health

Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL HEALTH RESEARCH ETHICS COUNCIL ANNUAL REPORT (2015-2016)

Foreword by the Minister of Health

The National Health Research Ethics Council's (NHREC) Annual Report 2015-2016 provides an opportunity for us to consider the many ways in which the conduct of ethical research affects our lives. Indeed, it gives us pause to reflect on the amount of time and energy required to ensure that the mechanisms involved in supporting and developing ethical research are acknowledged. In this, the final year of their term, the members of the NHREC have demonstrated their commitment to ethical research in a variety of ways. It is a matter of great pride and a pleasure to present some of the highlights of the NHREC's 2015-2016 achievements and activities.

The re-structuring of the NHREC into four working groups or committees continued to enable focus on the NHREC's 2015-2016 goals. The NHREC EXCO continued to oversee the functioning of the NHREC and working groups/ task-teams / committees and sub-committees. *The NDoH Ethics in Health Research: Principles, Structures and Processes* were signed off by this Office and published electronically in March 2015 with a hard copy version expected in due course. In addition, the Norms and Standards Working Group is currently engaged in two other highly anticipated guidelines, the revision and updating of the DoH 2006 *South African Clinical Trial Guidelines: Good Practice for Clinical Trials with Human Participants* as well as the development of ethics guidelines for biobanks in South Africa. The Complaints and Advisory Disciplinary Working Group (CADC) completed a Standard Operating Procedure (SOP) for disciplinary processes, sanctions and appeals in electronic format which was approved by Council. It responded to several complaints and queries received over the course of the year and all were resolved appropriately. The Quality Promotion & Enhancement Committee (QPEC) had a very busy and fruitful year continuing with auditing and provisionally registering human Health Research Ethics Committees. During November and December 2015, QPEC members and the Secretariat conducted on-site assessments of five (5) registered RECs. Additionally, the QPEC developed the Audit Plan and determined the schedule for auditing of Animal Research Ethics Committees (AREC) preparing for their registration. These audits were conducted by Council Members. The Legal and Regulatory Working Group continued to be pro-active

strengthening the legal framework for research ethics and research with human participants in South Africa.

As shown, the NHREC continues to fortify its association with RECs and ARECs through annual meetings, enriched communication, and open dialogue. I wish to communicate my thanks 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. Your work contributes significantly to the enhancement of dignity for all South Africa's people. I also wish to thank the managers and Health Research Directorate staff and secretariat for providing the NHREC with important support.

DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE: 9/10/2016

Acknowledgement by the Director-General

As highlighted in this 2015/16 Annual Report, the National Health Research Ethics Council (NHREC) had a demanding yet fruitful year. Of its many accomplishments, the Department is particularly pleased that the Council has published the second edition of the *NDoH Ethics in Health Research Principles, Processes and Structures*. Moreover, the NHREC's continuation of work on guidelines such as the *South African Clinical Trial Guidelines: Good Practice for Clinical Trials* with Human Participants is appreciated.

The continuing work of the Council in the tasks of auditing and registering RECs and ARECs in South Africa is valued. We are grateful for the continuing and cooperative efforts made by Council members as they work with a myriad of institutions and entities which are engaged in health research in South Africa. To address the unique and relevant health research challenges in our society is often frustrating and difficult. It is, therefore, with humility that we thank the NHREC members for giving their valuable time and effort to support ethical research in South Africa.

We express our gratitude to the members of the NHREC: Prof D du Toit (NHREC Chairperson), Prof D van Bogaert (NHREC Vice-Chairperson), Dr T Muthivhi, Dr S Ncanana, Adv L Nevondwe, Prof A Pope, Dr J Ramalivhana, Ms T Sebata, Dr M Sekhoacha, Dr Y Sikweyiya, Dr T Sithebe, Dr C Slack, Prof AA van Niekerk, and Ms T Zwane. The Department is also grateful for the following officials: Dr GV Andrews (Chief Operating Officer) and Ms T Zondi in providing guidance and strategic leadership to the NHREC. For assisting with the secretariat and logistical arrangements of the Council, we are grateful to Mr T Molebatsi, Mr J van der Westhuizen and Mr R Maluleke.

