health

Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL HEALTH RESEARCH ETHICS COUNCIL REPORT (2014-2015)

Foreword by the Minister of Health

The National Health Research Ethics Council's (NHREC) Annual Report 2014-2015 provides an opportunity to reflect on the importance of ethical practice in South African health research and on the impact the NHREC has on this endeavor. In this 2014-2015 reporting period, the members of the NHREC have demonstrated their commitment to ethical research in a variety of ways. Re-structuring the NHREC into four working groups or committees enabled greater focus on the NHREC's 2014-2015 objectives.

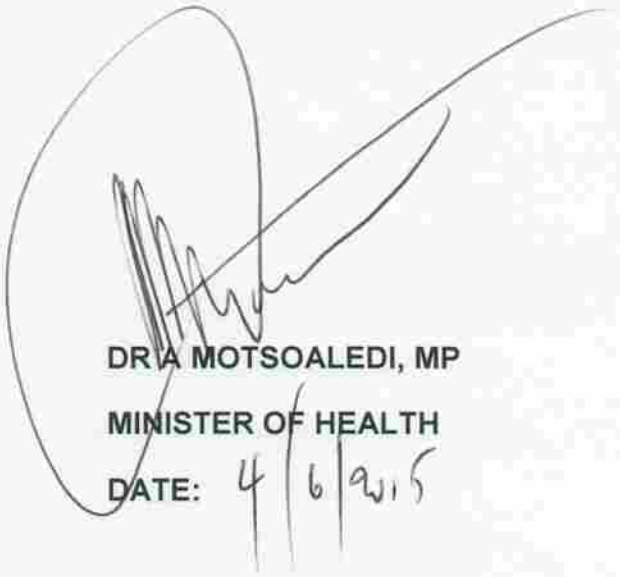
Some of the NHREC achievements include the long-anticipated review of the *Ethics in Health Research: Principles, Structures and Practice* with inputs from Research Ethics Committees (RECs), National Health Research Committee and other relevant stakeholders. This work now incorporates current trends, regulations, ethical guidelines, and includes an expanded look at different types of research methodologies.

The Council developed new Standard Operating Procedures for the management of disciplinary processes, sanctions and appeals. This committee finalised all cases that were referred to them during 2014-2015. The NHREC also provided capacity support through site-visits, guidance and technical expertise to all RECs that had critical findings during the 2012-2013 financial year. Certificates were developed and awarded to twenty-seven (27) fully registered RECs. Fifteen (15) RECs were provisionally registered and on-site assessments conducted by the Council members and NHREC Secretariat. The NHREC has now initiated the administrative process auditing of Animal Research Ethics Committees (AREC) in terms of Section 72 (6c) of the National Health Act.

The Council strives towards strengthening the legal framework of health research ethics in South Africa. During 2014-2015, the NHREC published and disseminated the Human Subjects Regulations. Additionally, the Council developed a procedure for the delegation of authority for non-therapeutic research on minor to RECs.

The NHREC continues to strengthen relations with RECs through yearly meetings and improved communication. I wish to express my gratitude to the Council members for their hard work and willingness to create an enabling environment for the further growth

of ethical health research in South Africa. I also wish to thank the managers and Health Research Directorate staff for providing the NHREC with vital support.



DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE: 4/6/2015

Acknowledgement by the Director-General

The National Health Research Ethics Council (NHREC) has had a busy and productive year. The Department is pleased that the Council, building upon the work of past-Councils and adding new thoughts and dimensions, has completed 2004 review of the DoH's *Ethics in Health Research: Principles, Structures and Practice*. The work of the Council in the continuation of auditing and registering RECs and ARECs in South Africa is appreciated. We value the cooperative efforts of Council members as they work with a variety of stakeholders including Research Ethics Councils institutions, and entities in the pursuit of excellence for all who are engaged in and benefit from ethical health research in South Africa.

We also thank NHREC members for giving their valuable time and effort, I express my gratitude to the members of the NHREC: Prof. D du Toit (NHREC Chairperson), Prof. D van Bogaert (NHREC Vice-Chairperson), Dr S Ncanana, Adv L Nevondwe, Prof A Pope, Dr J Ramalivhana, Ms. T Sebata, Dr M Sekhoacha, Dr T Sithebe, Ms C Slack, Prof AA van Niekerk, and Ms T Zwane.

