



**NATIONAL HEALTH RESEARCH ETHICS COUNCIL (NHREC)
ANNUAL REPORT 2018-2019**



Foreword by the Minister of Health

The National Health Research Council's (NHREC) Annual Report 2018-2019 provides an opportunity for reflection about regulating and supporting ethical research in South Africa. I wish to express our thanks and appreciation for the time and energy invested by the members of the NHREC into their role. This Council was appointed in November 2016. It is a pleasure to present some highlights of the NHREC's 2018-2019 achievements and activities.

The NHREC EXCO leads and oversees the functioning of the NHREC and its committees. The Complaints and Advisory Disciplinary Standing Committee (CADC) responded to queries received over the course of the year and all were resolved appropriately. The Quality Promotion & Enhancement Committee (OPEC) oversaw the completion of the quality assurance and re-certification audit visits of the remaining 21 HRECs. The Norms and Standards Committee (NASC) collaborated with the South African Health Products Regulatory Authority (SAHPRA) to revise and update the South African Good Clinical Practice: Clinical Trial Guidelines (SAGCP). This project is nearing completion, having been delayed by labour-related events in the NDOH. NASC has embarked on updating the DoH 2015 Ethics in Research Guidelines, where appropriate. The Animals in Research Committee (AIRC) has been active in providing guidance to ARECS.

The NHREC continues to facilitate close dialogue with HRECs and ARECs through the annual joint meeting, posting information on the updated website in the interim. I extend my thanks to Council members for their hard work and willingness to create an enabling environment for 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 supporting the NHREC

DR AMOTSOLEDI, MP
MINISTER OF HEALTH
DATE: 5/4/2019




Acknowledgement by the Director-General

As is highlighted in this 2018/19 Annual Report, the National Health Research Ethics Council (NHREC) has had another demanding but fruitful year. The Department is pleased that the Council continues work on the South African Good Clinical Practice: Clinical Trial Guidelines.

The NHREC ensures that health research related to the Department Annual Performance Plan and Strategic Plan is conducted in an ethical manner to strengthen the health system. The NHREC Annual Report provides an opportunity for reflection about regulating and supporting ethical research in South Africa. Some of the key achievements of the NHREC include completion of the auditing of registered HRECs with the NHREC to promote effective functioning of HRECs to raise standards and thus to ensure operation at the highest ethical standards and better protection for human participants in research.

We express our gratitude to the members of the NHREC: Prof A Pope (NHREC Chairperson), Dr M Sekhoacha (NHREC Vice-Chairperson), Prof T Brink, Dr T Burgess, Prof Engel-Hills, Dr J Gardner, Prof M Greeff, Dr B Mohr, Ms P Nkambule, Ms T Sebata, Prof Y Sikweyiya, Prof S Singh, and Dr N Tsotsi. The Department is also grateful to Dr GV Andrews (Chief Operating Officer) and Ms T Zondi (CD:HIRME) in providing guidance and strategic leadership to the NHREC. For assisting with secretariat and logistical arrangements for the Council, we are grateful to Dr T Muthivhi, Mr J van der Westhuizen, Dr L Malinga, and Mr R Maluleke.


MS M P MATSOSO
DIRECTOR-GENERAL: HEALTH
DATE: 5/4/2019

National Health Research Ethics Council (NHREC) Annual Report 2018-2019

Purpose: The National Health Research Ethics Council (NHREC) was established in September 2006 in terms of s 72(1) of the National Health Act 61 of 2003. The NHREC 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, for clinical trials and for research with 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 24 November 2016 for a three-year term:

Prof A. Pope (Chairperson), Dr M. Sekhoacha (Deputy Chairperson), Prof T. Brink, Dr T. Burgess, Prof P. Engel-Hills, Prof M. Greeff, Dr B. Mohr, Ms P. Nkambule, Ms T. Sebata, Prof Y. Sikweyiya, Prof S. Singh, and Dr N. Tsotsi. (**Note** Dr S. Ncanana resigned in 2018; Dr M Sekhoacha was appointed as Deputy Chairperson; no replacement member has been appointed)

Secretariat: In 2018-2019, the NHREC was supported by the NHREC Secretariat: Dr T. Muthivi, Mr J van der Westhuizen and Mr R Maluleke (logistics). Dr L Malinga joined the secretariat in November 2018.

