



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001. Cnr Struben and Andries Street, Tel: +27 (0) 12 395 8125/8113 Fax: +27 (0) 12 395 9249

Report for National Health Research Ethics Council (NHREC) 2011/2013



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001, Cnr Struben and Andries Street, Tel: +27 (0) 12 395 8125/8113 Fax: +27 (0) 12 395 9249

CONTENTS

Foreword by the Minister	3
Acknowledgement by the Director-General	4
1. Purpose	5
2. Membership	5
3. Activities for 2011/2013 Reported by Committees and Working Groups	5
3.1. Registration and Auditing	5
3.2 Human Health Research Involving Animals	8
3.3 Training Committee	9
3.4 Vulnerable People and Human Subjects in Health Research	11
3.5 Complaints and Disciplinary Committee	12
3.6 Material Transfer and Biological Specimens	14
3.7 Ethics in Health Research	15

Foreword by the Minister of Health

During the final year of the 2010-2013 term of office, the National Health Research Ethics Council (NHREC) audited 33 health Research Ethics Committees (RECs). The achievement by the NHREC shows compliance to section 72 of the National Health Act (NHA) No. 61 of 2003 and implementation of national and international health research ethics principles of respect for person's autonomy, non-maleficent and distributive justice.

The Council has strengthened relations with RECs through meeting once a year and continued to provide directive on ethics related matters. Progress has been made in the review of the 2004 South African guideline known as Ethics in Health Research: Principles Structures and Processes. Ground work for achieving this milestone has started and we look forward to the final product.

I want to express my gratitude to the NHREC for achieving the highlighted milestones for the period 2011-2013. I also want to thank members of the Council for serving the research community as their term of office will expire by May 2013. Continue to serve the nation in your different fields of expertise. Lastly, I want to thank managers and staff from Health Information Management Monitoring and Evaluation and Health Research Directorate for providing the NHREC with necessary support.



DR. A MOTSOLEDI, MP
MINISTER OF HEALTH

DATE: 18/5/2013



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001, Cnr Struben and Andries Street, Tel: +27 (0) 12 395 8125/8113 Fax: +27 (0) 12 395 9249

Acknowledgements by the Director-General

It has been another great and final year for the current term of office of the National Health Research Ethics Council (NHREC). The Department is aware of the good work the NHREC has been involved in, such as conducting independent of Research Ethics Committees (RECs) audit. On this basis I express my gratefulness to the following members of the NHREC: Prof. D. Du Toit – Chairperson, Prof. A. Dhai Deputy Chairperson, Ms B. Buthelezi, Ms M. Chetty, Prof. S. Essack, Ms. M. Haskins, Dr L. Horn, Ms G. Loots, Dr. N. Khomo, Prof. K. Moodley, Adv. L. Nevondwe, Mr. N. Ramuthaga, Prof. W. Shasha and Ms C. Slack for spending their valuable time performing the work of the Council.

I also acknowledge and appreciate the contributions of Mr. T. Masilela, from the Health Information Management Monitoring and Evaluation, Cluster Ms. K. Nevhutalu, Mr. T. Molebatsi and Mr. J. van der Westhuizen, from the Health Research Directorate, for providing Secretariat and technical support to the work of the NHREC. Lastly, thank you to Mr. R. Maluleke and Ms. R. Sanyane, for assisting with logistical arrangements of the Council activities.

Sincerely

MS MP MATSOSO

DIRECTOR-GENERAL: HEALTH

DATE: 14/6/2013



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001, Cnr Struben and Andries Street, Tel: +27 (0) 12 395 8125/8113 Fax: +27 (0) 12 395 9249

1. Purpose

The National Health Research Ethics Council (NHREC) is a national legislated body responsible for overseeing Health Research Ethics activities in the country.

2. Membership

Members of the NHREC were appointed by the Minister of Health on 11 May 2010. The current term of office will expire on 11 May 2013. Herewith are current members of the NHREC: Prof. Danie du Toit (NHREC Chairperson), Prof. Ames Dhai (NHREC Vice Chairperson), Ms K. Nevhutalu (NDoH and Head of Secretariat) Ms. Marzelle Haskins, Dr. Ngokoana Khomo, Prof. Keymanthri Moodley (resigned in January 2013), Ms. Cathy Slack, Dr. Lynn Horn, Ms. Nokuthula Buthelezi, Ms. Maliga Chetty, Prof. Sabiha Essack, Adv. Lufuno Nevondwe, Ms. Glaudina Loots, Mr. Nathaniel Ramuthaga and Prof. Welile Shasha.

