



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL HEALTH
RESEARCH ETHICS
COUNCIL



NATIONAL HEALTH RESEARCH ETHICS COUNCIL REPORT (2007 – 2009)

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Foreword

Human dignity, equality and the advancement of human rights are respected, promoted and protected under the Constitution of the Republic of South African of, 1996 (Act No. 108 of 1996) In particular section 12(2) of the Bill of Rights provides that *'Everyone has the right to bodily and psychological integrity, which includes the right (b) to security in and control over their body; and (c) not to be subjected to medical or scientific experiments without their informed consent'*.

In 2006, the National Health Research Ethics Council (NHREC) was established in terms of section 72 of the National Health Act, 2003 (Act No. 61 of 2003) with its core responsibility of addressing ethical matters relating to health research and to the advancement of health research ethics in South Africa. Its main functions are to determine guidelines for functioning of health research ethics committees; register and audit health research committees; and set norms and standards for conducting health research. This mandate means that the NHREC has responsibility to exercise oversight over the functioning of health research ethics committees and other health research in humans in the whole of South Africa.

All these functions are entrenched in the NHREC 2007/2008 Strategic Plan and 2009/2010 Business Plan as reflected in this report (2006 – 2009). The first term of office of the NHREC was from 2006 to 2009. Towards the end of term of office in August 2009, members of the NHREC were requested to extend their tenure to continue serving in the Council until such time that a new, Council was duly appointed.

The Council has gradually grown in performing its functions since its establishment in September 2006 as reflected in this report. The Council held its first quarterly meeting in January 2007. In June 2007, the first strategic planning session took place and achieved setting up operational structures such as

committees, working groups and functioning documents. In 2008/2009 the Council's performance gained momentum withstanding being newly established. While in the process of building its profile and raising awareness about its existence, the Council has in 2009/2010 registered and assessed 22 health research ethics committees. One of the objectives of the Council for 2010/2011 is to audit these registered health research ethics committees and continue to register, asses and audit newly established RECs as indicated in this report.

I commend the Council for executing their oversight function thereby registering health research committees and protecting the vulnerable populations. I expect that the new Council will continue with the vision and hard work of the current one, whose term will come to an end once the new Council is appointed. Finally, I thank the leadership of the Health Research Directorate for efficiently supporting the work of the Council.

A handwritten signature in black ink, consisting of a large, stylized 'M' followed by a series of loops and a final flourish.

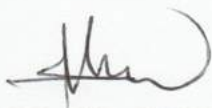
DR. A MOTSOLEDI
MINISTER OF HEALTH

Acknowledgements

I would like to thank the members of the National Health Research Ethics Council: Prof. D. Du Toit – Chairperson, Prof. A. Dhai Deputy Chairperson, Mrs. D. Biyela, Dr M. Groenewald, Ms M. Haskins, Dr N. Khaole, Dr N. Khomo, Ms E. Levendal, Prof L. London, Dr L. Makubalo, Prof L. Mazwai, Mr. N. Ramuthaga and Ms C. Slack who dedicated their time and efforts to achieve milestones indicated in this report. Special thanks go to the health Research Ethics Committees (RECs) who complied and registered with the National Health Research Ethics Council (NHREC).

I also would like to thank Ms. N. Mbelle, Mr. T. Molebatsi and Mr. J van der Westhuizen from the Health Research Directorate who ably 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.

I want to take this opportunity to congratulate and welcome the new NHREC for the period 2010 – 2013. I look forward to your contribution in overseeing the health research ethics work in the country.



MS. MP. MATSOSO

DIRECTOR-GENERAL: DEPARTMENT OF HEALTH

INTRODUCTION AND BACKGROUND

In October 2006 the Minister of Health appointed the National Health Research Ethics Council. The Council was operational since its first Council meeting on the 31 January 2007. The members of the Council interacted well with fellow colleagues and made good progress to achieve the goals that were set by the Council members and to complete the ad hoc tasks assigned by the Minister of Health from time to time. In this report I will attempt to cover the activities of the Council from its inception in October 2006 up until September 2009 when a new Council will be appointed for the next 3 years.

