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) 2010/2011

NATIONAL HEALTH
RESEARCH ETHICS COUNCIL

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Foreword by Minister of Health

The NHREC is in the second term of office which runs from 2010 to 2013. During the 2010/2011 financial year, the NHREC has evolved from operating with seven to five working groups (including the EXCO) and three committees as indicated in the comprehensive report. In the same financial year the NHREC assessed 32 Research Ethics Committees (RECs) in preparation of the independent audit. Ten additional RECs were registered according to the mandate of the National Health Act (NHA).

This Council met 4 times during the financial year and agreed to review the 2004 South African guideline known as Ethics in Health Research: Principles Structures and Processes. Ground work for achieving this milestone has started and the first four chapters have been reviewed. Among others, the NHREC has finalized ethical-legal audit framework for vulnerable persons in research; compiled standard operating procedures for complaints and developed a template for reference documents for RECs; and developed resource papers on payment of research participants and on community advisory groups. The NHREC oversight on composition, competence and operations of RECs is relevant to ensure that research intended to benefit the Negotiated Service Agreement (NSDA) is conducted in an ethical manner.

Firstly, I want to thank the NHREC for their achievements during 2010/2011. I expect the Council to continue working hard to achieve their planned activities for the remaining part of their term in office. Finally, I thank and urge the leadership of the Health Research Directorate to continue providing support to the work of the Council.

DR. A MOTSOALEDI
MINISTER OF HEALTH

Acknowledgements

I would like to express my gratitude and appreciation to the following members of the National Health Research Ethics Council: 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 who dedicated their time and efforts to achieve the targets of the Council. A special thanks to the health Research Ethics Committees (RECs) who continue to interact and complied with the National Health Research Ethics Council (NHREC).

I also express my acknowledgement to Mr. N. Ntuli, Ms. N. Mbelle, Mr. T. Molebatsi, Mr. J van der Westhuizen, Mr. B. Mdlovu from the Health Research Directorate who coordinated and provided Secretariat support to the work of the NHREC. To the administration team, Mr. R. Maluleke and Ms. R. Sanyane, thank you for providing your services to the NHREC.

MS. MP. MATSOSO
DIRECTOR-GENERAL: HEALTH

1. Purpose

The National Health Research Ethics Council (NHREC) was established in September 2006, in terms of Section 72[1] of the National Health Act, (Act No.61 of 2003). The NHREC is a national legislated body responsible for overseeing Health Research Ethics activities in the country.

2. Mandate

2.1 Section 72 (6) of the National Health Act (NHA) mandates the NHREC to:

- Determine guidelines for the functioning of Health Research Ethics committees (RECs).
- Register and audit RECs.
- Set norms and standards for conducting research on humans and animals and norms and standards for conducting clinical trials.
- Adjudicate complaints about the functioning of health RECs and hear any complaint by a researcher who believes he or she has been discriminated against by a health REC.
- Refer to the relevant statutory health professional council matters involving the violation or potential violation of an ethical or professional rule by a health care provider.
- Institute such disciplinary action as may be prescribed against any person found to be in violation of any norms and standards or guidelines set for the conducting of research in terms of this Act.
- Advise the national department and provincial departments on any ethical issues concerning research.
- Set up working groups /task teams/sub-committees to carry out its functions.

3. Membership

3.1 The NHA mandates the Minister of Health to appoint at most fifteen (15) persons to the NHREC, after consulting with the National Health Council from

persons nominated by interested parties at the invitation of his/her notice in the government gazette as follows:

- Nine (9) with extensive experience and knowledge in health research ethics
- A representative from the community
- A representative from the Department
- A representative of the pharmaceutical industry
- A representative from the Medicines Control Council
- A person with extensive knowledge in animal health research ethics, and,
- A person with extensive knowledge in law.

Members of the NHREC are appointed for a period of three (3) years and may be reappointed for one (1) or more further terms. The first term of office for the NHREC ended in May 2010. Directly afterwards the second term began, the first meeting of this new term of office took place in August 2010.