MS MP MATSOSO

DIRECTOR GENERAL: HEALTH

DATE: 03/10/2016

National Health Research Ethics Council (NHREC) Annual Report 2015-2016 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 mandated to determine guidelines for functioning of research ethics committees; to audit and register research ethics committees; to set norms and standards for research involving human participants, clinical trials and use of animals; to adjudicate complaints about research ethics committees; and to advise the national department and provincial departments on ethical issues concerning research.

Membership: The following persons were appointed to the NHREC by the Minister of Health on 21 August 2013:
Prof. D du Toit (Chairperson), Prof. D van Bogaert (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 N Sithebe, Dr C Slack, Prof AA van Niekerk, and Ms T Zwane.

The current NHREC comprises Prof. D du Toit (Chairperson), Prof. D van Bogaert (Vice-Chairperson), Dr T Muthivhi, Dr S Ncanana, Adv L Nevondwe, Prof A Pope, Dr J Ramalivhana, Ms. T Sebata, Dr M Sekhoacha, Dr Y Sikweyiya, Dr N Sithebe, Dr C Slack, Prof AA van Niekerk, and Ms T Zwane.

Secretariat: In 2015-2016, the NHREC was supported by the NHREC Secretariat: 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 or 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) 2013-2016 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; Dr C Slack and the NHREC Secretariat: Mr T Molebatsi; Mr J van der Westhuizen and Mr R Maluleke.

Objective 2015-2016	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.

Activities of the NHREC EXCO 2015-2016

Objective 2013-2014	Progress	Comment
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 or committees comprised of Council members and EXCO (as *ex officio* 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 their activities and major achievements follows.

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1) NHREC NORMS AND STANDARDS WORKING GROUP

Mandate: This Working Group

- drafts norms and standards for research involving humans, clinical trials and use of animals;
- drafts standard operating procedures, policy documents, and statements of expected conduct for the NHREC.

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

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

Objective 2014-2015	Progress	Comment
1. Publish DoH 2015 publication *Ethics in Health Research: Principles, Structures and Processes*	The DoH guidelines *Ethics in Health Research: Principles, Structures and Processes* were signed off by the Minister Dr A Motsoaledi and published electronically on1 March 2015.	Published electronically.
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 the Council members and the NHREC Secretariat for their input and assistance in this on-going process.

Activities 2015-2016

The Norms and Standards Working Group's major undertaking in the reporting period was to revise the Department of Health's 2004 publication *Ethics in Health Research: Principles, Structures and Processes.* This undertaking was completed at the end of November 2014; signed off and approved with effect from 1 March 2015.

The 2015 guidelines (2nd editions) incorporate current trends, regulations, ethical guidelines as well as guidance concerning a variety of types of research conducted in South Africa. The publication provides a succinct and reader-friendly guide to ethical practice in research.

Work on the revision and updating of the DoH 2006 *South African Clinical Trial Guidelines: Good Practice for Clinical Trials with Human Participants* is underway, having been initiated in February 2015. A preliminary draft of the revision was circulated for early input from MCC, and a further revision was circulated in May 2016 to REC Chairs for input from their various constituents. The current Working Group hopes to complete the revision by the end of 2016 but acknowledges the constraints due to its term of office ending in August 2016 and because of capacity deficits.

Planned and Ongoing Activities of the Norms and Standards Working Group

Planned Objective 2016-2017	**Progress**	**Comment**
1. Continue the revision of DoH 2016 3rd edition publication *Good Clinical Practice Guidelines*	Preliminary draft circulated to MCC (March 2016); REC chairs (May 2016)	It is unclear whether the task can be completed within 2016 because of capacity deficits; additional co-opted capacity may be required which has budgetary implications
2. Develop MoU with National Research Committee to facilitate better communication and consultation regarding overlap of mandates	Minimal progress	Necessary to promote more cohesive and integrated outcomes that are cognizant of ethical implications
3. Develop ethics guidelines for biobanks in South Africa	Planning phase not yet completed; some overlap with ASSAf ELSI Consensus Study on	Likely to require additional co-opted capacity with expertise in clinical ethics as well as

	Genetics & Genomics.	in research ethics re biobanks; has budgetary implications

2) THE COMPLAINTS AND ADVISORY DISCIPLINARY COMMITTEE (CADC)

Mandate: This Committee

- adjudicates complaints about Research Ethics Committees;
- hears complaints from researchers who believe that a Research Ethics Committee has discriminated unfairly against them;
- refers matters involving allegations of unethical or unprofessional conduct by a healthcare provider to the relevant statutory health professional council or body;
- Institutes 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: 2013 – 2016 Adv L Nevondwe (Chair), Prof A Pope, Dr S Ncanana, Ms T Sebata, Dr M Sekhoacha and Ms T Zwane.