Thanks also goes to 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 NHREC. For assisting with the logistical arrangements of the Council, I am grateful to Mr R Maluleke.

Sincerely,

MS MP MATSOSO

DIRECTOR GENERAL: HEALTH

DATE: 30/5/2015

National Health Research Ethics Council (NHREC) Annual Report 2014-2015 NHREC Committees and Working Groups

Purpose: The National Health Research Ethics Council (NHREC) was established in September 2006 in terms of the National Health Act 61 of 2003, section 72(1). It is the statutory body responsible for ensuring that health research is conducted ethically in South Africa. The Council is responsible for setting the norms and standards for Research Ethics Committees and for ensuring compliance.

Membership: The following persons were appointed as NHREC members by the Minister of Health on 21 August 2013:
Prof. D du Toit (NHREC Chairperson), Prof. D van Bogaert (NHREC Vice-Chairperson), Prof A Dhai, Dr S Ncanana, Adv L Nevondwe, Prof A Pope, Dr J Ramalivhana, Dr L Schoeman, Ms. T Sebata, Dr M Sekhoacha, Dr T Sithebe, Ms C Slack, Prof AA van Niekerk, and Ms T Zwane.

The NHREC records its sadness at the sudden passing of Dr Lizette Schoeman in 2014 and its appreciation for her excellent work while a council member.

The current NHREC includes the following persons: Prof. D du Toit (NHREC Chairperson), Prof. D van Bogaert (NHREC Vice-Chairperson), Dr S Ncanana, Adv L Nevondwe, Prof A Pope, Dr J Ramalivhana, Ms. T Sebata, Dr M Sekhoacha, Dr T Sithebe, Ms C Slack, Prof AA van Niekerk, and Ms T Zwane.

Secretariat: In 2014-2015, the NHREC was supported by the NDoH's Research Directorate Secretariat: Ms K Nevhutalu, Mr. T Molebatsi, Mr. J van der Westhuizen and Mr. R Maluleke (logistics).

NHREC Executive Committee (NHREC EXCO)

Mandate: The NHREC EXCO is responsible for:

- NHREC operations between scheduled meetings
- Overseeing the functioning of the working groups/task teams/committees
- Identifying and approving specialists for co-option to working groups/task teams/ committees as necessary
- Formulating a strategic plan for the NHREC in consultation with all NHREC members
- Formalising relationships by way of Memoranda of Agreement/Understanding with key stakeholders such as the Medicines Control Council and other professional bodies.
- Ensuring the visibility of the NHREC and highlighting its activities amongst stakeholders
- Initiating and maintaining regular communication with relevant stakeholders
- Consulting, collaborating and cooperating with the National Health Research Committee as necessary
- Drafting reports on NHREC activities and tabling such reports with the Director General and Minister of Health as appropriate

Membership:

The NHREC's Executive Committee (NHREC EXCO) 2014-2016 consists of the Chair, Prof D du Toit; the Deputy Chair, Prof DK van Bogaert; the Chairs of each Working Group or Committee: Dr S Ncanana; Adv L Nevondwe; Prof A Pope; Ms C Slack and the NHREC Secretariat: Mr. T Molebatsi; Mr. J van der Westhuizen; Mr. R Maluleke and Ms K Nevhutalu.

Activities of the NHREC EXCO 2014-2015

Objective 2014-2015	Progress	Comment
Oversee the functioning of the NHREC and working groups/task teams/committees and sub-committees.	On-going	The NHREC EXCO wishes to thank the Council members and the NHREC Secretariat for their continued dedication and support.
Review the existing Code of Conduct for NHREC Members.	The existing NHREC Code of Conduct was reviewed by the NHREC EXCO and Council Members.	The NHREC Code of Conduct was compiled as stipulated by regulations in section 90 (1) (s) of the Act. Deviation from the Code of Conduct by NHREC members constitutes misconduct.

NHREC WORKING GROUPS AND COMMITTEES

The NHREC has four working groups/ committees comprised of Council members and EXCO as *ExOfficio* members. The working groups and committees are:

- The Norms and Standards Working Group
- The Complaints and Advisory Disciplinary Committee
- The Quality Promotion and Enhancement Committee
- The Legal and Regulatory Working Group

A brief description of the activities and major achievements of these Working Groups and Committees follows.