NHREC Executive Committee (NHREC EXCO)

Mandate: The NHREC EXCO is responsible for:

- NHREC operations between scheduled meetings
- Overseeing functioning of committees
- Identifying and approving specialists for co-option to committees as necessary
- Formulating a strategic plan for the NHREC in consultation with all NHREC members
- Ensuring visibility of the NHREC and highlighting its activities amongst stakeholders
- Initiating and maintaining regular communication with relevant stakeholders
- Consulting, collaborating and cooperating with SAHPRA and 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 Executive Committee (EXCO) 2018-2019 consists of the Chair, Prof A Pope; the Deputy Chair, Dr M Sekhoacha; the Chairs of each Committee: Dr B Mohr (AIRG); Dr Y Sikweyiya (CADC); Prof S Singh (NASC); Ms T Sebata (QPEC) and the NHREC Secretariat: Dr T Muthivhi, Dr L Malinga, Mr J van der Westhuizen and Mr R Maluleke.

Activities of the NHREC EXCO 2018-2019

Comment	Progress	Objective 2018-2019
<p>The NHREC EXCO thanks Council members and the NHREC Secretariat for their continued dedication and support.</p>	<p>The Chair of the National Research Committee, Dr Edith Madela-Mntla, and the NHREC agreed to share Agenda & Minutes for the quarterly meetings so that both entities keep up with matters being managed.</p>	<ul style="list-style-type: none"> • Oversee functioning of the NHREC and committees • Receive requests for guidance & assistance from HRECs & ARECs • Liaise with other research regulatory authorities to keep each other informed

- The committees comprise of Council members and the EXCO as *Ex Officio* members. The committees are (in alphabetical order):
 - The Animals in Research Committee
 - The Complaints and Advisory Disciplinary Committee
 - The Norms and Standards Committee
 - The Quality Promotion and Enhancement Committee
- A brief description of the major achievements of the Committees follows.

1. ANIMALS IN RESEARCH COMMITTEE (AIRC)

- Mandate: The mandate of the Animals in Research Committee is to:
 - give effect to the mandate in the NHA to produce national benchmark ethics guidelines and best practice standards for all research using animals

Membership: The 2018-2019 membership is: Dr B Mohr (Chair); Prof T Brink (Deputy Chair); Prof M Greeff; Prof P Engel-Hills; Ms T Sebata & Dr N Tsotsi
Secretariat: Dr T Muthivhi, Mr Jacques van der Westhuizen, Mr Ronald Maluleke

Activities of the Animals in Research Working Group 2018-2019

The WG updated and expanded the AREC Registration form and AREC Annual Report form, to strengthen the national database of relevant information and to collect annual statistics. The forms are in fillable PDF format which enables electronic extraction of information into a database and improves the efficiency of quality-assurance audits, as well as provides meaningful data for the national annual meeting with RECs.

2. THE COMPLAINTS AND ADVISORY DISCIPLINARY STANDING COMMITTEE (CADC)

Mandate: The mandate of the Complaints and Advisory Disciplinary Committee is to:

- Adjudicate complaints about the functioning of Research Ethics Committees
- Hear complaints from researchers who believe that a Research Ethics Committee has discriminated unfairly against them
- 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

NHREC COMMITTEES

Membership: The 2018-2019 membership is: Prof Y Sikweyiya (Chair), Dr J Gardner (Deputy Chair); Dr M Sekhoacha; Prof T Brink; Prof P Engel-Hills and Prof S Singh
Secretariat: Dr T Muthivhi; Mr J van der Westhuizen; Mr R Maluleke.