3. Activities for 2011/2013 reported by NHREC Committees and Working Groups

3.1 Registration and Auditing Committee

Membership: Ms. M Haskins (Chairperson), Prof. D Du Toit, Prof. A Dhai, Dr. L Horn and Ms. C Slack

Secretariat: Ms. K Nevhutalu, Mr. T Molebatsi and Mr. J Van der Westhuizen

Activities for 2011/13



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001. Cnr Struben and Andries Street, Tel: +27 (0) 12 395 8125/8113 Fax: +27 (0) 12 395 9249

The Registration and Auditing Committee (RAC) is mandated to register and audit Research Ethics Committees (RECs) that conduct health research on human participants.

- The RAC finalized the specifications determining requirements to appoint independent REC auditors. The audit specifications were based on Department of Health (DoH) 2004 Ethics in Health Research guidelines document.
- The extended RAC represented the NHREC (with observer status) at the appointment of independent REC auditors by NDoH. The appointment of REC auditors was based on the Departmental policies and regulations.
- Thirty-three (33) RECs were audited by independent auditors on behalf of the NHREC during 2012.
- The audit findings were sent to respective RECs to confirm accuracy. The draft audit report was updated to incorporate amendments.
- The NHREC adopted the REC audit report during the 07 August 2012 quarterly meeting. The REC audit report has since been submitted to the National Department of Health management to consider the findings.
- REC Audit summary findings:
 - Thirty (90.3%) RECs were well established and resourced.
 - Six (18%) RECs had more than 70% of either gender.
 - Twenty (61%) RECs had monitoring procedure stated in their Standard Operating Procedures (SOPs) and 13 (39%) did not state their monitoring procedure in their SOPs.
 - Twenty four (73%) RECs had complaints procedure in their SOPs, with five (15%) providing complainants the right to forward their complaints to the NHREC.



- Eight (24%) RECs had no lay members, and eleven (33%) had one lay member whilst two (6%) had more than two lay members.
- Four (12%) RECs had no legally trained members.
- Not all RECs had formal notice of appointment and assurance of legal protection on record.
- Six (18%) RECs conducted no induction for their new members.
- Training records were not consistently available. Where training was not done, financial constraints, lack of national training standards and requirement were cited as reasons.
- Twenty-seven (81%) RECs had SOPs.
- Three (9%) RECs had draft SOPs.
- The remaining three (9%) RECs did not have SOPs.

During the annual NHREC – REC meeting of May 2012, the NHREC and auditors updated RECs Chairpersons and representatives about the progress of REC audit.

Objective	Progress	Comment
Audit Research Ethics Committees	REC audit completed and report submitted to the Department.	Audited 33 ARECs

Plan for 2013/14

- Develop a plan to address concerns raised by REC audit.
- Implement the plan to address concerns raised by REC audit.



health

Department
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001, Cnr Struben and Andries Street, Tel: +27 (0) 12 395 8125/81113 Fax: +27 (0) 12 395 9249

3.2 Human Health Research Involving Animals

Membership: Prof. D du Toit (Chairperson), Ms. G Loots, Prof. S Essack, Dr. L Horn, Prof. A Dhai,

Secretariat: Ms. K. Nevhutalu, Mr. T Molebatsi and Mr. J Van der Westhuizen

Activities for 2011/13

- The Human Health Research Involving Animals Working Group is mandated to register Animal Research Ethics Committees (ARECs) that review research conducted on animals for human health benefit.
- Eleven (11) Animal RECs have registered with the NHREC by mid 2012 and have been allocated unique identification numbers. Since January 2012 the completed Animal RECs registration forms were captured onto the Animal REC database for collection and analysis. The NHREC Secretariat verified data received from ARECs through evaluation based on set criteria to identify gaps for ARECs. In 2012, the Working Group with assistance from the Secretariat and other NHREC members conducted assessment site visits on all registered Animal RECs.
- The NHREC met Animal RECs Chairpersons and representatives at the annual Health Research Ethics Committees (RECs) meeting during May 2012. The meeting decided to involve Animal RECs at subsequent annual meetings. Animal RECs also declared their willingness to interact with the NHREC.