1) NHREC NORMS AND STANDARDS WORKING GROUP

The Norms and Standards Working Group consolidated the previous NHREC (2011-2013) working groups: Health Research on Animals, Regulations Related to and Protection of Vulnerable Human Research Participants and Material Transfer.

Mandate: The mandate of the NHREC's Norms and Standards Working Group is to:

- Set norms and standards for conducting research on human and animals and norms and standards for conducting clinical trials.
- Advise the National Department of Health (NDoH) as well as Provincial Departments on any ethical issues concerning research.

Membership: The 2013-2016 membership includes: Prof A Pope (Chair); Prof D du Toit (*ExOfficio*); Prof D van Bogaert (*ExOfficio*); Dr S Ncanana; Dr J Ramalivhana; Dr M Sekhoacha; Ms C Slack; Prof AA van Niekerk and Ms T Zwane.

Secretariat: Mr. T Molebatsi; Mr. J van der Westhuizen; Mr. R Maluleke and Ms K Nevhutalu.

Activities of the Norms and Standards Working Group 2014-2015

Objective 2014-2015	Progress	Comment
1. Revise NDoH 2004 publication *Ethics in Health Research: Principles, Structures and Processes*	The NDoH guidelines: *Ethics in Health Research: Principles, Structures and Processes* was re-written and was completed in November 2014	Awaiting approval and publication by NDoH
2. Submit all approved/ endorsed guidelines and relevant research ethics information to the Secretariat for uploading on the NHREC website	On-going	The Norms and Standards Working Group thanks Council members and the NHREC Secretariat for their input and assistance in this on-going process.

The Norms and Standards Working Group's major undertaking in 2014-2015 was to update the Department of Health's 2004 publication *Ethics in Health Research: Principles, Structures and Processes*. This undertaking resulted in a complete revision of this work. The publication now incorporates current trends, regulations, ethical guidelines as well as guidance concerning the variety of types of research conducted in South Africa. The 2015 edition of the NDoH's *Ethics in Health Research: Principles, Structures and Processes* represents a succinct and reader-friendly guide to ethical practice in research. It awaits publication by the NDoH.

The Norms and Standards Working Group posted the following documents and information for researchers, RECs, and all interested parties on the NHREC website in 2014-2015: *Ethics in Health Research: Principles, Structures and Processes* (NDoH 2015).

Planned and On-going Activities of the Norms and Standards Working Group

Planned Objective 2015-2016	Progress	Comment
1. Revise NDoH 2006 2nd Edition publication *Good Clinical Practice Guidelines*	Initiated in February 2015	It is anticipated that the task will take more than one year to complete because of capacity deficits; likely to require additional co-opted capacity; has budgetary implications
2. Develop MoU with National Research Committee to facilitate better communication and consultation regarding overlap of mandates	Concept to be designed and discussed	Necessary to promote more cohesive and integrated outcomes that are cognizant of ethical implications
3. Develop ethics guidelines for biobanks in South Africa	The request was discussed on the 11th February 2015. Still at the discussion and planning phase.	Likely to require additional co-opted capacity with expertise in clinical ethics as well as in research ethics re bio banks; has budgetary implications

During the years 2015–2016, the Norms and Standards Working Group will revise the NDoH's publication *Good Clinical Practice Guidelines 2nd Edition*, 2006. This decision and discussion concerning its revision was initiated at the Council meeting 11 February 2015. Upon reflection, the Council determined that co-option of additional experts in the field is needed.

In 2015-2016, the Norms and Standards Working Group will develop a Memorandum of Understanding (MOU) with the National Research Committee for the purpose of enhancing communication between the bodies. This is an important step in communication designed to avoid confusion that may occur when obligations overlap as well as to build strong supportive relationships needed for ethical research practice in South Africa.

In the NHREC Council meeting of 11 February 2015, the issue of biobanks in South Africa was raised. The NHREC's particular focus is on ethical issues, for example guidelines concerning the ethical aspects of biobanking (as opposed to the creation, operation, or general regulation of biobanks). The Council agreed to cooperate with other persons and entities in this field. As many ethical topics arise in the biobank arena, it was decided that further discussion and planning are needed before a concise plan of action can be developed.

2) THE COMPLAINTS AND ADVISORY DISCIPLINARY COMMITTEE (CADC)

The CADC is a committee of the NHREC which derives its mandate from the National Health Act, 61 of 2003 (the Act) particularly section 72.