3.2. The current NHREC membership is as follows:

- Prof. Danie du Toit (Chairperson)
- Prof. Ames Dhai (Vice Chairperson)
- Mrs. Nokuthula Buthelezi
- Mrs. Maliga Chetty
- Prof. Sabiha Essack
- Mrs. Marzelle Haskins (Convener– Registration & Auditing Working Group)
- Dr. Lynn Horn
- Dr. Ngokoana Khomo (Convener– Complaints and Disciplinary Committee)
- Mrs. Glaudina Loots (Convener– Material Transfer and Biological Specimens Working Group)

- Prof. Keymanthri Moodley (Convener– Ethics in Health Research Working Group)
- Adv. Lufuno Nevondwe
- Mr. Nathaniel Ramuthaga (Convener– Training Committee)
- Ms. Cathy Slack (Convener– Human Subjects and Vulnerable Populations Working Group)
- Prof. Welile Shasha.

4. Working Groups

The first task of the new NHREC was to delineate its roles, responsibilities and terms of reference as articulated in the NHA by means of a constitution. Professor Essack formulated the NHREC Constitution which was duly adopted on 17 November 2010.

NHREC has constituted itself into 03 standing committees and 04 working groups, viz:

- Registration and Auditing Committee
  Convener: Mrs. Haskins; Members: Mrs. Buthelezi, Prof Dhai, Prof du Toit and Dr Horn
- Human Subjects and Vulnerable Populations Working Group
  Convener: Ms Slack; Members: Mrs. Buthelezi, Mrs. Chetty, Prof Dhai and Prof du Toit
- Training Committee
  Convener: Mr Ramuthaga; Members: Prof Du Toit, Prof Dhai, Prof Essack, Mrs. Haskins and Dr. Khomo
- Human Health Research involving Animals Working Group
  Convener: Prof du Toit; Members: Prof Dhai, Prof Essack, Dr Horn and Mrs. Loots
- Complaints and Disciplinary Committee

Convener: Dr Khomo; Members: Prof. Dhai, Prof. du Toit, Mrs. Chetty, Prof. Essack, Dr. Horn and Adv. Nevondwe

- Ethics in Health Research Working Group
  Convener: Prof Moodley Members: Prof Dhai, Prof du Toit, Mrs. Haskins, Mrs. Loots, Dr. Khomo, Ms. Slack and Mr. Ramuthaga
- Material Transfer and Biological Specimens Working Group
  Convener: Mrs. Loots; Members: Mrs. Buthelezi, Mrs. Chetty, Prof du Toit, Prof Dhai, , Dr Khomo, Prof Moodley and Prof Shasha

5. Meetings of the NHREC

5.1 NHREC meetings are held four (4) times a year. During the 2010/2011 financial year, the NHREC met three times, in August 2010, November 2010 and February 2011. The current office of the NHREC started in the middle of the financial year 2010/2011. Members of the NHREC for were appointed and notified on 16 May 2010.

5.2 The Working Groups and Committees held the following meetings via teleconferences for the period 2010/2011.

- Registration and Auditing Committee (20 April 2010, 16 September 2010 and 2 February 2011)
- Human Subjects and Vulnerable Populations Working Group (29 July 2010, 20 October 2010 and 7 February 2011)
- Training Committee (16 September 2010, 7 June 2010 and 4 February 2011)
- Human Health Research involving Animals Working Group (14 September 2010; 1 February 2011)
- Complaints and Disciplinary Committee (21 September 2010; 4 February 2011)
- Ethics in Health Research Working Group (29 September 2010; 8 February 2011)
- Material Transfer and Biological Specimens Working Group

6. The Executive Committee (EXCO)

6.1 EXCO Membership:

Chairperson, Prof du Toit, Vice Chairperson, Prof Dhai, Secretariat representative, Chairperson of Working Group co-opted.

7. Working Groups Activities

7.1 Working Group Composition and Operations

The NHREC has five working groups and three committees including the EXCO. They are: EXCO; Human Health Research involving Animals Working Group; Registration and Auditing of Research Ethics Committee; Regulations Related to Protection of Vulnerable Human Research Participants Working Group; Training Committee; Transfer and Biological Specimen Working Group; Complaints and Disciplinary Procedures Committee and Ethics in Health Research Working Group.

A Working group is constituted of four (4) – five (5) persons. All NHREC working groups met a few times respectively between September 2010 and February 2011. All Working groups developed their terms of references (TOR) documents to guide their own functioning.

7.2. Health Research on Animals Working Group

7.2.1 Purpose

To set norms and standards for conducting health research on animals.

