



correctional services

Department:
Correctional Services
REPUBLIC OF SOUTH AFRICA

Standard Operating Procedures

Research Ethics Committee

September 2016

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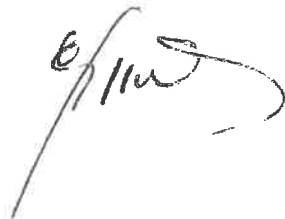


ACKNOWLEDGEMENTS

The Department of Correctional Services (DCS)' Standard Operating Procedures for Research Ethics Committee were drawn on the following ethical guidelines: Department of Health (2015) Ethics in health research: principles, structures and processes. Second edition; Council for International Organisations of Medical Sciences (CIOMS) (2015) International guidelines for biomedical research involving human subjects; Nuffield Council on bioethics. The ethics of research related to healthcare in developing countries; World Health Organisation (WHO) (2011) Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. ISBN 978 92b4 150295 5; and Institute of the National Academy of Sciences. (2006) Ethical Considerations for Research Involving Prisoners. <http://www.nap.edu>

It also draws on the following guidelines of Research Ethics Committees: Human Sciences Research Council Research Ethics Committee Terms of Reference; Stellenbosch University (2011) Standard Operating Procedure: Research Ethics Committee: Human Research (Humanities). 24 November 2011; South African Medical Research Council Ethics Committee (2010) Standard Operating Procedures; University of Pretoria (2014) Standard Operating Procedure. <http://www.up.ac/healthethics>; and World Health Organisation (2012) IARC Ethics Committee (IEC) Standard Operating Procedure (SOPs).

The Department wishes to thank Professor A. Pope of the Law Faculty of the University of Cape Town and current member of the National Health Research Ethics Council and Professor D. Wassenaar, Principal Investigator (PI) of the South African Research Ethics Training Initiative, University of KwaZulu Natal and current chairperson of the Human Sciences Research Council (HSRC) Research Ethics Committee for their comments on the draft Standard Operating Procedures (SOPs) for the DCS Research Ethics Committee.

A handwritten signature in black ink, appearing to be 'E. Pope', is written over a horizontal line.

1. INTRODUCTION

Research is important for the Department of Correctional Services (DCS) in its endeavour to inform evidence based practices. In carrying out its functions the DCS adheres to human rights values enshrined in the Constitution of South Africa. The DCS recognises the vulnerability of its inmate population in research and has thus established a Research Ethics Committee to promote ethical research to ensure that the interests of the participants are adequately protected on all proposed research. The protection provided by this Committee extends to other offender populations (parolees and probationers) whose liberty is also restricted.

The DCS Research Ethics Committee (DCS REC) is responsible for ethics review of all proposed research in the Department of Correctional Services involving human participants and review of records. This includes research conducted by external researchers, DCS personnel and DCS institutional research that is submitted for review.

Due to the vulnerability of offenders, the DCS REC shall require in reviewing research applications evidence of appropriate training, ethics certification and oversight/ supervision for junior researchers.

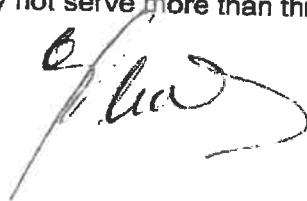
2. CONSTITUTING THE RESEARCH ETHICS COMMITTEE

The REC consists of a multi-disciplinary team reflecting a broad range of expertise in social sciences, health sciences, corrections and research. To ensure independence of the committee, members may be drawn from institutions not attached to the DCS, namely: academic institutions, independent research institutions, human rights institutions and Non-Governmental Organisations (NGOs).

2.1 Nomination and appointment of members

A transparent process of appointment will be implemented. Invitation for nomination will be publicised to the Department and stakeholders. The National Commissioner of Correctional Services approves the final list of nominations.

All appointees receive appointment letters indicating the term of office and indemnity against personal liability, and other information like how to claim for reimbursement for travel and accommodation expenses. Members are appointed for a term of three years, which may be renewed. A member may not serve more than three consecutive terms.