Secretariat: Mr T Molebatsi, Mr J Van der Westhuizen and Mr R Maluleke.

Activities 2015/16

The Committee reviewed Standard Operating Procedures (SOP) for disciplinary processes, sanctions and appeals. The SOP was subsequently approved by Council on 11 February 2015.

Complaints received by CADC

1)NHREC/CADC031115-014 (ethics of exome sequencing)

2)NHREC/CADC250216-015 (March 2016 complaint from WSU students)

3)WCPHRC query (March 2016)

4) NHREC/CADC010716-016 (July 2016)

Objective	Progress	Comment
Finalise SOP's for Disciplinary processes, sanctions and appeals	Reviewed and finalised in February 2015	Document finalised.
Finalise all cases which are reported	All cases were finalised	
Publish SOP's on the NHREC website	finalised	The document is published on the website.

Plan 2016/17

Finalise all the cases which are reported within a period of 30 days from the date when the complaint is lodged.

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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:

- Determines guidelines for functioning of Health Research Ethics Committees (RECs).
- Audits and registers RECs.

Membership: The 2015-2016 membership included: Dr S Ncanana (Chair); Prof D du Toit (*ex officio*); Prof D van Bogaert (*ex officio*); 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 and Mr Ronald Maluleke

Activities of the Quality Promotion & Enhancement Committee (QPEC)

Objective 2015-2016	Progress	Comment
Provisional registration of RECs	Three Health RECs received provisional NHREC registration	The provisionally registered RECs adhered to NHREC Ethical guidelines for provisional registration

RECs were provisionally registered in line with NHREC guidelines. These RECs include:

- Northern Cape Department of Health Provincial Health Research and Ethics Committee
- North West University Vaal Triangle Campus(NWU-VTC)Humanities and Health Research Ethics Committee (HHREC)
- Life College of Learning Research Ethics Committee
- University of Western Cape Humanities and Social Sciences Research Ethics Committee
- University of Western Cape Biomedical Research Ethics Committee

The documents received from these RECs were reviewed by the QPEC. They included terms of reference, a checklist for REC application, SOPs, application for registration, conflict of interest and confidentiality agreement, and research ethics protocol examination.

Objective 2015-2016	Progress	Comment
Monitoring and Evaluation of RECs: On-site assessment of provisionally registered RECs	During November and December 2015, QPEC members and the Secretariat conducted on-site assessments of five(5) provisionally registered RECs	Of the five on-site visits, three (i.e. NWU REC, Life Healthcare REC and Rhodes University REC). REC were determined to be operating according to the DoH Ethics Guidelines. Two RECs remain under development: (Northern Cape REC: there is some improvement in how the REC operates. However, capacity is still a challenge. The committee has a dual role, that of ethics review as well scientific review. Walter Sisulu University also has capacity issues as well as processes that are not clearly defined. These issues are being addressed by their new Chair)

A total number of five RECs were visited by QPEC members and the Secretariat between November and December 2015. Three of these RECs appeared to be generally well managed (operating with best practices and according to DoH guidelines). These RECs are:

- North West University REC,
- LifeHealthCare REC and
- Rhodes University REC

Two RECs that registered earlier were revisited to provide feedback on evaluation and Identification of gaps

- Rhodes University REC
- Walter Sisulu University Health Research Ethics& Biosafety Committee

Some of the best characteristics shown by these RECs include:

- Policies and SOPs well defined
- Proper evidence of protocol review
- Administrative: Proper filing of documents, supported by their respective administrative bodies or a secretariat
- Evidence of members being trained in the principles of research ethics

RECs Annual Report Assessment: As part of Monitoring and Evaluation (M&E), QPEC assessed and analysed the RECs 2014 annual reports. The following was established:

- Membership: composed as per NHREC guidelines. However, some RECs have a challenge with recruiting and retaining community representatives or lay persons.
- Review of protocols
  - Average turnaround times: 4 to 8 weeks
  - More than 95% of applications received were approved
  - 22 protocols approved under delegated ministerial consent
- Monitoring & Evaluation
  - Active monitoring not done, limited capacity
  - Passive monitoring was done (i.e.RECs receive progress reports from researchers)
  - Fewer RECs than in previous years reported adverse effects
- Ethics Training

- RECs members do attend research ethics training

The feedback on the RECs Annual Report was also sent to all RECs.

