

# CIRCULATORY DISORDERS RESEARCH FUND

## Grant Application 2004

The purpose of this document is to outline the conditions of this grant and the requirements of applications.

### 1 THE CDRF

The CDRF was conceived in 2002 and today is a not for gain company comprising a Board nominated by the following Founding Members:

- Lipid and Atherosclerosis Society of South Africa (LASSA)
- National Kidney Foundation of South Africa
- Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA)
- South African Heart Association
- South African Renal Society
- Southern African Hypertension Society
- Southern African Stroke Foundation
- Vascular Society of Southern Africa (VASSA)

The Board is chaired by Professor John Milne who will hold this post for two years from 2003. The Vice Chairperson is Professor Derick Raal. The CDRF is managed by an Executive Director, Dr Vicki Pinkney-Atkinson.

Nearly R2 million has been raised through the generosity of the following donors:

- AstraZeneca
- Aventis
- Boehringer Ingelheim
- Merck
- MSD
- Netcare Chairman's Fund
- Novartis
- Pfizer
- Roche
- Sanofi-Synthelabo
- Servier Laboratories
- Solvay

The Founding Members have also made contributions from their Society Funds.

### 2 OBJECTIVES OF THE FUND

When the CDRF was established it stated the following objectives.

- To establish and administer a national research fund that promotes research into circulatory disorders related to atherosclerosis, its related risk factors and complications.
- To raise sufficient funding to be sustainable.
- To foster world-class research and researchers in the field of circulatory disorders by providing ongoing mentoring and evaluation according to stipulated outcome criteria

### 3 SCOPE OF THE FUND

- Applicants must be resident in South Africa for the duration of the research.
- Clinical entities encompassed by the fund: circulatory disease related to atherosclerosis, associated risk factors and complications.
- Types of research: Clinical, basic science and epidemiological research. Drug trials are specifically excluded. Qualitative research may be funded.
- The awards may be for up to three years from the date of the first application provided that the agreed outcome criteria are met.
- The Board of the Fund will make the final decision on the scope which is binding.

### 4 APPLICATION DATES

Applications can be made twice in 2004 with the following closing dates: 1 March for July 2004 awards AND 1 September for December 2004 awards.

### 5 SUCCESSFUL APPLICATIONS

- Should the CDRF Board for funding accept a project the applicant will be notified in writing. The funds will be paid into the Institution's Research Trust or similar account in

the private sector, for the exclusive use of the applicant to whom the Grant is awarded. If the award is for more than one year then the money will be paid over a number of years and each tranche will depend on a satisfactory progress report for the previous year.

- All publications and presentations arising from the project for which funding is awarded should acknowledge the source of funding.
- A final report must be submitted to the Research Fund within three months of completion of the project. All scientific publications emanating from supported research must be acknowledged. One reprint of every publication must be forwarded to:

Dr VJ Pinkney-Atkinson  
P O Box 122, River Club 2149, South Africa  
Phone:011-706-4196 Fax:011-706-4915  
Cell: 083-3838-159  
Email: [v.pinkney-atkinson@absamail.co.za](mailto:v.pinkney-atkinson@absamail.co.za)

## 6 SCIENTIFIC ADVICE

Certain applicants will be offered scientific advice by a relevant experienced person in their field and region. The nature and extent of this mentoring will depend on the level and nature of the application.

Applicants who are not successful in their first attempt will be offered mentoring for a period of not longer than one year. The purpose of the mentoring is to assist the applicant to improve the research design, implementation and grant application. If the application is still not successful after one year, then mentoring will be withdrawn. If the mentor is not satisfied with the progress, then the mentoring process may be terminated before that time.

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## 1 APPLICANT INFORMATION

The purpose of this section is to get adequate information on the researcher (single applicant) or the principal researcher. The principal researcher is the person who has the sole or joint responsibility for the design, conduct, delegation of the research responsibilities, analysis and reporting of the research

***Please follow the headings and sub-headings in the order given below in your application. Failure to do so will delay your application.***

### 1.1 Biographical information.

Full Name of Principal Researcher(s) or accountable person in the case of a unit application

Work Address

Home Address.

Telephone Numbers: cell, work, home. Fax: number.

E-mail address.

Date of Birth.

Attach a full curriculum vitae of the principal researcher/applicant.

### 1.2 Present Professional Status

Public or private sector, full or part-time. Give details of appointments.

Institution and Department in which employed.

Capacity and Type of Current Work and duration.