Human Health Research involving Animals Working Group: Membership

Chair: Prof du Toit; Members: Prof Dhai, Prof Essack, Dr Horn and Mrs. Loots

Report: Human Health Research involving Animals Working Group

Formerly the Working Group was known as the Animal Health Working Group. The name was changed to the Human Health Research involving Animals Working Group (HHRAWG) on 14th September 2010 at a meeting of the Working Group.

The Working Group was established to set norms and standards for conducting human health research involving animals.

2010/2011 Activities

During September 2010, the Working Group (WG) re-affirmed their mandate as indicated in the preamble and Section 72 (6c) of the NHA based on the advice from NDOH legal unit that is the WG was to exercise oversight of research conducted on animals for human health benefit. The WG proposed that section 72 (6c) should be changed to include "set norms and standards for conducting research on humans and animals, including norms and standards for animal research for human health benefit". The Working Group adopted the "Application for Registration of an Animal Research Ethics Committee (AREC)" as a variation of the application for RECs. During 2010, the HHRAWG developed and submitted a workplan and budget for the 2010/2011 financial year. The workplan focused mainly on the listing and registration of Animal RECs that deal with human health research.

7.3 Registration and Auditing of Research Ethics Committee

7.3.1 Purpose

To oversee the implementation of the registration and auditing of Research Ethics Committees (RECs) in South Africa.

Registration and Auditing of Research Ethics Committee Membership:

Chair: Mrs. Haskins; Members: Mrs. Buthelezi, Prof Dhai, Prof du Toit and Dr Horn

REGISTRATION AND AUDITING WORKING GROUP (RAWG) REPORT FOR 2010

The Registration and Auditing Working Group (RAWG) was established to draw up a framework and oversee the registration, assessment and auditing processes of

RECs registered with the NHREC. A call for RECs to register with the Council was made in February 2008. The criteria for the auditing procedure were based on the Department of Health Research Ethics Guidelines Ethics in Health Research: Principles, Structures and Processes (2004).

The RAWG developed and submitted a Terms of Reference (ToR) document. Twenty-two (22) RECs have registered with the NHREC by mid 2009 and have been allocated unique identification numbers. From July – August 2009 the completed REC registration forms were captured onto a REC database for collation and analysis. The NHREC Secretariat verified data received from RECs by evaluating and assessing the data received by an assessment form linked to certain criteria to identify gaps for RECs. During October 2009, the RAWG, with assistance from the secretariat and other NHREC members conducted assessment visits on all the registered RECs. Qualitative and quantitative reports on the outcome of the assessment visits were drawn up and distributed by the secretariat.

2010/2011 Activities

At the beginning of 2010, the RAWG developed and submitted a workplan and budget for the 2010/2011 financial year. The workplan focused mainly on assessment and auditing of registered RECs. The working group has also finalised working procedures for the auditing of registered RECs by the NHREC. The REC audit working procedures document describes the background, objectives, audit programme, and action plan of the RAWG.

During 2010/2011, the RAWG was involved in the following activities:

- Finalized the working procedures for the auditing of Research Ethics Committees
- Developed RECs audits mandate.
- Assisted in setting up and training RECs in North West and Northern Cape Provinces

7.4 Regulations Related to Protection of Vulnerable Human Research Participants Working Group

7.4.1Purpose

To promote the protection of human research participants categorised as vulnerable groups.

7.4.2. Regulations Related to and Protection of Vulnerable Human Research Participants Working Group Membership

Chair: Ms Slack; Members: Mrs. Buthelezi, Mrs. Chetty, Prof Dhai, and Prof du Toit

VULNERABLE PERSONS WORKING GROUP: REPORT FOR 2010/11

This group has merged with the Human Subjects Regulations Working Group.

There are persons who are susceptible to increased research harm or to compromised consent because of intrapersonal, interpersonal and contextual factors (so-called 'vulnerable persons'). In most ethical-legal frameworks such persons are accorded increased protection. This working group of the NHREC has been involved in *research* functions, that is, an assessment of the current protections afforded by the SA framework, as well as *capacity building* and support functions, such as the development of resource papers on issues of interest to the protection of vulnerable groups.

2010/2011 Activities

The development of draft amendments to s71 of the National Health Act, and submission to the Legal Unit in the DOH

- The finalisation of an ethical-legal audit of the South African framework for vulnerable persons in research.
- The dissemination to RECs and the MCC of a resource paper on payment.

- The dissemination to RECs and the MCC of a resource paper on Community Advisory Groups.
- A meeting with the Legal Unit to debate the Human subjects regulations.