Objective 2015-2016	Progress	Comment
Auditing of Animal Research Ethics Committees (ARECs)	The council has audited 17 ARECs. The audit team is currently writing a report.	It is envisaged that the audit will be finalised by 17 September 2016.

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 was done by NHREC members and the Audit Report will be published soon.

Objective 2014-2015	Progress	Comment
Improvement of the REC reporting template for yearly REC submission of data to the NHREC	A REC reporting template was improved and distributed to all REC Chairs.	Thirty-Nine (39) RECs submitted their annual reports in 2015. Follow-up on the RECs that are delayed is on-going.

REC Reporting Template was improved and distributed to RECs. RECs are expected to report yearly using the template. Thirty-Nine (39) RECs RECs submitted annual reports for the year 2015.

2016/17 Plan

The QPEC will implement the following objectives:

Planned Objectives 2016-2017	Progress	Comment
1. Auditing of ARECs	The Audit Plan was developed and implemented	To follow up on the audit report recommendations

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.

Planned Objectives 2016-2017	Progress	Comment
2. Auditing of Health and Human RECs	The NHREC will also embark on auditing health and human RECs that are currently on provisional registration.	

Planned Objective 2017-2017	Progress	Comment
3. Registration of new RECs and ARECs, continue with REC audits, assessments	On-going REC provisional registration and on-site assessment visits will	

and on-site visits for fully registered and provisionally registered RECs and ARECs, increase communication and build capacity in research ethics	continue.	

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.

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4) The Legal and Regulatory Working Group 2015-2016

Mandate: The Legal and Regulatory Working Group is mandated to strengthen the legal framework for research ethics and research with human participants in South Africa

Membership: The 2013-2016 membership comprised Dr C Slack (Chair); Prof D du Toit (*ex officio*); Prof D van Bogaert (*ex officio*); Prof A Pope; Adv L Nevondwe; Dr M Sekhoacha; and Dr T Sithebe.

Secretariat: Mr T Molebatsi; Mr J van der Westhuizen and Mr Ronald Maluleke

Activities 2015-2016

Objective	Progress	Comment
To ensure that regulations for research with human participants are developed and disseminated to research stakeholders	Feedback was requested from Research Ethics Committees (RECs) about the adequacy of the regulations. Support was provided on several queries about the regulations to research stakeholders.	Generally, positive feedback was received by 4 RECs on the human subjects regulations.

To ensure adequate operationalisation of s71 of the National Health Act (NHA, 2003) requirement that 'non-therapeutic' child research obtains Ministerial Consent	Feedback was solicited on Operational Guidelines developed by the Working Group to help RECs and researchers to implement a delegation of power from the MoH to those RECs fully registered with the Council, and advice/ support was provided to stakeholders who sent queries about how to implement these Operational Guidelines.	Awareness-raising should continue to help stakeholders to implement this short-term solution to this restrictive component of s71. Those RECs currently unable to provide delegated ministerial consent because they have not yet achieved full registration should be audited as soon as possible.
To ensure law reform for s71 of the National Health Act (NHA, 2003).	There was liaison with DoH and its legal unit to keep momentum regarding implementation of proposed amendments to s71 already approved by the Minister of Health.	There should be on-going attention to the issue of law reform of s71 because some norms (e.g. mandatory parental consent for child research) constrain otherwise ethicallyacceptable research.
To ensure inputs to national guidelines	Inputs were made to the SA Department of Health 2015 *Ethics in Health Research: Principles, Processes and Structures*. Also, Inputs were also made to guidelines for Good Clinical Practice to ensure harmonisation with national guidelines.	There should be ongoing attention to possible remaining tensions between the NHA (2003), regulations, and national guidelines and advice provided to stakeholders.

Conclusion:

As evident in this Report, the NHREC has accomplished much during this term of office. However, we are aware that there are many challenges that lie ahead as we endeavour to ensure that South African research ethics systems and infrastructure are continuously appraised, supported and strengthened. The end result for which we strive is consistent excellence in health research for all South Africans. The NHREC wishes to thank sincerely the NHREC Secretariat and other persons and entities who have continuously supported our endeavours.

Prof D du Toit

Chairperson: National Health Research Ethics Council

Date: 19/09/2016