THE MANDATE OF THE NATIONAL HEALTH RESEARCH ETHICS COUNCIL (NHREC)

The National Health Research Ethics Council is established in terms of section 72 (1) of the National Health Act (Act No 61 of 2003). The inaugural meeting of the NHREC was held on the 31 January 2007. The Ethics Council consists of not more than 14 persons nominated by interested parties at the invitation of the Minister of Health by notice in the Government Gazette and is appointed by the Minister after consultation with the National Health Council.

The Council is appointed for a three-year term starting 1st October 2006 to 30th September 2009.

The functions of the Council are stipulated in section 72(6) of the Act as to -

- (i) determine guidelines for the functioning of health research ethics committees;
- (ii) register and audit health research ethics committees;
- (iii) set norms and standards for the conducting of research on humans and animals;

- (iv) adjudicate complaints about the functioning of health research ethics committees and hear any complaint by a researcher who feels that he or she has been discriminated against;
- (v) refer to the relevant statutory health professional council matters involving the violation or potential violation of a professional or ethical rule by a health care provider;
- (vi) 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 the Act; and
- (vii) advise the National Department of Health and the provincial departments of health on any ethical issues concerning research.

Résumés of NHREC Members who served on the Council from 2006 to 2009:

Professor Daniel du Toit

Professor D. du Toit is a member and Chairperson of the NHREC. He is also NHREC Executive Committee (EXCO) member and chairs the Animal Ethics Working Group. He is the Head of the Department of Biomedical Sciences, Faculty of Science at the Tshwane University of Technology (TUT). He has a PhD in Medical Science, Human Physiology. His membership to Health Research organisations, forums, councils includes, Executive Member of Council for International Organisations of Medical Sciences (CIOMS); Board Member of Medical Research Council (MRC); Chairperson of MRC Research Ethics Committee and Animal Ethics Committee; Member of TUT Research Ethics Committee. His areas of focus are in medical sciences, research, and ethics.

Professor Ames Dhai

Professor A. Dhai is a member of the NHREC. She is also a member of the NHREC EXCO. She is the Director of the Steve Biko Centre for Bioethics at the University of the Witwatersrand Medical School. She has an MBChB (Natal) and specialised as an

Obstetrician, Gynaecologist; LLM, and a Diploma in International Research Ethics. Her membership to health research organisations, forums, and councils membership to the MRC Ethics Committee, established and chairs the Hospice Palliative Care of South Africa Research Ethics Committee and is Co-Chairperson of the Wits Human Research Ethics Committee (Medical). She also serves on the Medical and Dental Board of the Health Professions Council of South Africa, is on the Council of the Colleges of Obstetricians and Gynaecologists of South Africa, and is a member of the Human Rights, Ethics and Professional Development Committee of the Health Professions Council, and the Human Rights and Ethics Committee of the South African Medical Association. She was recently appointed onto the National Biotechnology Advisory Committee which has been tasked to offer specialist advice to the Minister of Science and Technology. Her special interests are in issues related bioethics and medical law.

Dr. Lindiwe Makubalo

Dr Lindiwe Makubalo is a member of NHREC. She is the Department of Health representative in the NHREC. She is further responsible for the Cluster: Health Information Epidemiology Evaluation and Research (HIEER) at National Department of Health. She has a PhD in Epidemiology. Dr Makubalo serves on a number of national bodies. Her membership to the health research organisations, forums, and councils include a member of the MRC board and the Chairperson to the Scientific and Technical Advisory Committee of the WHO Board of Alliance for Health Policy Systems Research.

Ms. Dudu Biyela

Ms. D. Biyela is a member of the NHREC. She is the community representative in the Council. She is a retired nurse and former social health researcher which started at Hlabisa hospital. She holds a number of diplomas in Nursing, Midwifery, Clinical care and a Bachelor of Community and Development (University of Kwa-Zulu Natal). Her membership to the health research organisations, forums, and councils includes Interim National Health Research Ethics Committee, Interim Hlabisa Hospital Board, Human

Rights Forum for Umkhanyakude District Municipality, Local Aids Committee for Hlabisa local Municipality, Chairperson Hlabisa Senior Citizens Forum, HIV/AIDS Committee for Lutheran Church.