This working group has developed and disseminated several substantive resource papers for stakeholders in the South African research environment.

7.5. Training Committee

7.5.1Purpose

- To establish basic competencies for research ethics training recommended/required of individuals who serve on Research Ethics Committees and for researchers conducting health research.

Training Committee Membership:

TRAINING AND GCP WORKING GROUP REPORT FOR 2010/11

Chairperson: Mr. N Ramuthaga, Members: Prof. D Du Toit, Prof. A Dhai, Prof. S Essack, Mrs. M Haskins and Dr. N. Khomo

The following was accomplished by this working group during the previous term of office of the NHREC that ended in May 2010:

- The minimum curriculum for training of Health Research Ethics Committee members in South Africa was defined and approved by the NHREC.
- The Council together with South African GCP Training stakeholders (Academia, Industry and Private trainers) met and agreed on the minimum content for GCP training in South Africa. This has been submitted to the HPCSA for review and accreditation who has invited the sub-committee to address the accreditors at a national forum meeting planned for 2011 to provide guidance on the review process.

- The working group also acted on primary findings from the RAGWG that there was a general need for ethics capacity building in the country reflected by the feedback received from various assessment visits to the RECs in all 9 provinces within South Africa. Owing to limited resources of time and funding, the National Health Research Committee identified key priorities and provinces where intervention was needed as a matter of urgency. Three provinces were identified for the initial attention to determine an overview of set up and ethics as well as GCP training required for RECs to function optimally.

2010/2011 Activities

Northwest Training workshops

The Training working group organized 3 ethics training workshops on the following respective dates and provinces: 16-17 September 2010 at Northwest, 06-07 December 2010 at Northern Cape and 10-11 March 2011 at Eastern Cape. NHREC members and those of the Training working group attended and facilitated the three workshops.

The scope of workshop training covered basic highlights of Good Clinical Practice (GCP) training describing the steps involved in clinical development; the scope and intent of guidelines and regulations that govern clinical research and differences between the investigator's and the sponsor's responsibilities in clinical research. How to plan effective recruitment and enrolment activities for Clinical trial patients; when these activities can occur; activities required during recruitment and enrolment and conduct the informed consent process in compliance with applicable regulations were covered as were steps involved in data management; processes required for investigational product; strategies to maximize participant retention and compliance, biological specimen handling and the Audit Inspections and Publications-ICH-GCP/SA GCP.

7.6. Material Transfer and Biological Specimen Working Group

7.6.1 Purpose

To deliberate on the Material Transfer Agreements (MTA) document and ethical issues pertaining to Human Tissue samples.

Working Group on Material Transfer: Members

Chair: Mrs. Loots; Members: Mrs. Buthelezi, Mrs. Chetty, Prof du Toit, Prof Dhai, Dr Khomo, Prof Moodley and Prof Shasha

Report: Material Transfer and Biological Specimens Working Group 2010/2011

The Material Transfer and Biological Specimen's Working Group Ad-Hoc Committee was established during a NHREC meeting on the 23rd September 2009.

Formerly the Material Transfer and Biological Specimens Working Group were known as the Material Transfer Agreement Working Group. The members for the then MTAWG were Ms Levendal (Chairperson), Mrs. Haskins, Dr Groenewald, Mr Ramuthaga, Dr Khoale, Prof Dhai and Prof London.

The Working Group name changed to the Material Transfer and Biological Specimens Working Group at a meeting of the new NHREC on 11 August 2010 and was constituted with the following members:

Chairperson: Mrs. Loots; Members: Mrs. Buthelezi, Mrs. Chetty, Prof Dhai, Prof du Toit, Dr Khomo, Prof Moodley and Prof Shasha.

The purpose of the Material Transfer and Biological Specimens Working Group:

- To deliberate on the MTA document and the ethical issues pertaining to Human Tissue samples.

2010/2011 Activities

During 2010, Material Transfer and Biological Specimen's Working Group developed and finalized the Terms of Reference for the Working Group.

Prof M Pepper from University of Pretoria Chairperson of the Committee that is tasked with finalization of Chapter 8 of the NHA presented to the NHREC at a meeting held on 16 February 2011 on the amendments to Chapter 8 of the National Health Act and Regulations thereof.

7.7. Complaints and Disciplinary Procedures Committee

7.7.1. Purpose

To set guidelines for the National Health Research Ethics Council for dealing effectively with complaints regarding ethic of research on human or animal populations.