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001, Cnr Struben and Andries Street, Tel: +27 (0) 12 395 8125/8113 Fax: +27 (0) 12 395 9249

Objective	Progress	Comment
Register Animal Research Ethics Committees (ARECs).	Registered 11 ARECs.	Ongoing as applications are received.
Assess Animal Research Ethics Committees.	Assessed 11 ARECs.	Completed.

Plan for 2013/14

- Finalize the working procedures for the auditing of Animal Research Ethics Committees.
- Perform the auditing of Animal RECs registered with the NHREC.

3.3 Training Committee

Membership: Mr. N Ramuthaga (Chairperson), Prof. D du Toit, Prof. A Dhai, Prof. W Shasha, Ms. MHaskins and Prof. S Essack

Secretariat: Ms. K Nevhutalu, Mr. T Molebatsi and Mr. J Van der Westhuizen

Activities for 2011/13

- Reviewed regulations relating to minimum training recommendations for ethics committee members and researchers on minimum curriculum and publish it on the NHREC website.
- Reviewed and determined research ethics documents for publishing on the NHREC website and basic training of Health Research Ethics Committee members and researchers. The following documents were finalised and published on the NHREC website:



- o Data Safety Monitoring Board; Ethics in Health Research: Principles, Structures and Processes (2004); Guidelines for Good Practice in the Conduct of Clinical Trials Guidelines with Human Participants in South Africa (2006); Health Professions Council of South Africa Guidelines on research ethics, and biotechnology research; Declaration of Helsinki 2008; Council for International Organizations of Medical Science Guidelines; International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP); Belmont Report; and Bill of Rights of Constitution of South Africa.

Objective	Progress	Comment
Update NHREC website with ethics training regulation material	Complete	Reviewed and updated ethics training regulation material
Uploading reference documents for Research Ethics Committee members and other stakeholders on NHREC website.	Completed	Reviewed and uploaded reference documents for the Research Ethics Committee members and stakeholders on NHREC website.

Plan for 2013/14

- Review extensively the Audit final report for Training Requirements of various levels of Ethics Committees registered and audited by the Council.
- Perform Gap analysis in terms of training capacity of highly functional and resourced Ethics Committee against those in development.
- Define advisory capacity or sources of assistance which can enable the resource constraint RECs to seek help and capacitating of these RECs.



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001, Cnr Struben and Andries Street, Tel: +27 (0) 12 395 8125/8113 Fax: +27 (0) 12 395 9249

3.4 Vulnerable Persons and Human Subjects in Health Research Working Group

Membership: Chair: Ms. C Slack; Members: Ms. N Buthelezi, Ms. M Chetty, Prof. A Dhai, and Prof. D du Toit

Secretariat: Ms. K Nevhutalu, Mr. T Molebatsi and Mr. J Van der Westhuizen

This working group has merged with the Human Subjects Regulations Working Group. The working group aims to strengthen the ethico-legal framework for human participants with a focus on promoting the welfare of vulnerable participants. It undertakes research and resource-development activities.

Activities for 2011/13

The working group actively participated in the Council's brief to Research Ethics Committees at a meeting on 3rd May 2012 on the implications of section 71 National Health Act (Act 61 of 2003) provisions for health research ethics. Working group members prepared documents and briefed the Director-General of Department of Health regarding the implications of section 71. Members were further involved in briefing meetings with the Deputy Minister and Minister for Health where complexities regarding section 71 were outlined, and possible strategies debated.

- **Human Subjects Regulations:** The working group finalized regulations for Human Subjects. They also finalised an Appendix – form A that will assist role-players to apply for non-therapeutic research with minors to the Minister or his delegated authority.
- **Resource Documents:** The ethical-legal audit of the SA framework for vulnerable participants was published on the NHREC website. Two resource



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001, Cnr Struben and Andries Street, Tel: +27 (0) 12 395 8125/8113 Fax: +27 (0) 12 395 9249

documents for research stakeholders, namely on Payment and Community Advisory Groups, were finalized by incorporating comments from RECs and making revisions.