Dr. Nathaniel Khaole

Dr. N. Khaole is a member of the NHREC and an official of the National Department of Health. He is the Director for Women's Health and Genetics. He has the following qualifications MBChB (Natal); Diploma in Health Services Management and Post Graduate Diploma in International Research Ethics. His membership to Health Research organisations, forums, councils includes, registered with the Health Professions Council of South Africa (HPCSA); a member of the South African Medical Association; a member of the Southern African Society for Human Genetics and a member of the South African Medical Research Council (MRC) Ethics Committee. Dr. Khaole's areas of interests and expertise are in Bioethics, Clinical Genetics and Dysmorphology and Health Service Management.

Dr. Marcelle Groenewald

Dr. M. Groenewald is a member of the NHREC. She is a Principal Medical Officer and Manager of the Allergy Service Unit, 1 Military Hospital Pretoria, where she consults as a clinician in mainly paediatric allergic diseases. She holds the following qualifications; a MBChB (Pretoria), a Diploma in Child Health, Colleges of Medicine DCH(SA) and a Post Graduate Diploma in International Research Ethics. Her membership to Health Research organisations, forums, councils includes a Founder Member and Vice-Chairperson of the South African Medical Association Research Ethics Committee. Her areas of focus are in clinical research and paediatric diseases, mainly Allergic Rhinitis, Asthma, Allergic Skin Diseases and Atopic Eczema, Food Allergy, Diagnostics and Therapeutic Immunotherapy.

Ms. Marzelle Haskins

Mrs M. Haskins is a member of the NHREC. She chairs the NHREC Registration and Auditing Working Group. She is currently the Managing Director for Pharma-Ethics Research Ethics Committee. Mrs. Haskins has a BLC, LLB, (UP). Her membership to Health Research organisations, forums and councils includes member of the Pharma-Ethics Research Ethics Committee; Member of Public Responsibility in Medicine and Research (PRIM&R). Her areas of focus are related to the informed consent process, genetic research and research on vulnerable populations.

Mr. Nathaniel Ramuthaga

Mr N. Ramuthaga is a member of the NHREC. He chairs the NHREC Training Working Group. He is currently Regional Clinical Operations Head responsible for Africa and Middle East. He has a BSc. in Microbiology, Physiology and Biochemistry, BSc Honours and a MSc. in Microbiology and Molecular Biology. He is a registered Medical Scientist and Professional Natural Scientist with the Health Professions Council in South Africa (HPCSA) and SACNASP respectively. He has both university teaching experience and over 10 years of pharmaceutical drug development in Africa. He has received training in ICH-GCP and other ethics related fields. He is also involved in ICH-GCP/Ethics capacity building both in South Africa and other African states. His areas of focus are Clinical Research Conduct i.e. Drug Development, training and capacity building in ICH-GCP related to ethics.

Dr. Ngokoana Khomo

Dr. N.E Khomo is a member of the NHREC. She chairs the NHREC Complaints and Disciplinary Working Group. She is retired. Dr. Khomo has a BSc (Pharm) UNIN, MBChB (Medunsa), MMED (Community Health) Medunsa, DTM&H, DPH, DHSM (Wits). Her membership to health research organisations, forums and councils includes, a member of the Medicines Control Council (MCC), (Clinical Trials Committee and Biological Committee. She was part of the task teams that compiled the Guidelines for HIV vaccine clinical trials, Microbicide Clinical Trials and SA GCP guidelines for Clinical

Trials. Further she is chairperson of the National Certification Committee on Polio Eradication and Inter- Country Certification Committee for Lesotho Swaziland and South Africa. Dr. Khomo has served on numerous Ministerial advisory bodies to name a few, TB Advisory- AIDS Advisory- Air Pollution Advisory- and Integrated Advisory committees. Her areas of focus are Health Systems, Health Service management, and Child Health. She is very passionate in ensuring that GCP is adhered to on clinical trials and advocated for the appointment of GCP inspectors by the MCC, thus ensuring that the Rights of research participants who are poor and vulnerable are respected.