Membership of the DCS REC shall include an ex-inmate with grade 12 level of education to represent the inmate population. The chairperson and deputy chairperson are nominated by the members of the Research Ethics Committee and appointed by the National Commissioner. Upon appointment members sign confidentiality agreement forms, and sign acceptance of the code of conduct and terms of reference of the REC. Members may resign from the REC before the end of their term of office and this is done in writing and addressed to the Chairperson.

2.2 The composition of the Research Ethics Committee

All REC members must have documented proof of research ethics training, renewed at least once within a period of appointment.

The Research Ethics Committee must consist of nine members with the following experience:

- At least three members from academic institutions with expertise in two or more of research ethics, human rights, social sciences and health sciences;
- A least two members with experience in NGO work or a human rights activist with social science background and an interest in correctional work.
- At least one ex-inmate with a grade 12 level of education;
- At least three staff members including an official from centre level where a majority of research is undertaken. DCS members should have expertise in different areas of social sciences;
- An additional ad hoc member with legal expertise may be co-opted or invited to review particular research proposals;
- Further independent members may be co-opted to provide special review expertise on specific research proposals but will not be part of decision making.

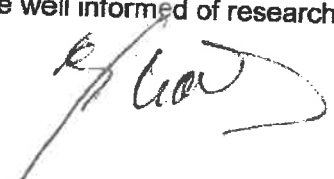
The quorum consists of 50 percent plus one member including the chairperson.

The REC meets bi-monthly, except for December and January, i.e. six times a year.

2.3 Expectations of REC members

REC members are expected to:

- Ensure they are well informed of research ethics principles on an ongoing basis;



- Ensure they have familiarised themselves appropriately and rigorously with a research proposal prior to deciding whether it is acceptable on ethical grounds;
- Declare the existence of a conflict of interest regarding any research proposal before each meeting's deliberations; and
- Attend at least half of the meetings scheduled for the year. Failure to attend the required number of meetings may lead to termination of membership to the committee.

2.4 Responsibilities of the Chairperson

The Chairperson:

- Allocate each research proposal to at least two REC members for comprehensive review;
- Ensures that the remaining members receive a synopsis and the informed consent documentation for each proposal;
- Arrange expedited reviews in appropriate cases;
- Submit annual reports to the National Commissioner and to the National Health Research Ethics Council (NHREC) in March each year reflecting on the REC activities of the financial year.

2.5 Responsibilities of the Secretariat

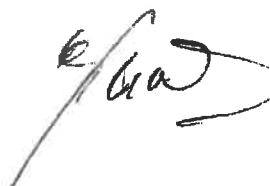
The Research Directorate provides administrative and secretariat support to the REC.

Before the REC meeting, the Secretariat:

- Receives applications in accordance with the schedule for submission of applications;
- Assesses the applications for administrative compliance and completeness; if not request for outstanding information;
- Informs the Chairperson about the applications, providing the title and synopsis for each so that the Chairperson can allocate review responsibilities;
- Compile and distribute meeting agenda and research applications with supporting documents at least three weeks before the meeting; and
- Follow up with the reviewers during the week before the scheduled meeting to ensure that the reports are submitted on time.

During the REC meeting, the Secretariat:

- Records apologies and ensures that the attendance register is signed by each member;



- Ensures that members have declared conflict of interests, if any; and
- Take detailed minutes of the deliberations and decisions.

After the meeting, the Secretariat:

- Compile the minutes;
- Notifies the applicants in writing within two weeks of outcome of the REC meeting;
- Ensures that the revision requirements, if any are clearly communicated to the applicants;
- Requests revision within a four months' time period;
- Follows up with researchers regarding revision of applications where necessary and refer these matters to the Chairperson;
- Assists the Chairperson to compile the annual REC reports;
- Attend to the REC registration and ongoing communication with the NHREC;
- Files all meeting documentation and manage the database related to the REC; and
- Assist with arranging training for REC members.

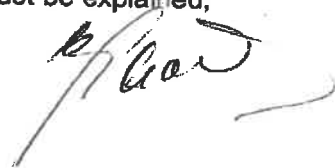
3. APPLICATION REQUIREMENTS

3.1 Submission procedures

Applications are submitted to the REC secretariat within the Research Directorate. The application may be submitted in scanned format or hard copy with relevant signatures.