Mandates: The mandate of the NHREC's Complaints and Advisory Disciplinary Committee is to:

- Adjudicate complaints about the functioning of Research Ethics Committees
- Hear a complaint from a researcher who believes that a Research Ethics Committee has discriminated unfairly against him/her
- Refer matters involving allegations of violation of ethical or professional rules or standards by a health care provider to the relevant statutory health professional council or body

- Institute remedial measures and disciplinary action where warranted, to facilitate compliance with legal, ethical and professional norms and standards as required for responsible conduct of research

Membership: The 2013-2016 membership includes: Adv. L Nevondwe (Chair), Prof D du Toit (*ExOffico*); Prof D van Bogaert (*ExOffico*); Prof. A Pope, Dr. S Ncanana, Ms. T Sebata, Ms E Zwane and Dr. M Sekhoacha.

Secretariat: Mr. T Molebatsi; Mr. J van der Westhuizen; Mr. R Maluleke and Ms K Nevhutalu.

Activities of the Complaints and Advisory Disciplinary Committee 2014-2015

The CADC handled three complaints in 2014-2015 with the following reference numbers: NHREC/CADC091613-011, NHREC/CADC042814-012 and NHREC/CADC052814-013.

Objective 2014-2015	Progress	Comment
1. Examine a complaint registered on 16 September 2013 concerning alleged protocol violations. Code NHREC/CADC091613-011	Discussion, mediation and review with relevant bodies.	Case finalised
2. Examine a complaint registered on 28 April 2014 concerning alleged protocol violations and confidentiality issues. Code NHREC/CADC042814-012	Discussion, mediation and review with relevant bodies.	Case finalised
3. Examine a complaint registered on 8 May 2014 concerning alleged non-compliance with the SOP of a Research Ethics Committee. Code NHREC/CADC052814-013	Meetings, discussion, mediation and review with relevant bodies.	Case finalised
4. Finalise SOPs for disciplinary processes, sanctions and appeals.	This document was reviewed and accepted by Council 11 February 2015	SOPs for Disciplinary Processes, Sanctions and Appeals is now in place.
5. Publish the SOP of the CADC on the NHREC website.	Submitted to Secretariat for website publication	Available on NHREC website

The categories of complaints included misinterpretation of a SOP of a Research Ethics Committee, and two allegations of protocol violations, one of which included an alleged breach of confidentiality. Through thorough documentation, meetings and examination

of each case with all parties involved, the CADC was able to finalise all of the cases presented during the year under review.

Standard Operating Procedures developed by the CADC for the management of Disciplinary Processes, Sanctions and Appeals were developed and operationalised by the NHREC at the 11 February 2015 meeting. This aims to fortify the procedures involved in the management of complaints.

Planned and On-going Activities of the Complaints and Advisory Disciplinary Committee 2015-2016

Planned Objective 2015-2016	Progress	Comment
1. The CADC will finalise all cases reported within a period of 30 days from the date when the complaint is lodged	Ongoing	

The CADC realises that complainants may show concern when, due to the time involved in data gathering, a response to their initial complaint is delayed. The CADC aims to finalise complaints within 30 days from the date when a complaint is lodged.

3) WORKING GROUP: QUALITY PROMOTION AND ENHANCEMENT COMMITTEE (QPEC)

Mandate: This is a new committee consolidating the former working groups on (1) Training and (2) the Registration and Auditing of Research Ethics Committees. It gives effect to the following mandates of the NHREC:

- Determine guidelines for the functioning of Health Research Ethics Committees (RECs).
- Register and audit Health RECs.

Membership: The 2014-2015 membership included: Dr S Ncanana (Chairperson); Prof D du Toit (*ExOfficio*); Prof D van Bogaert (*ExOfficio*); Ms T Sebata; Dr T Sithebe; Dr N Ramalivhana; Dr M. Sekhoacha and Prof A Pope.

Secretariat: Mr. T Molebatsi; Mr. J van der Westhuizen; Mr. Ronald Maluleke and Ms K Nevhutalu

*Dr S Ncanana was appointed as the Chair after sudden death of Dr L Schoeman in 2014.

