



EDCTP

# Support for ethics courses and seminars

## Expanding GCP training in Africa

The ERECCA project focuses on capacity development in two niche areas in the African context - Good Clinical Practice (GCP) and Research Ethics Review. GCP training has become a compulsory requirement for researchers in South Africa and in other parts of Africa. In collaborative projects where international funders are concerned GCP training is mandatory. Most researchers have some form of basic GCP training but have a need to update this training on a regular basis (either annually or every 2-3 years). For many experienced researchers, time away from the trial site is inconvenient.



Prof. Keymanthri Moodley,  
project coordinator

The ERECCA project includes course development that is web-based allowing research teams to conduct their refresher GCP training either from their sites or from home via the internet. This web based training programme will also be accessible from other parts of Africa.

The Research Ethics Review programme aims to develop capacity for research ethics committees in South Africa. The programme will be presented as a seminar at the University of Stellenbosch and the EDCTP grant will allow Research Ethics Committee members from previously disadvantaged institutions to participate.

### Background

Public health is informed by evidence based medicine, which is dependent on clinical trials conducted in accordance with the highest scientific and ethical

standards. Most researchers in Africa focus on infectious diseases that are a public health priority – HIV, TB and malaria. To a large extent, these diseases are stigmatised in South Africa and hence attention to informed consent for research and confidentiality is crucial in these trials. The courses and seminars offered as part of the ERECCA programme will meet this need and ensure that clinical trials are conducted in accordance with local and international ethical and GCP standards.

### ERECCA - Course content

The ERECCA project focuses on two important players in clinical trial research— research teams and research ethics committee (REC) members.

A Refresher GCP course is under development for experienced investigators and team members who have completed

a basic GCP course three or more years ago. This course will be internet-based using web CT. It will be accessible throughout Africa. The course refreshes knowledge on the history of research ethics and provides updates on guidelines and regulations, electronic data management

and investigator non-compliance. Topics of current interest such as genetic research, international transfer of blood and human tissue samples, HIV prevention trials and legal issues relating to clinical trials are also covered. Course material is presented in a modular format.

The ERECCA project will contribute to GCP training in Africa using web-based technology to present a Refresher GCP programme

## Project at a glance

### Acronym

ERECCA

### Official title

Enhancing research ethics capacity and compliance in Africa

### Project Coordinator

Keymanthri Moodley, South Africa  
Bioethics Unit, University of Stellenbosch

### Participants

- Landon Myer, South Africa
- Lyn Horn, South Africa
- Gordon Page, South Africa
- Dawn Kolbe, South Africa
- Johan Hattingh, South Africa

### Total budget

€ 70,000

### EDCTP budget

€ 70,000

### Project duration

24 months

### Start date

01 September 2006

### End date

30 August 2008

A Seminar on Research Ethics Review will be offered to all REC members of the faculty as well as other faculties and universities in the Western Cape.

### Intermediate objectives

- To extend Refresher GCP courses to a wider audience via WEB CT
- To develop new capacity for ethics review.

### Final objectives

- To improve compliance with national and international standards of ethical review;
- To expedite the ethics review process via improved training
- To strengthen expertise in the ethical conduct of clinical trials in South Africa.

### Expected Outcomes

GCP training will lead to improved compliance with ICH GCP and SAGCP. This will lead to improved participant protection.



Seminars in research ethics will lead to improved, efficient clinical trial review.

### Synergy with EDCTP programmes

In keeping with EDCTP goals, this programme will promote awareness of the history, principles, codes and guidelines of health research ethics and will increase knowledge and application of contemporary ethical issues in health research in the African context.



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COMMISSION

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### For more information

EDCTP The Hague

T +31 70 344 0880/0897

F +31 70 344 0899

E [info@edctp.org](mailto:info@edctp.org)

I [www.edctp.org](http://www.edctp.org)