Ms. Elise Levendal

Elise Levendal is a member of the NHREC. She is currently the Interim Director of the Medical Research Council's (MRC), South African Aids Vaccine Initiative (SAAVI). She is also the Programme Manager for the Masikhulisane SAAVI Community Involvement Programme. She has a BA in Sociology and Psychology [UNISA] and a Masters in Public Health through the University of the Western Cape where her thesis focussed on community involvement in health. Her areas of focus is enabling, facilitating and ensuring community involvement in health and health research.

Professor Leslie London

Prof. L. London is a member of the NHREC. He chairs the NHREC Vulnerable People Working Group. He is a Public Health Specialist and currently the Director of the School of Public Health and Family Medicine and Head of its Health and Human Rights programme. His teaching and research in public health includes human rights and ethical issues including dual loyalty and human rights concerns in public health practice. He has been theme coordinator for the Network on Equity in Health in Southern Africa (EQUINET), conducting research into the relationship between equity and human rights. He assisted the Truth and Reconciliation Commission's investigation into the Health Sector under apartheid in South Africa in 1997, and was short listed for the Nelson Mandela Health and Human Rights Award in 1998. He has previously

served on the Advisory Committee on Human Rights, Ethics and Professional Practice for the Health Professionals Council of South Africa and on Boards and Committees of health and human rights non-governmental organisations. Prof London serves on the Provincial panel for drug resistant TB in the Western Cape. He has co-convened a Train-the-Trainer programme in Health and Human Rights for teachers of students in the health professionals since 1998. His areas of focus include an interest in the role of human rights in public health policies.

Professor Lizo Mazwai

Prof. L. Mazwai is a member of the NHREC. He is Professor of Surgery, Chief Specialist and Chairman of the Department of Surgery, Faculty of Health Sciences and Nelson Mandela Academic Hospital at the Walter Sisulu University (WSU) for Technology and Science. His qualifications include an MBChB. His membership to health research organisations, forums and councils includes Member Medical Research Council (MRC) Grants Committee, Director, Ethics Institute of South Africa (ETHISA) His areas of interest and expertise are research in Trauma and Critical Care.

Ms. Cathy Slack

Ms. C. Slack is a member of the NHREC. She chairs the NHREC Human Subjects Regulations Working Group. She is a clinical psychologist and project manager for the HIV AIDS Vaccines Ethics Group (HAVEG) at the University of KwaZulu-Natal, South Africa. She has researched the ethical-legal framework for research in South Africa and developed tools to help South African role-players apply ethical-legal norms for research, especially with children. She has also been part of the WHO-UNAIDS Ethics, Law and Human Rights Working Group of the African AIDS Vaccine Program (AAVP) since 2001, and as part of this group she has been involved in researching the needs of research ethics committees in selected African countries and developing training activities and resources. Ms Slack was part of the expert panel that assisted to draft the UNAIDS/WHO (2007) guidance document: *Ethical considerations in biomedical*

prevention trials. She was a key contributor to the SA Medical Research Council's (2003) *Guidelines on ethics for medical research: HIV vaccine preventive vaccine research.* Her areas of interest and expertise are in standard of care, informed consent and child participation in trials.

ACTIVITIES OF THE NATIONAL HEALTH RESEARCH ETHICS COUNCIL FOR PERIOD JANUARY 2007 TO SEPTEMBER 2009

National Health Research Ethics Council (NHREC) Meetings

According to the National Health Research Ethics Council (NHREC) Regulations, the Council is mandated to meet four times a year. Other ad hoc meetings are on the discretion of the NHREC Chairperson. The NHREC held nine meetings during 2007, 2008 and 2009. The meetings were held on the following dates:

2007

31 January 2007

20 March 2007

29 -30 June 2007

21 September 2007

21 November 2007

2008

28 February 2008

29 May 2008

29 August 2008

26 November 2008

2009

18 – 19 February 2009

20 May 2009

23 September 2009

18 November 2009

WORKING GROUPS

The NHREC established working groups during the NHREC meeting which was scheduled for 21 September 2007. The terminology for these working groups was discussed at length. The term “subcommittee” was also debated. On the advice of the Legal Unit of the Department of Health it was decided to use the term “working group” as some groups were established to get the NHREC started as a function. They might be dissolved in the future and be incorporated into other working groups.