Applications should include the following information:

- A summary of why this research has social value and why it must be done with a vulnerable group and description of ethical considerations (i.e. analysis of the ethics of the project and measures to manage it);
- All data collection instruments e.g. interview schedules, questionnaires and observation schedule proposed;
- A clear description of how research participants will be recruited, who will recruit them, and how informed consent will be attained and by whom;
- Attached informed consent documentation, recruiting advertisements and posters;
- Language level, vocabulary and readability levels suitable for potential participants must be addressed;
- Any conflict of interest for the researcher(s) must be mentioned and measures to manage it must be explained;



- Students must submit at least a provisional ethics approval indication from the University-based Research Ethics Committee;
- Measures to protect confidentiality of data and to prevent unauthorised access must be described;
- The fate of data post-study must be described; and
- Proof of research ethics training.

In addition to the application and detailed research proposal, the following supporting documentation is required:

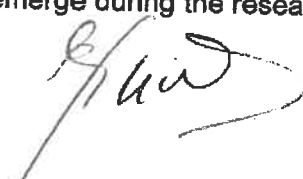
- A copy of the Identification Document/ Card that will be used to enter a correctional centre setting;
- A copy of the signed indemnity form agreeing to indemnify the Department against any injury that may occur when conducting research; and
- A G179 application form must be completed in full and signed by relevant parties.

The application to conduct research should reach the REC Secretariat (Research Directorate) at least 14 days before the scheduled REC meeting. The dates of the REC meetings are posted on the Department of Correctional Services' website. The secretariat will acknowledge receipt of completed application forms and liaise with the applicant in case of incomplete application forms. The researchers will be informed in writing about the outcome of their application within 14 days of the REC meeting.

3.2 Responsibilities of the researcher

Researchers are responsible for ensuring that:

- They are academically qualified and have the necessary experience and expertise to undertake the particular study in terms of field of study as well as the proposed research methodology;
- Student applications identify the supervisor who will have oversight responsibility for the student's work;
- Research is conducted ethically which means the researcher is expected to be familiar with the relevant ethical codes, especially Department of Health 2015 Ethics in Health Research and the requirements and procedures of the DCS Research Ethics Committee;
- Any deviation or amendment from an approved proposal is not implemented without prior approval from the REC; any ethical concerns or need for changes in research design that emerge during the research must be reported to the REC;



- Reports on the status of the research are submitted annually or as appropriate.
- The REC and research participants are informed when the study is terminated early or when the project has been completed; and
- Research participants are given access to a copy, of the research report, on request, in a format tailored to the recipient.

4. REVIEW PROCESS

4.1 Preparation for the meeting

All complete applications received 14 days before the date of the next REC meeting are included on the Agenda. The secretariat circulates an electronic version of a proposal and supporting documents to all members of the REC. Each proposal is allocated by the Chairperson to two REC members, as primary and secondary reviewers. The primary reviewer leads the discussion of the particular proposal at the REC meeting. All members are expected to read all applications tabled, even if they are not the assigned reviewers.

4.2 REC Deliberations

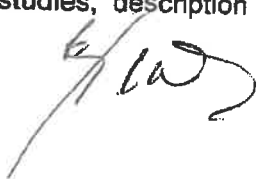
REC members must constitute a quorum before a meeting can proceed. In evaluating proposals committee members will be guided by the framework developed by Emmanuel et al. (2004) for clinical research in developing countries which has been considered relevant in social research (Wassenaar and Mamotte 2012). Amongst others, the framework places emphasis on the following principles in ensuring research is ethical: community engagement, social value, scientific validity, fair subject selection, favourable risk benefit ratio, informed consent and respect for participants.

In line with this ethical framework, the following sections of the research proposal are given special consideration by the committee:

Research design of the study: Ensure that the design is scientifically sound.

Recruitment of research participants: This includes consideration of how the researcher will recruit participants and the inclusion and exclusion criteria for research participants.