### 1.3 Registered Qualifications

- List all academic and professional qualifications, institution, year of each qualification (diploma, degree).
- Any awards or distinctions received.
- Registration with HPCSA or other professional body.

### 1.4 Postgraduate Degree Or Further Training

- If you or one of the research team is registered for a postgraduate degree related to this project indicate the following:
  - Name of degree PhD, M Med, MSc, etc
  - Title of dissertation/ theses,

- Supervisors,
- Date of first registration,
- Faculty, University,
- Publications and presentations arising from the work
- Progress to date.
- Future plans: if you intend to specialise in a particular discipline please note the discipline and where you intend to undertake training. If you are established in a specialist discipline, state your future plans.

### **1.5 Membership Of Professional Societies**

- Indicate if you are you a member of any of the following professional societies:
  - Lipid and Atherosclerosis Society of South Africa;
  - National Kidney Foundation of South Africa;
  - Society for Endocrinology, Metabolism & Diabetes of South Africa;
  - South African Heart Association;
  - South African Renal Society;
  - Southern African Hypertension Society;
  - Southern African Stroke Foundation;
  - Vascular Society of Southern Africa.
- Indicate if you are you a member of any of other relevant local or international professional society.
- Indicate if you have held any official positions in this/these societies.

### **1.6 Referees**

Names and addresses of three referees and their relationship to you or your unit.

## **2 RESEARCH TEAMS/ UNITS.**

If you involved in a research unit OR team describe the unit (focus, number of staff, location, years established, head of unit).

You need to give full details of the team who will work on the project. Describe your level of involvement, type of research, duration of association with the unit.

## **3 PROJECT INFORMATION.**

### **3.1 Project Title.**

**3.2 Scope Of The Project.** The relationship of the research project to atherosclerosis must be clearly indicated. Failure to do this will compromise your application.

### **3.3 Project Objective.**

### **3.4 Proposed Research Protocol.**

Submit summary with a more detailed annexure.

### **3.5 Budget.**

Give a breakdown of the budget for the project. Give information of operational funds (personnel etc), capital funds (equipment), total budget. State other sources of funding: applied for and granted. The method of budgetary control must be stated.

### **3.6 Project Time Lines.**

Outline the times at which the various aspects of the project will be completed and the full duration of the project.

### **3.7 Design Of Research Activity.**

*This section MUST be completed for ALL projects*

- Indicate roughly what percentage of your research activity can be classified into each of the following categories: laboratory experiment, animal experiment, clinical trial.
- Indicate what provision has been made for the statistical analysis of the results including the use of statistical packages and a statistician (including sampling.) This section requires that the statistics that are to be used be clearly stated, including those efforts taken to determine sample size.
- If a qualitative methodology is to be used then details of the methodology and the method of analysis must be given. The format in which the results will be presented must be shown.

### **3.8 Outcomes And Progress Reports.**

- The stated research outcomes for judging this award should be recommended by the applicant.
- If the applicant desires funding for more than one year then the outcomes for each year need to be stated.

### **3.9 Time Devoted To This Research.**

How much time will you or the unit devote to this research? State number of hours per week averaged over a year.

### **3.10 Supervisor Of Research.**

Name, status, institution.

### **3.11 Facilities**

State where the research will be carried out (e.g. at your own institution, and/or other institution.)

### **3.12 How Will The Research Benefit South Africa?**

Give details.

## **4 PUBLICATIONS AND PAPERS PRESENTED AT SCIENTIFIC MEETINGS *RELEVANT TO THIS PROJECT***

Note this section refers to any publications by the primary researcher, unit, applicant that is *relevant to the current project*. Give details as required. Publications: peer reviewed and other.

## **5 ETHICAL APPROVAL**

This Fund subscribes to rigorous ethical control. We have used the Department of Health's *Guidelines for Good Practice in the Conduct of Clinical Trials involving Human Participants* as our guide. The principles contained there in are universal. This publication can be obtained from:

Mr Ronald Mluleka.

National Ethics Research Foundation, Private Bag x828, Pretoria, 0001

Phone: 012-3120766 Fax: 012 3120784

Please furnish the original application for ethical approval and the official and signed evidence from the following committees (where relevant) indicating their consent to proceed with your research project:

- Pharmacy and Therapeutics Committee.
- Human Ethics Committee.

- Animal Ethics Committee.
- Other official Faculty research bodies.