The following working groups were established:

- Animals utilised in Health Research for the benefit of Humans
- Registration and Accreditation of Research Ethics Committees
- Training Working Group
- Complaints and Advisory Working Group
- Vulnerable Populations Working Group
- Human Subjects Regulations Working Group

The NHREC working groups meet as and when required depending on the workload and availability of the group members.

The following members serve on the different Council Working Groups:

Registration and Auditing Working Group

Mrs. Marzelle Haskins (Chairperson)

Dr. Marcelle Groenewald

Ms. Cathy Slack
Prof. Ames Dhai
Dr. Lindiwe Makubalo
Prof. D du Toit

Training Working Group

Mr. Nathaniel Ramuthaga (Chairperson)
Prof. Ames Dhai
Ms. Marzelle Haskins
Dr Marcelle Groenewald
Prof. Danie du Toit

Complaints and Disciplinary Working Group

Dr. Ngokoana Khomo
Mr. Nathaniel Ramuthaga
Dr. Marcelle Groenewald
Prof Danie du Toit
Prof. Ames Dhai

Vulnerable Populations Working Group

Prof. Leslie London (Chairperson)
Ms. Cathy Slack
Ms. Dudu Biyela
Ms. Ann Strode
Ms. Elise Levendal
Prof. Danie du Toit

Human Subjects Regulations Working Group

Ms. Cathy Slack (Chairperson)
Ms. Ann Strode (co-opted member)
Dr. Lindiwe Makubalo

Prof. Ames Dhai
Prof. Danie du Toit

WORKING GROUP MEETINGS

Vulnerable Populations Working Group

05 February 2008

Human Subjects Regulations Working Group (HSRWG)

08 April 2008

08 August 2008

12 May 2009

Registration and Auditing of Research Ethics Committees

11 June 2008

Training Working Group

23 June 2008

2007 ACTIVITIES

Activity: Set up a functional office for the Council.

Progress: Council office established with the assistance of the Directorate Health Research in December 2006. In July 2007 Prof du Toit was seconded to the department for six months. During this time it was required to secure the smooth running of the newly established National Health Research Ethics Council.

- One of the functions of the Council is the registration and auditing of Research Ethics Committees. This will be one of the main functions of the NHREC. A working group has been established. Criteria for the registration that will be used are defined in the National Ethics Guidelines of the Department of Health (DoH).
- The NHREC has established various working groups which have been co-ordinated by Prof. du Toit.

Activity: An investigation into the Cellulose Sulphate (SC) trial

Progress: The final investigation report has been compiled and forwarded to Minister of Health's office in August 2007.

Activity: Register and audit Research Ethics Committees (RECs).

Progress: On 21 November 2007, the NHREC finalised the application forms for the registration of RECs. It will be a priority of the NHREC to complete the REC audit in 2010 which is one of the main functions of the NHREC. A working group was established to draw up a framework and oversee the assessment and auditing processes of RECs registered with the Council. 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 published in 2004.

Activity: Setting-up of various working groups for the NHREC.

Progress: On 21 September 2007 the NHREC established working groups. These working groups have different areas of focus which include registration and auditing of RECs; training; vulnerable populations; human subjects in research; complaints and disciplinary as well as animal health research.

Activity: Establish links between the National Health Research Ethics Council (NHREC), National Health Research Committee (NHRC) and the Medicines Control Council (MCC).

Progress: On 15 October 2007 Dr. N. Khomo on behalf of MCC met with the NHREC Chairperson to initiate the links between the two regulatory bodies. A further meeting to establish links between the NHREC and MCC took place on 25 January 2008. The NHREC and NHRC have established a working relationship. The NHRC organised a symposium which was hosted by DOH and invited the NHREC Chairperson to actively participate, in order to establish links between the two statutory institutions. During the symposium, NHREC chairperson gave a presentation on the composition, mandate and functions and of the Council.

2007 - NHREC REPORTS AND DOCUMENTS (ANNEXURES B, C & G)

- An investigation into the randomised controlled trial of 6% Cellulose Sulphate Gel and the effect on vaginal HIV transmission (**ANNEXURE C**)
- Code of Conduct Document for NHREC members (**ANNEXURE B**)
- NHREC Regulations published to invite public comments (**ANNEXURE G**)
- Research Ethics Registration Form
- Draft Terms of Reference (TOR) of all Working Groups

Most of the above-mentioned documents are available from the NHREC and NDOH website and Secretariat.