Activities of the Quality Promotion and Enhancement Committee (QPEC)

Objective 2014-2015	Progress	Comment
1. Follow-up with RECs audited in 2012/2013: GAP Analysis	All RECs that had critical findings during the 2012/2013 financial year were re-visited	Two of the six RECs are provisionally registered and will be audited during the next session. Four of the Six RECs had complied with the recommendations and were granted full registration.
2. Develop certificates for fully NHREC registered RECs	With the Secretariat, developed certificates and received Council affirmation as to its content and publication	Certificates for fully NHREC registered RECs were dispatched to relevant REC Chairs
3. Review applications for provisional NHREC	Five RECs received provisional NHREC	The provisionally registered RECs adhered to NHREC

registration	registration	Ethical guidelines for provisional registration
4. On-site assessment of provisionally registered RECs	During November and December 2014, QPEC members and the Secretariat conducted on-site assessments of nine (9) provisionally registered RECs	Of the nine (9) on-site visits, six (6) of the RECs were determined to be operating according to the NHREC Ethical Guidelines. Three (3) RECs remain under development
5. Develop specification document for a service provider to perform the auditing of Animal Research Ethics Committees (ARECs) in conjunction with the NHREC QPEC Committee and Secretariat	The QPEC has finalised a specification document for the auditing of ARECS	In terms of Section 72 (6c) of the National Health Act No. 61 of 2003, the National Health Research Ethics Council (NHREC) is mandated to "set norms and standards for conducting human health research involving animals". It is expected that the auditing of ARECs will commence in 2015.
6. Develop a REC reporting template for yearly REC submission of data to the NHREC	A REC reporting template was designed and distributed to all REC Chairs.	Sixteen (16) RECs submitted their annual reports in 2014. Follow-up on the RECs that are delayed is on-going.

Out of 33 RECs audited in the 2012/13 financial year, 6 RECs had critical findings.

The QPEC developed an NHREC certificate for fully registered RECs. These were awarded to 27 RECs that were audited by independent auditors on behalf of NHREC

during 2012. The certificate is used as an indication that an REC is in good standing with the NHREC.

Fifteen (15) RECs were provisionally registered in line with NHREC guidelines. These RECs included:

- University of South Africa Department of Health Studies: REC
- Rhodes University REC,
- University of Limpopo REC,
- University of Venda REC,
- University of Johannesburg Faculty of Education REC
- University of KwaZulu-Natal Human REC.
- South Africa Optometric Association (SAOA) REC
- Limpopo Provincial Research Ethics Committee
- North West University Human Health REC
- University of the Witwatersrand Human REC(Non-Medical)

Animal RECs registered (5)

- Ceva Animal Health Ethics Committee
- North West University Animal REC (Mafikeng Campus)
- North West University The Ethics Committee on Animal Care, Health and Safety in Research (AnimCare)
- V-Tech Veterinary Solutions Pharmacy V-Tech Animal Ethics Committee
- University of Limpopo Animal Ethics Committee University

The documents that were received from these RECs were reviewed by the QPEC. Such documents included for example, their terms of reference, checklist for REC application, SOP, application for registration, conflict of interest and confidentiality agreement, and research ethics protocol examination.

A total number of 9 RECs were visited by QPEC members and the Secretariat between November and December 2014. Six of these RECs appeared to be generally well

managed (operating on best-based practices and according to the NHREC guidelines). These RECs are:

- The University of KwaZulu-Natal HREC,
- University of Johannesburg HREC,
- University of Johannesburg Education REC,
- UNISA REC,
- Office of the Premier in Limpopo REC, and
- North West University REC.

Some of the characteristics shown by these RECs include:

  - Proper evidence of protocol review.
  - Supported by their respective administrative bodies or a secretariat
  - Proper filing of documents
  - Evidence of members being trained in research ethics
  - Decisions are made by the REC (exceptional case with UJ REC where it seems most decisions are made by the Chair and then the REC rectifies the decision)

The following three (3) RECs remain under development and the QPEC is working with them to increase their research ethics capacity.

- Lilitha Nursing College
- South African Optometrics Association
- Correctional Services Research Ethics Committee

The QPEC was tasked to drive the process of auditing Animal Research Ethics Committees (ARECs) registered with the NHREC. One of the undertakings involved in the setting of ethical norms and standards for conducting human health research involving animals is their auditing. All ARECs in South Africa are required by law to register with the NHREC.The audit will be done by independent institution to be appointed through NDoH processes. Thus far a specification document has been

finalised. The document was also sent to NSPCA for comment and input as experts in the field.