Ethical approval must be:

- Completed (not being processed.)
- Current – not for a project where the data was collected for another project
- Approval from the relevant body
- Reflect the name of the principal researcher.
- Contain the exact name of the current project.
- Reflect the current research proposal.

Failure to fully supply this information will preclude your research protocol from being assessed for the Research Grants. If you feel that ethics approval is not required then this must be clearly motivated.

## **6 SUBMISSION OF APPLICATIONS**

All applications and reports should be submitted electronically using either MSWord or WordPerfect. All annexures not in the above format should be scanned and submitted as JPEG documents on a disc. Any documents not received by 17:00 on the closing date will be held over until the next application date for consideration.

The Scientific Committee will advise the Board of the Circulatory Diseases Research Fund of its recommendations about the applications. The Board of the CDRF will announce the successful applicants on or by the due date. The Scientific Committee will comprise persons from the Founding Member's societies. Other persons will be requested to serve on the Committee according the research applications received.

This paragraph is to be inserted into the application letter at the relevant point.

*I acknowledge that should I receive a grant from the Research Fund it is my intention that I will work in South Africa for a period of not less than three years after completion of the project. I, the undersigned, hereby undertake to comply with the conditions of the award should a grant be made to me.*

## **ANNEXURE A: CIRCULATORY DISORDERS RESEARCH FUND PRINCIPAL RESEARCHER**

The Circulatory Disorders Research Fund subscribes to rigorous ethical control. We have used the Department of Health's *Guidelines for Good Practice in the Conduct of Clinical Trials involving Human Participants* as our guide. The principles contained there in are universal. This publication can be obtained from:

Mr Ronald Mluleka. National Ethics Research Foundation, Private Bag x828, Pretoria, 0001  
Phone: 012-3120766 Fax: 012 3120784

**THE PRINCIPAL RESEARCHER (PR)** : is a South Africa based scientist who has a sole or joint responsibility for the design, conduct, delegation of project responsibilities, analysis and reporting of the project. The PR is accountable to the CDRF and any regulatory authorities as required by these Guidelines. The PR should be knowledgeable about the topic being researched and in the case of a multi-centred study there must be a local PR attached to each site. It is unacceptable to have an "absentee" PR who is based in another country.

### **RESPONSIBILITY OF THE PR AND PARTICIPATING RESEARCHER**

In most cases, projects are conducted by a PR. She/he is the person responsible for the conduct of the research project and the project site(s).

The following section outlines the responsibilities of the PR and other investigators designated by the PR to undertake certain project related activities in the conduct of research projects.

### **COMPETENCIES AND RESPONSIBILITIES OF THE PR**

Prior to commencement of the project, the PR must:

- Be a South African based scientist
- Ensure that approval(s) from the relevant approved local ethics committee, and, if applicable, the MCC is (are) obtained and that the project is issued a study number by the National Health Research Ethics Council;
- Have good knowledge of the protocol, related documents and the regulatory requirements of the regulatory authority(ies) and other relevant legislation;
- Have read, understood and agreed to work according to the protocol, the Declaration of Helsinki, ICH Guideline for Good Clinical Practice, these Guidelines and other relevant legislation;
- Document clearly the sequence of events to be followed in the conduct of the project including timeframes, roles and responsibilities;
- Ensure the availability of all necessary facilities, equipment and finance to conduct the project;
- Develop proper mechanisms to ethically obtain informed consent of participants;
- Accept the involvement of monitors to review and verify the quality control procedures and conduct data verification;
- Accept the possibility of audit and/or inspection by an independent auditor appointed by the sponsor, regulatory authority or ethics committee;
- Generate the information package for the participants.
- Ensure proper safety reporting procedures.

### **QUALIFICATIONS AND AVAILABILITY**

The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the project, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through an up-to-date curriculum vitae and/or other relevant documentation requested by the CDRF, the ethics committee, and/or the regulatory authority(ies).

The investigator should be aware of, and should comply with GCP and the applicable regulatory requirements.

The investigator/institution should permit monitoring and auditing by the CDRF, and inspection by the appropriate regulatory authority(ies).

The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant project-related duties.

### **ADEQUATE RESOURCES**

The PR should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable participants within the agreed recruitment period.

The investigator should have sufficient time to properly conduct and complete the project within the agreed project period.

The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the project to conduct the project properly and safely.

The investigator should ensure that all persons assisting with the project are adequately informed about the protocol, and their project-related duties and functions.