2008 ACTIVITIES

Activity: NHREC website

Progress: For its visibility and profiling, a Council website was developed. The website is functional and can now be visited on the following address; www.nhrec.org.za

Activity: Registration of Research Ethics Committees (RECs)

Progress: In February 2008 an advert was published in national newspaper requesting RECs to register with the Council. To date 22 RECs have registered with the Council. The registered RECs have been allocated unique identity registration numbers.

List of RECs registered with NHREC (ANNEXURE K)

Biomedical Research Ethics Committee, University of KwaZulu Natal; Committee for Human Research 1, University of Stellenbosch; Committee for Human Research 2, University of Stellenbosch; Ekurhuleni Health District Research Ethics Panel (EHDREP); Ethics Committee of the Faculty of Health Sciences, University of the Free State; Faculty of Health Sciences Research Ethics Committee, Durban University of Technology; Health Research Ethics & Bio Safety Committee, Walter Sisulu University; Health and Wellness Sciences Research Ethics Committee, Cape Peninsula University of Technology; Human Research Ethics Committee, University of the Witwatersrand; Human Sciences Research Council Research Ethics Committee; Hospice Palliative Care Association Research Ethics Committee; Faculty of Health Science Research Ethics Committee, University of Pretoria; McCord Research Ethic Committee; McCord Hospital; Medical University of Southern Africa Research Ethics Committee (MREC); Medical Research Council Research Ethics Committee (MRCREC); 1 Military Hospital Research Ethics Committee; Pharma-Ethics Research Ethics Committee(Pty)Ltd; Polokwane Mankweng Hospital Research Ethics Committee; Research Ethics Committee, University of Cape Town; South African National Blood Service Medical and Research Ethics Committee; South African Medical Association Research Ethics Committee(SAMAREC); Tshwane University of Technology Research Ethics Committee

Activity: Standard Operating Procedures (SOPs) for registration and auditing Research Ethics Committees (RECs).

Progress: The SOPs have been drafted and are being finalised by the Registration and Auditing Working Group (**ANNEXURE I**).

Human Subjects in Research Working Group (HSRWG)

Activity: Draft Regulations (R135): Regulations related Research on Human Subjects.

Progress: The National Health Act (No. 61 of 2003) regulates research with human subjects. Section 71 within this chapter, deals with the legal protections of research participants. It was identified as a section requiring implementation of the regulations. On the 23rd February 2007, draft regulations were published for public comment in the Government Gazette (R 135). Eight sets of public comments on the draft regulations were received. The NHREC established a working group in September 2007 which was mandated to finalise the regulations.

The working group prepared a revised draft of the regulations. Changes in the final draft regulations include the following that a section on genetic/stem cell research has been deleted, risk standards for research with minors and mentally disabled have been revised to bring them in line with norms in the Department's ethics guidelines and international norms and a section on Ministerial Consent for non-therapeutic health research has been added. There was close consultation with the Legal Unit in the Department of Health in drafting the revision.

2008 NHREC REPORTS AND DOCUMENTS (ANNEXURES G AND I)

- Regulations related to the National Health Research Ethics Council (R 134) (**ANNEXURE G**)
- Draft Standard Operating Procedures (SOPs) for registration and auditing of Research Ethics Committees (RECs) (**ANNEXURE I**)
- NHREC Brochure finalised (**ANNEXURE N**)

- Final Terms of Reference of all working groups (**ANNEXURES E, J, L & M**)

The above-mentioned documents are available on the NHREC and NDOH websites and Secretariat.

2009 ACTIVITIES

Registration and Auditing Working Group (RAWG)

The RAWG developed and submitted a Terms of Reference (TOR) document. Furthermore the working group has finalised Standard Operating Procedures (SOPs) for registration and auditing RECs. Twenty-two (22) RECs have registered with the NHREC. These RECs have been allocated unique identification numbers. In July – August 2009 the completed REC Registration Forms were captured into a REC database for collation and analysis. During October – November 2009, the RAWG and NHREC Secretariat assessed information received from RECs to verify the data. The RAWG plans to subsequently, audit RECs registered with NHREC and further encourage remaining RECs to register with NHREC. The RAWG has developed and submitted a workplan and budget for the 2009/2010 financial year. The workplan focuses mainly on assessment and auditing of registered RECs.