- The following documents were finalised by the working group and published on the NHREC website:
 - Ethical-Legal Protection for vulnerable research participants in South Africa an audit of relevant laws and ethical guidelines National Health Research Ethics Council (NHREC); Payment of Trial participants in South Africa: Ethical considerations for Research Ethics Committees; and Guidelines for Community Advisory Groups.

3.5 Complaints and Disciplinary Committee (CDC)

Membership: Dr. NE Khomo (Chairperson), Prof. D du Toit, Prof. A Dhai, Prof. E Essack, Adv. L Nevondwe, Dr. L. Horn and Ms. M Chetty.

Secretariat: Ms. K Nevhutalu, Ms.A Mabotja (NDoH Legal Advisor), Mr. T. Molebatsi, and Mr. J. van der Westhuizen

Activities for 2011/2013

The Committee is mandated to develop and implement Standard Operating Procedures for disciplinary processes, sanctions and appeals.

- The following documents were finalised by the working group and published on the NHREC website
 - Guidelines for the Management of Complains



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001, Cnr Struben and Andries Street, Tel: +27 (0) 12 395 8125/8113 Fax: +27 (0) 12 395 9249

- Standard Operating Procedures for Disciplinary processes, sanctions and Appeals.
- Complaints handled
 - The Complaints and Disciplinary Committee handle two cases with the following reference numbers: NHREC/CDC150311-009 and NHREC/CDC080520121-010 during the financial year. The first case was successfully completed. While the second case is pending finalization.

Activities for 2011/2013

Objective	Progress	Comment
Finalise SOPs for Disciplinary processes, sanctions and appeals	Finalised March 2012	To be circulated to RECs for comment
Finalise legal issues regarding the working and status of the Committee.	Drafted legal issues regarding the workings and status of the Committee	Document finalized.
Review regulations to ensure complaints and discipline are covered.	Not covered in the draft regulations	To be included in the next draft document.
Publish SOPs on the NHREC website	Completed	Document finalized.

Plan 2013/14

1. Finalise review of regulations to ensure complaints and discipline are covered.



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001, Cnr Struben and Andries Street, Tel: +27 (0) 12 395 8125/8113 Fax: +27 (0) 12 395 9249

3.6 Material Transfer and Biological Specimens Working Group

Membership: Ms. G Loots (Chairperson); Prof. A Dhai, Prof. D du Toit, Prof. W Shasha, Dr. N Khomo, Ms. M Chetty and Ms. N Buthelezi,

Secretariat: Ms. K. Nevhutalu, Mr. T. Molebatsi and Mr. J. Van der Westhuizen

Activities 2011/13

The Material Transfer and Biological Specimens Working Group are mandated to determine health research ethical matters related to the Material Transfer Agreement (MTA) document and Human Tissue samples in South Africa.

- A benchmark study on international trends on MTAs was conducted by the Working Group and completed by July 2011.
- The Secretariat consolidated Material Transfer Agreements (MTAs) from all Research Ethics Committees (RECs) in South Africa registered with NHREC. This was done to analyze the nature and extent of MTAs used by RECs.

Objective	Progress	Comment
Develop Material Transfer Agreement for South Africa.	Ongoing	To be finalized in the next financial year.

Plan 2013/14

1. Finalize the Material Transfer Agreement for the NHREC and publish on the Council's website.



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001, Cnr Struben and Andries Streef, Tel: +27 (0) 12 395 8125/8113 Fax: +27 (0) 12 395 9249

3.7 Ethics in Health Research Working Group.

Membership: Prof. K. Moodley (Chairperson); Prof. A Dhai, Prof. D du Toit, Ms. M Haskins, Ms. C Slack, Mr. N. Ramuthaga, Dr. N. Khomo Dr. L. Horn and Prof. S. Essack

Secretariat: Ms. K. Nevhutalu, Mr. T. Molebatsi and Mr. J. Van der Westhuizen

Activities 2011/13

The working group aims to review the Ethics in Health Research guidelines: Principles, Structures and Processes.

- Chapters 1-5 of the document have been reviewed. Chapter 6-9 are in undergoing review process.

Objective	Progress	Comment
Review the Ethics in Health Research guidelines: Principles, Structures and Processes.	Ongoing	To be finalized in the next financial year.

Plan 2013/14

1. Finalize review of the Ethics in Health Research Guidelines: Principles, Structures and Processes.