### **MEDICAL CARE OF PROJECT PARTICIPANTS**

A qualified medical practitioner, who may be the PR or a sub-investigator for the project, should be responsible for all project-related medical decisions.

During and after a subject's participation in a project, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the project. The investigator/institution should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.

It is recommended that the investigator informs the subject's primary health care provider about the subject's participation in the project if the subject has a primary health care provider and if the subject agrees to the primary health care provider being informed.

Although a subject is not obliged to give his/her reason(s) for withdrawing prematurely from a project, the

investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the subject's rights.

### **INFORMED CONSENT**

The PR is responsible for ensuring that an adequate information package, in an acceptable format, is available for use in the process of seeking informed consent from participants to participate in the project. In all instances both written and verbal informed consent should be obtained. Verbal consent, where the participant is illiterate, should be obtained in the presence of and countersigned by a literate witness.

The PR, co-investigator, or designated person as defined in the protocol, should then seek the participant's informed consent to participate in the study in accordance with the principles outlined in the Declaration of Helsinki, and in these guidelines.

If the project is a multi-site, and/or multi-country study, the site PR must ensure that informed consent procedures take cognizance of the characteristics of the site participants and tailor the informed consent content and procedures accordingly.

Both the informed consent discussion and the written informed consent form and any other written information to be provided to participants should include explanations of the following:

- (a) That the project involves research
- (b) The purpose of the project
- (c) The project treatment(s) and the probability for random assignment to each treatment (where appropriate)
- (d) The project procedures to be followed, including all invasive procedures
- (e) The subject's responsibilities

Once consent to participate in the project has been obtained, a copy of the signed informed consent form and source document identifying the project and recording the dates of participation should be kept with the project records and a copy of signed informed consent form should be provided to the participant.

If the participant can identify a usual medical practitioner, the PR, should seek consent from the participant to inform their usual medical practitioner of their entry into the study. The PR should only inform the medical practitioner on approval from the participant.

Although a subject is not obliged to give his/her reason(s) for withdrawing prematurely from a project, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the subject's rights.

### **COMPLIANCE WITH PROTOCOL**

The investigator should conduct the project in compliance with the protocol agreed and, if required, by the regulatory authority(ies) and which was given approval by the ethics committee.

The investigator should not implement any changes to the protocol without prior review and documented approval from the ethics committee. An exception to this would be where it is necessary to eliminate an immediate hazard(s) to project participants, or when the change(s) involve only logistical or administrative aspects of the trial (e.g. change in monitor(s), change of telephone number(s)). The regulatory authority and the ethics committee should be informed of any changes in retrospect.

The PR, or person designated by the investigator, should document and explain any changes to the approved protocol.

Where necessary, the investigator may implement a change to, the protocol to eliminate an immediate hazard(s) to project participants without prior ethics committee. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be documented and submitted:

- (a) to the ethics committee for review and approval;
- (b) to the CDRF and,
- (c) to the regulatory authority(ies) if applicable.

(d)

#### **CHANGE OF PRINCIPAL RESEARCHER**

If the PR withdraws for any reason(s) before completion of the study, a suitably qualified successor should be appointed by the sponsor to take over responsibility for the conduct of the project.

Before the project continues, information about the new PR (in similar form to that submitted for the original investigator) should be presented for approval to the relevant ethics committee. If practicable the change in PR should also be notified to the participants in the project and the regulatory authority.

#### **DATA MANAGEMENT**

The PR is responsible for the collection, quality, recording, maintenance and retrieval of source data arising from the research project.

The investigator must be available for agreed visits by the monitor during the project and also co-operate in the data editing, quality control and audit

#### **SAFETY ISSUES**

Decisions and actions relevant to the clinical management and safety of the participant in acute situations are the responsibility of the investigator. The investigator is responsible for ensuring that adequate provisions are made for dealing with any unexpected adverse events that may occur in the project participants. During the progress of the project the investigator is obliged to be acquainted with, and consider, new data relevant to the research.

#### **PROGRESS REPORTS AND FINAL STUDY REPORTS**

The PR is obliged to submit progress reports as required by the sponsor, the regulatory authority and/or the relevant ethics committee(s). These reports should contain information on how the study is progressing, the number of participants included in relation to the number expected, the number of dropouts and withdrawals and if the planned time schedule is still appropriate. A final report on completion of the study should also be submitted. The format and frequency of reporting shall be as prescribed.

#### **PROJECT OUTCOME**

All projects should be analysed.