REC Reporting Template was developed and launched in Jan 2015. RECs are expected to report yearly using the template. This was distributed to REC Chairs. Thirty seven (37) RECs submitted annual report for year 2014.

Additional Activities of the QPEC 2014-2015 included

- Contribution to the development of the NDoH's 2014 *National Health Research Ethics Guidelines,*
- The recommendation made (and approved by Council) not to use Levels in the registration of RECs,
- To undertake a gap analysis from the audit results and identify areas for capacity development, and
- To define the basic content of training required for REC members.

Planned Objectives 2015-2016	Progress	Comment
1. Auditing of ARECs	The specification document for service provider (auditor) request has been submitted to the NDoH	Upon approval of a service provider the auditing of ARECs will commence
2. Registration of new RECs and ARECs, continue with REC audits, assessments and on-site visits for fully registered and provisionally registered RECs and ARECs, increase communication	On-going REC provisional registration and on-site assessment visits will continue.	

and build capacity in research ethics		

Following the NDoH process, when a service provider has been approved, the QPEC will proceed with the auditing of 18 Animal RECs. The QPEC will assist in the drafting of the Audit report, analysis of the findings and the communication and discussion of the findings with the relevant ARECs. This process will include considerations of capacity building thus strengthening the ethics of animal research.

The QPEC Committee will continue to register RECs and ARECs, provide provisional registration for new RECs and ARECs, audit, assess and conduct on-site visits to RECs for the purpose of ensuring that all health research performed in South Africa is based on and adheres to ethical practice.

4) The Legal and Regulatory Working Group 2014-2015

The purpose of the Legal and Regulatory Working Group is to strengthen the legal framework for research ethics and research with human participants in South Africa.

Membership: The 2014-2015 membership included: Ms C Slack (Chairperson); Prof D du Toit (*ExOfficio*); Prof D van Bogaert (*ExOfficio*); Prof A Pope; Adv L Newondwe; Dr M Sekhoacha; and Dr T Sithebe

Secretariat: Mr. T Molebatsi; Mr. J van der Westhuizen; Mr. Ronald Maluleke and Ms K Nevhutalu

Activities of the Legal and Regulatory Working Group 2014-2015

Objective 2014-2015	Progress	Comment
1. To ensure that Human Subjects regulations are developed and disseminated	Public comments on draft two of the Regulations were received and integrated in late 2013. Inputs obtained from the NDoH Legal Unit in July 2014. A submission was prepared for the Minister of Health. Regulations were published 19 Sep 2014. Regulations were disseminated to all RECs in Oct 2014	Future work will involve getting feedback from affected stakeholders about the adequacy of the regulations
2. To ensure adequate operationalization of s71 requirement that non-therapeutic child research obtains Ministerial Consent	A proposal was developed for the Minister of Health to consider. It concerned the delegation his authority regarding 71. Namely, that it should be given to NHREC registered RECs This was approved by the Minister of Health and a Letter of Delegation from the Minister of Health was disseminated to all RECs in Oct 2014. Operational guidelines were drafted by the Legal and Regulatory Working Group to assist RECs in the implementation of this delegation.	Future work will involve getting responses from affected role-players about this short-term solution
3. To ensure law reform for s71	Law reform proposal for the amendment ofs71 was approved by	Future work will involve

	the Minister of Health 07/10/2014	working with the Legal Unit on implementing amendments to s71 as long-term solution
4. To ensure inputs to the NHREC ethical guidelines	Comprehensive inputs were made on the ethical guidelines	

Planned Objectives 2015-2016	**Progress**	**Comment**
Objective 1. Future work will involve obtaining feedback from affected stakeholders concerning the adequacy of these changes to the regulations.	Inputs will be obtained at regular meetings with key stakeholders such as REC-NHREC liaison forum. Meetings will be held with the Legal Unit to plan implementation of law reform.	

The Legal and Regulatory Working Group will continue to strive towards strengthening the legal and ethical framework in which health research is conducted in South Africa. This involves reviewing the National Health Act 61 of 2003 as it relates to ethical research in South Africa and addressing relevant points of interest and concern.

Conclusion: The NHREC has accomplished much during the 2014-2015 period. Yet many challenges remain for the coming years as we continue to strive for excellence in all aspects of health research. The NHREC wishes to thank the NHREC Secretariat and all other persons and entities who have continuously supported our endeavors.