Care and protection of research participants: This includes consideration of some of the following issues – whether psychological and other care services shall be provided during and after the research (cost borne by the researcher); supervision of junior researchers for more than minimal risk studies; description of plans to make the results available to research



participants; and incentive and/ or compensation for research participants. The use of incentives is not encouraged for inmates to avoid undue influence i.e. participating in the research to obtain goods offered by researcher(s).

Protection of research participant confidentiality: indication of persons that will have access to personal data of participants; how confidentiality will be ensured; measures to keep data in safe storage; and length of time the data will be kept in storage.

Informed consent: clear and detailed description of the process of obtaining informed consent; and description of how the results will be made available to participants.

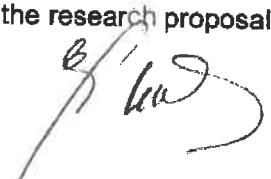
Within the scope of the review the competence of the researcher to conduct research is also assessed. The competence is usually evidenced by education and experience information. The Principal Investigator has an important role to play overseeing the research by ensuring implementation of the proposal and protection of participants. Researchers must provide proof of research ethics training.

4.3 REC decision-making

Members of the REC discuss each proposal under consideration. The discussion should be respectful and open to hearing different opinions based on ethical reasoning. The Chairperson must encourage respectful conduct and provide adequate time for debate and discussion. The decision about proposals is made by only those present in a meeting. In other words, if a member cannot attend a meeting, he or she may submit comments for consideration but cannot ordinarily question a decision made by a quorate meeting.

The following procedures are followed for decision-making:

- A member of the REC must withdraw from the meeting during discussion of a research proposal that poses conflict of interest for him/her;
- Decisions at the meeting are made through consensus as far as possible; if consensus cannot be reached, a majority vote decides the outcome;
- The REC is authorised to make the following decisions after reviewing research proposals:
 - Approve the research proposal;
 - Approve the research proposal with conditions (The response may or may not need to be brought back to the REC);
 - Request modification of research proposal before approval (require re-submission of the proposal to the REC); and
 - Reject the research proposal;



- The REC chairperson may invite a Principal Investigator to attend the meeting to clarify issues that may be raised; and
- The proceedings of each REC meeting must be minuted and minutes confirmed as a correct reflection at the next meeting.

In compliance with NHREC research ethics guidelines (2015) the DCS REC operates in compliance with this SOP (as amended from time to time) and no other party or official may overrule or undermine REC decisions and recommendations.

5. EXPEDITED REVIEW

Expedited review will be used in rare circumstances for minimal risk research only. Its use shall be clearly motivated. This expedited review shall apply to only minimal risk research. The Chairperson will nominate two committee members to be part of the expedited review process. The decision of the expedited review shall be tabled to the full Research Ethics Committee for ratification.


6. COMMUNICATING REC DECISIONS

6.1 Minutes

The minutes of the REC meeting must include a record of the following:

- The committee members present and absent;
- Any interests declared;
- Submission of written comments by members absent from the meeting;
- The decisions of the REC on the research applications in the following manner:
 - For approved applications, any conditions or advice given to the applicant.
 - For conditionally approved applications, a statement of additional information required and how this information will be considered by the REC.
 - For applications that were rejected, reasons for the rejection and an indication of whether it is rejected outright or may be resubmitted after major revision.
- The number and outcome of any vote taken; and
- The number of any dissents from a decision and the reasons given.

6.2 Communicating decision



The decision of the REC must be communicated to the applicant in writing within 14 days of the meeting. The feedback letter must give a clear explanation of the REC decision and, where applicable, the suggestion(s) for the amendments and review.

Communication to the applicant must include specific information about the research project such as the: title of the study reviewed; name of the applicant; name of the study; date of the decision; duration of the approval; request for progress report; and a need to notify the REC when study is completed and provide them with the final research report. In case of conditional approval the researcher shall be provided with a suggestion for revision and in case of rejection reasons for such a decision on ethical grounds.

Communication must be sent to internal stakeholders (Regional and Area Commissioners) informing them about the research applications.

