals with the following deadlines (at 12 p.m., Central Europe Time):

- i. April 1st
- ii. October 1st

Announcement of the awarded projects will be by the Secretariat of ISN Research Committee on August 30th (for April submission) and January 15th (for October submission) respectively. Announcements of successful applications will be placed on the ISN web-site (www.ISN-online.org).

8. Requirement of awarded project

The Applicant of the awarded project should provide the Secretariat of the ISN Research Committee with the brief but detailed report of ongoing results and outcomes every six months. On this basis, a decision whether to continue financial support of the specific project for another year if requested by the applicant, will be made. Moreover, a report of the activities related to a given project should be furnished by the project coordinator at the annual meeting of the ISN Research Committee. Results/outcomes of all awarded projects will be reviewed periodically by the ISN council.

9. Financial allocation provided in support of the Call for Proposals

There is no fix amount of funding allocated for this call and thus for the awarded applications. These amounts are established every year by the ISN Council and ISN GO according to the global resources available. The maximum number of projects to be awarded is 3 to 4 at each of the two rounds of the Call yearly. In general, the application ranked first should be granted with 15,000 US \$; from rank 2 to 3 (or 4) the grant is 10,000 US \$. However, ISN reserves the right not to award all available funds. Moreover, if projects receive an additional year of funding, this will restrict the number of new projects that can be funded. 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 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 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.

10. 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 COMGAN Research Committee according to the annual fund assigned to the Committee by the ISN Council. For the 2006 projects, the budget request for each proposal should not be more than US \$ 15,000. This amount is intended for reagents, equipments, computers and internet connection, educational materials and office supplies, nurses/health care workers, laboratory technicians. It must be emphasized that the budget is not for individual salary support but only for project support. Nevertheless, the ISN 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 Research Committee encourages the applicant's institution to consider the prevention program as part of its 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.

11. 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.

12. Ethical committee approval and informed consent

ISN recognizes the limitation of human study committees in developing countries. Nevertheless, the ISN 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.

13. ISN Kidney Disease Data Center

As an integrated activity with the development of specific preventive projects, it is critical to create an ISN Data Center for Kidney Disease (KDDC) to collect and analyze data from the screening and intervention projects in developing countries. This would allow a global data collection and surveillance on chronic kidney diseases, hypertension, diabetes and cardiovascular disease in emerging countries. ISN encourages applicants responding to the present Call, whose proposal is funded, to send their data to KDDC located at the Secretariat of the ISN Research Committee. A general electronic template is already available for early detection and management programs. Through the Data Center, the ISN Research Committee can better justify funding support of the projects from the ISN council and from industry/foundation partners to receive additional funds. Moreover, with this approach, ISN will be able to clearly document the significant impact of prevention program and activities in a certain area or situation around the world.

ANNEX A
APPLICATION TEMPLATE
KHDC PROPOSALS

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

1. Country/region where the project takes place
2. Project title
3. Name and address of the coordinating Institution (Applicant)

Legal name:

Address:

Head of the Institute:

4. Name of the local coordinator of the project

Position:

Contact Address:

Email:

Phone no:

Fax no:

5. Duration of the project (in months)

Section B: *Project description (maximum 10 pages)*

This section should include:

- a. Rationale of the project in the context of the need of the Applicant's country
- b. Objectives of the program
- c. Plan of the project and methodology
- d. Expected outcomes
- e. Description of the Applicant's Institution.

(When was your organization founded and when did it start its activities? What are the main activities of your organizations at present? Evidence of the capacity to manage and implement the present project).

Section C: *Relevant references to the project*

Section D: *Detailed budget for the action*

Section E: *Short summary of the project (maximum 1 page)*

Section F: *Informed consent document*

(The document should be specific for the proposal and in the local language of the subject/patient who participates to the study. It must also include a statement that the data collected will insure the privacy rights of individual subject/patient. A standard form that can be translated into different languages - and adapted to local needs - is provided in Annex B).

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: _____ Date: _____

Doctor's name: _____

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