The Vulnerable Population Working Group (VPWG)

The VPWG developed and submitted a Terms of Reference Document and a workplan and budget for the 2009/2010 financial year. It has commented extensively on Council documents and other Workgroup Terms of Reference and programmes. It has four Council members and one co-opted member (Ann Strobe).

The Working Group has finalized the following outputs to date:

- A working definition of vulnerability to guide future work
- A proposed guideline for RECs regarding payment of study participants

The Working Group is close to final versions of the following outputs

- Audit of the ethical-legal framework to identify gaps in protection for vulnerable study participants, which will provide a basis for recommendations to Council for further regulatory and other actions.
- Guideline on Community Advisory Groups (**ANNEXURE A**)

Planned activities in future:

- Generation of a select number of briefs or fact sheets
- Short articles for NHREC and other Ethics-related newsletters
- Compilation of a database of organizations representing different vulnerable groups for future consultation on matters relating to the protection of vulnerable groups in health research
- Development of a guideline on addressing the problem of 'over-researched' communities

Human Subjects Regulations Working Group (HSRWG)

The HRSWG developed and submitted a Terms of Reference Document. The working group has completed the collation of public comments on the regulations related to human subjects in research. Subsequently, the Working Group Chairperson had meeting with legal representative of DOH on 12 May 2009, to finalise the regulations. The regulations have been submitted to DOH legal unit for finalisation and translation to other languages. The Regulations will soon be published for implementation. The HSRWG has developed and submitted a workplan and budget for the 2009/2010 financial year. The workplan focuses mainly on the following points:

- To prepare a memo for the heads of all RECs advising them of the issuing of the HS regulations and implications for the review of protocols.
- To prepare a submission to the Minister setting out concerns with Ministerial Consent for all non-therapeutic research and argue for delegation of this function to RECs.
- To prepare a submission on how s71 of the NHA could be strengthened.

Training Working Group (TWG)

The TWG have developed and submitted the Terms of Reference Document (TOR). The working group has also developed and submitted a workplan and budget for 2009/2010. The work plan focuses mainly on the introduction of the training curriculum for RECs members and other NHREC review documents, to relevant stakeholders such as chairpersons of RECs and their members, through a workshop and other mediums of communication.

Complaints and Disciplinary Working Group (CDWG)

The CDWG has drafted a terms of reference document (TOR) which was submitted to legal unit for finalisation. The working group has also developed and submitted workplan and budget for 2009/2010 financial year.

2009 NHREC REPORTS AND DOCUMENTS

- Functioning of Research Ethics Committees.
- Decisions and Monitoring Reporting Forms.
- Conflict of Interest Policy for REC members
- Declaration of Conflict of Interest by the Investigators
- Declaration of Conflict of Interest by the REC members
- Conflict of Interest Policy for Investigators.
- Guidelines for Payment of Research Participants.

The above-mentioned documents are available on the NHREC websites and Secretariat.

PLANNED ACTIVITIES FOR 2009/2010 (ANNEXURE H)

CONCLUSION:

The NHREC Chairperson feels privilege to have chaired the Council during the period 2006 – 2009. He is of the opinion that the new Council will continue where the current

one has left-off and serve the broader Research Ethics Community. The Chairperson believes that the new Council will consolidate and develop much of the early work of this Council. He expects that the progress demonstrated in 2006-2009 will in some way go towards strengthening ethics review, and enhanced protection of research participants, as envisioned in the National Health Act (2003).

The NHREC Chairperson would also like to thank all Council Members for sacrificing their time to make the initial functioning of the National Health Research Council a success, as well as members of the Secretariat for their assistance.

SIGNED: PRETORIA

DATE: 12 April 2010

CHAIRPERSON:

A handwritten signature in black ink, appearing to read 'D. du Toit', written over a light blue grid background.

Professor D. du Toit

Compiled by:
Mr. Thabo Molebatsi
Ms. Ntombizodwa Mbelle
Mr. Jacques Van der Westhuizen