7. MONITORING OF RESEARCH

Researchers are required to report any adverse event during their research and these include physical, emotional and social harm. These adverse events may not necessarily be a result of research itself but could have been reported or occurred during the research process. The reports are submitted to the secretariat that conducts an initial screening and, if necessary, refer the matter to the Chairperson and the REC for full review.

The REC monitors the implementation of research it approves. Apart from the status reports the REC may decide to conduct random inspection of research sites, signed consent forms and records of interviews in order to ensure that human rights of participants are protected. In circumstances where the REC determines that the project is non-compliant with the approved protocol and interests of participants are at risk, the REC may withdraw the approval.

Researchers are expected to adhere to the ethical values of confidentiality of participants, appropriate acknowledgement of those who have contributed to or been involved in the research project and of sharing their findings with participants and their community. Therefore, the researchers have an obligation to share their research findings with REC and DCS. As part of monitoring the research, with regard to confidentiality and anonymity, the REC requires submission of completed final reports.

8. COMPLAINTS AND APPEAL PROCEDURES



8.1 Complaints from Research Participants

Complaints about possible wrongdoing or research-related misconduct must be directed to the REC Secretariat. These include adverse event as a result of research and deviations from the approved research proposal. These complaints may be submitted to the Head of Centre or Independent Correctional Centre Visitors (ICCVs) where the research was implemented and forwarded to the REC Secretariat for attention. If the matter has not been satisfactorily addressed by the REC, the complaint may be directed to the NHREC.

8.2 Appeal Procedures

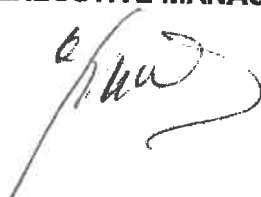
Researchers have a right to appeal the decisions of the REC. The request for appeal must be addressed to the chairperson of the REC. The right to appeal and the appeal process will be communicated to applicants whose studies were rejected. The appeal must contain a clear motivation of the reasons for the appeal. The chairperson will then identify an independent subject expert to review the proposal and make recommendations to the REC. The recommendations of the subject expert and the appeal motivation will then be tabled at the following REC meeting for further deliberation. Further dissatisfaction with the outcome of the appeal may be directed to the NHREC for adjudication on the matter.

9. RECORD KEEPING

All research related documentation reviewed must be stored for a period of fifteen years and as guided by National Archives and Records Service of South Africa Act (Act No. 43 of 1996), as amended. The REC meeting documentation must also be archived. Specifically the following documents must be kept:

- Copies of signed appointment letters of REC members and all other signed documents related to the appointments;
- The agendas and minutes of the REC meetings;
- Copies of all research proposals, consent documents and status reports and final reports; and
- Copies of all correspondence between the researchers and the REC.

10. REPORTING TO EXECUTIVE MANAGEMENT



The DCS Research Ethics Committee must submit to the National Commissioner an annual comprehensive report of its activities. The report must include: number and types of projects approved, details of studies not approved, any complaints regarding the research and action taken, list of completed research, and REC membership.

11. ADOPTION OF AND CHANGES TO STANDARD OPERATING PROCEDURES

The Standard Operating Procedures must be circulated to all relevant internal and external stakeholders including REC members for comments. Following this extensive consultation, Standard Operating Procedures are submitted for approval by the National Commissioner through the Directorate Policy Procedure and Coordination. Any amendments to the documents thereafter require endorsement by the National Commissioner.

12. REGULATORY FRAMEWORK

The REC is guided by national and international guidelines on research ethics and operates within the research ethics regulatory framework and policies of the government of South Africa including:

- The Constitution of the Republic of South Africa, 1996;
- National Archives and Records Service of South Africa Act (Act No. 43 of 1996);
- National Department of Health (2015) Ethics in Health Research: Principles, structures and processes;
- Correctional Services Act, (Act No. 111 of 1998);
- The World Medical Association Declaration of Helsinki 2008 (updated in 2013);
- Council for International Organisations of Medical Sciences (CIOMS) (2015) International guidelines for biomedical research involving human subjects.

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