Activities of the Complaints and Advisory Disciplinary Committee 2018-2019

Objectives 2018-2019	Progress	Comment
<ul style="list-style-type: none"> Finalisation of audits of HRECs 	Most have been completed; registration certificates issued; some still outstanding due to revisions required	QPEC thanks Council member colleagues & the Secretariat for their assistance, support and input
<ul style="list-style-type: none"> Assessment & registration process for 	On-going ad hoc REC assessments and site visits	Administrative process revised and working well

Activities of the Quality Promotion & Enhancement Committee (QPEC)

Secretariat: Dr T. Muthivhi; Mr. J van der Westhuizen; Mr. Ronald Maluleke.
(Deputy Chair): Dr T Burgess; Dr B Mohr; Ms P Nkambule and Dr N Tsotsi
Membership: The 2018-2019 membership is: Ms T Sebata (Chair); Prof M Greeff

- Support RECs in organizational and administrative functions
 - Conduct quality assurance and re-certification audits (every five years)
 - Assess and register RECs (ad hoc)
 - Determine guidelines for assessing the functioning of Research Ethics Committees (RECs)
- is to:

Mandate: The mandate of the Quality Promotion and Enhancement Standing Committee

2. QUALITY PROMOTION AND ENHANCEMENT STANDING COMMITTEE (QPEC)

<ul style="list-style-type: none"> Approval requirements for clinical investigation on medical device Quorum for ARECs Legal status of DoH 2015 Ethics in Research Guidelines SA ethics approval for study by foreign company in SA Retention period for hard copies of documents 	Resolved Resolved Resolved Resolved Resolved	
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Comment	Progress	Objectives 2018-2019
On-going discussions with CTC SAHPRA, regarding revised documents. Update to be provided at NHREC meeting in May 2019.	On-going	<ul style="list-style-type: none"> • Revise NDOH 2006 2nd Edition publication <i>Good Clinical Practice Guidelines</i>
The Norms and Standards Working Group thanks Council members and the NHREC Secretariat for their input and assistance in this on-going process.	On-going	<ul style="list-style-type: none"> • Upload guidelines and relevant research ethics information on NHREC website; keep it refreshed and informative
Likely to require additional co-opted capacity with expertise in clinical ethics as well as in research ethics re bio banks; has budgetary implications	On-going	<ul style="list-style-type: none"> • Develop ethics guidelines for biobanking practice in South Africa

Activities of the Norms and Standards Working Group 2018-2019

Mandate: The mandate of the Norms and Standards Committee is to:

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

Membership: The 2019 membership is: Prof S Singh (Chair); Dr T Burgess (Deputy Chair); Dr T Burgess, Dr J Gardner, Prof Y Sikweyiya; and Ms T Sebata

Secretariat: Dr T Muthivhi; Mr J van der Westhuizen; Mr R Maluleke.

3. NHREC NORMS & STANDARDS COMMITTEE

Administrative process revised and working well	On-going ad hoc REC assessments and site visits prior to full registration; some completed; others still in process	<ul style="list-style-type: none"> • Assessment & registration process for RECs that wish to register
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<p>The draft documents to be discussed at the NHREC meeting in August 2019.</p>	<p>On-going</p>	<ul style="list-style-type: none"> • Developing an informed consent document for Genetics and Genomics research
<p>NHREC thanks Dr K Viljoen & Prof Cilliers (UFH) for developing the draft guidelines on internet and social media research</p>	<p>On-going</p>	<ul style="list-style-type: none"> • Compiling a concise guideline for internet and social media research
<p>The draft documents to be discussed at the NHREC meeting in August 2019.</p>	<p>On-going</p>	<ul style="list-style-type: none"> • Developing a guideline on open access of stored data (data sharing)
<p>The updated sections of the DoH 2015 guidelines on ethics review and processes will be discussed at the NHREC meeting in August 2019.</p>	<p>On-going</p>	<ul style="list-style-type: none"> • Updating identified sections of the DoH 2015 guidelines on ethics review and processes.
<p>Will ensure future efficiency of the Council</p>	<p>A comprehensive SOP was developed to give clear guidance on these processes</p>	<ul style="list-style-type: none"> • To streamline the processes followed from application to registration and the audit of registered RECs that follows
<p>It has provided meaningful data for the national annual meeting with RECs</p>	<p>A Pdf fillable format was created for both forms to ensure a streamlined process</p>	<ul style="list-style-type: none"> • The committee updated and expanded the HREC Registration form as well as the HREC Annual Report form, to strengthen the national database of relevant information and to collect annual statistics