COMPLAINTS AND ADVISORY DISCIPLINARY COMMITTEE

MEMBERS 2010/2011

Chairperson: Dr N E Khomo, Prof. A. Dhai, Prof. D. du Toit, , Mrs. M Chetty, Prof. E Essack, Dr. L. Horn and Adv. L Nevondwe

One of the functions of the NHREC is to manage complaints submitted to it either by researchers, RECs, other bodies or the public The Committee thus had to compile standard operating procedures (SOPs) for the management of complaints, delineate disciplinary processes and sanctions of those found to have violated ethical rules and standards of research and provide recourse to appeal against decisions of the NHREC.

The Complaints and Disciplinary Committee (CDC) was established in 2007. It had 3 members and was supported by the secretariat. Since 2011 the membership of the committee has increased to six members listed above and the secretariat.

The Complaints and Disciplinary Committee was established to provide a framework for the management of complaints and ethics related health research misconduct.

2010/2011 ACTIVITIES

During 2010/2011, committee was involved in the following activities:

Two teleconference meetings were held and accomplished the following:

- Finalised terms of reference.
- Refined the previous CDC document and complied SOPs for complaints.
- The Complaints form was accepted and its use has already been implemented.
- Six complaints were received from the participants and researchers and four were finalised and resolved.

7.8. Ethics in Health Research Working Group

7.8.1. Purpose

To deliberate on substantive ethical issues that arise in the conduct of research in South Africa, to incorporate some of these issues in the revision of the official research ethics guidance document of the Department of Health – "Ethics in Health Research: Principles, Structures and Processes" published in 2004 and to issue an NHREC position statement on these matters.

Ethics in Health Research Working Group: Membership

Prof Keymanthri Moodley (Chairperson), Prof Ames Dhai, Prof Danie Du Toit, Mrs. Marzelle Haskins, Mrs. Glaudina Loots, Dr. N. Khomo, Ms. Cathy Slack and Mr. Nathaniel Ramuthaga

The guideline "Ethics in Health Research: Principles, Structures and Processes" (blue book) was last updated in 2004. Since then numerous changes had occurred in NHREC and the National Health Act prompting a need to review and revise the ethical guidelines. It was also noted that NHREC played a national role in coordinating activities in research ethics and so had a responsibility to debate and deliberate important substantive issues in research ethics with a view to formulating a policy document on these issues. It is on this basis that this working group was constituted.

This new WG was constituted on 11 August 2010 at a meeting of the full council (NHREC) for the express purpose of updating the Ethics in Health Research guidelines in South Africa. The chairperson was appointed and members of the WG comprised the chairs of all the other working groups as well as the executive committee and the secretariat. The group held its first teleconference on 29 October 2010 and terms of reference as well as a work plan for updating the Ethics in Health Research guidelines in South Africa were discussed. It was decided then that during the course of updating the ethics guidelines, various substantive issues in research ethics would emerge and the WG would incorporate these matters into the Ethics in Health Research guidelines in South Africa. After review of the ethics guidelines, a decision would be taken to develop a separate policy document outlining the position of NHREC.

2010/2011 Activities

- Development of Terms of Reference for Working Group.
- Review of guideline: Ethics in Health Research: Principles, Structures and Processes. Chapters 1-4 have been completed an approved by NHREC for dissemination to the wider stakeholder community.
- Deliberation and debate on substantive ethical issues in research.
- Development of Policy Statement from NHREC on Substantive Issues in Health Research Ethics

8. Summary of NHREC Activities in <u>2010/2011</u>

8.1 Finalised Regulations:

8.1.1 Human Research Subjects submitted to NDOH legal unit.

8.1.2 NHREC Regulations published.

8.2 Established an REC registration system where 10 RECs registered with NHREC.

8.3 Developed working relations with other research regulatory bodies, such as National Health Research Committee (NHRC), Medicines Control Council (MCC) and Health Research Ethics Committees (RECs).

8.4 Developed resource documents on ethical issues such as:

8.4.1Templates for reference documents for RECs and for logging complaints.

8.4.2 Website and publicity material.

CHAIRPERSON:
Prof. D. du Toit

8. Summary of NHREC Activities in 2010/2011

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CHAIRPERSON:
Prof. D. du Toit

Report compiled by:

Ms. Khanyisa Nevhutalu

Mr. Thabo Molebatsi

Mr. Jacques van der Westhuizen