

**NHREC**

**D du Toit**

**27 August 2009**

# NHREC

Section 72(1) of the National Health Act,  
Act No. 61 of 2003

National Health Research Ethics Council

# NHREC

Ensure that the conduct of health research done on Human subjects is

- Ethically acceptable
- Research participants enjoy benefit of research
- Protected from infavourable conduct

# NHREC

Clinical Research in South Africa requires attention in order to protect

- Human Rights
- Dignity and Integrity

of our Research Participants as well as the reputation of our Scientific Community and Institutions

# REGISTRATION OF REC's

## Registration of all Health Research Ethics Committees

- Council appointed a sub-committee for registering and auditing of ethics committees
- Registering of ethics committees have commenced in 2008
- Monitoring of Health Research

# REGISTRATION AND AUDIT

- Why registration and audit of RECs?
- NHREC will be responsible for the audit of the activities of ethics committees
- All ethics committees must be registered with the NHREC
- An institution and its ethics committee shall provide information from its records to NHREC on request

# REGISTRATION AND AUDIT (cont.)

- An institution and its ethics committee must report annually to the NHREC information relevant to its procedure including:
  - Membership / membership changes
  - Number of meetings
  - Confirmation of participation
  - number of protocols presented, approved and rejected
  - Monitoring procedure in place
  - Complaint procedures and number of complaints handled

# REGISTRATION AND AUDIT (cont.)

- Registration and audit of RECs is to ensure that all RECs in South Africa will meet these criteria on an ongoing basis
- Assist RECs in evaluating and promoting research proposals according to established ethical and scientific standards, and provide public with assurances that ethical review in SA is carried out according to predefined national standards

# APPROACH TO REGISTRATION AND AUDIT

- National Health Act provides for regulations to be developed to support the establishment of the NHREC
- The National Health Act forms the legal background against which the registration and audit process will be implemented

# THE REGISTRATION PROCESS

- Creating and maintaining a dynamic inventory of active RECs
  - Mandatory listing of RECs
  - List will be made publicly available by NHREC
  - Follow-up process or audit is done continuously

# PROPOSED LEVELS OF RESEARCH ETHICS COMMITTEES (RECs)

## LEVEL 1 REC

- Can not review research that:
  - involve drug research
  - biomedical research
  - high budget research
  - high technology
  - potentially hazardous
  - collaborative international health research
  - multi-centre studies
  - long-term studies

Minimal risk to study – not an unlimited period – expected to enhance review capabilities and move towards Level 2 accreditation within a maximum of 5 years

# PROPOSED LEVELS OF RESEARCH ETHICS COMMITTEES (RECs) (Cont.)

## LEVEL 2 REC

- Has the capability to review all types of health research

## Interaction important

- NHREC
- MCC

# ACTIVITIES OF THE NHREC FOR 2007/2008

## Establishing of an office for the NHREC

- Establishing a code of conduct for the NHREC

# ACTIVITIES OF THE NHREC FOR 2007/2008/2009

- Drafting of regulations for:
  - NHREC
  - Research on human subjects
- Establishing of various sub-committees
  - Genetic research
  - Research on animals
- Various working groups

# CONCLUSION

- The establishment of the NHREC will ensure greater reciprocity between REC'S
- Protect research participants and research institutions against unethical conduct