



Standard Operating Procedures for Scientific Review of Proposals for Research with Humans Prior to submission to the SAMRC Research Ethics Committee

1.0 Introduction

- 1.1 Research proposals need to be scientifically sound in order to be ethical. Peer review is the normative scientific practice for guaranteeing quality in research design.
- 1.2 Further, SAMRC funded research normally has no external review process and so external scientific review prior to REC submission is needed to assure quality of internally funded research
- 1.3 It is a requirement that proposals are subject to scientific review prior to having other aspects of the ethics of their design considered.
- 1.4 The SOP outlines the procedures for submission of proposals for scientific review prior to review by the SAMRC Research Ethics Committee
- 1.5 The SOP applies to all new research proposals, whatever the funding source, as well as amendments to the design of the study. It does not apply to amendments that are administrative or relate to matters that are primarily of ethical nature i.e. changes of an administrative in nature, to consent forms, location of sites or staffing.

2.0 Procedures

2.1 Stage 1 of scientific review conducted within Units

2.1.1 All proposals that stem from a Unit must be submitted to the Unit Director for review prior to submission to pre-REC scientific review. The Unit Director must provide assurance that the proposal meets acceptable scientific standards. It must have been reviewed within the Unit and any problems identified and corrected. Further the Unit Director must assure that should the proposal be approved by the REC and funding be available, that the research work is a priority for the investigators and for the Unit. It is acceptable for Unit Directors to assure their own proposals.

2.1.2 All proposals submitted to the pre-REC scientific review must be accompanied by the attached form (appended to SOP)

2.2 Stage 2 of scientific review managed through the Office of the Executive Scientist

2.2.1 Submissions will enter the second stage of scientific review through submission to the email address scientificreview@mrc.ac.za accompanied by the completed form.

2.2.2 Emails will be received by Bianca Dekel and will have initial screening for completeness. It is not necessary for proposals to have investigator CVs, consent forms and information sheets or letter of research access prior to submission for scientific review. However, the full proposal in the appropriate SAMRC format with an abstract, table of contents, body of the proposal, questionnaires and/or a

scope of inquiry for qualitative research and any other relevant scientific documents must be included. There must also be page numbering. Please include all appendices (besides the budget, if in Excel format) within the protocol document so that only one document is sent out to reviewers.

2.2.3 Any proposals not meeting initial screening requirements will be returned to the Principal Investigator with the email copied to the Unit Director indicating that the within Unit stage of scientific review was not adequately conducted.

2.2.4 Bianca Dekel will inform the Executive Scientist for Research Strategy that there are complete proposals, together with reviewers suggested by the applicant and by the MRC database.

2.2.5 Proposals will be screened scientifically by the Executive Scientist for Research Strategy and if there are obvious problems with the proposal it will be returned to the Principal investigator for amendment. If there are no obvious problems, reviewers will be approached by the Office of the Executive Scientist and the proposal sent to reviewers by that Office

2.2.6 Administrative action following up on reviews will be conducted by Bianca Dekel

2.2.7 Reviews received will be collated by Bianca and sent to the Principal Investigator

2.2.8 The Principal Investigator must respond to every issue raised by reviewers either through making changes to the proposal with tracked changes or by rebuttal. The proposal must be resubmitted via the email address scientificreview@mrc.ac.za, clearly marked as a resubmission, with a version that has tracked changes and a letter stating how every point was addressed.

2.2.9 Bianca Dekel will send these two documents to reviewers and receive a reply stating that all issues have been satisfactorily addressed or that some issues remain outstanding

2.2.10 Bianca Dekel will send the revised proposal with tracked changes and the reviews and responses to the reviewers and replies to these responses to the Executive Scientist for final assessment.

2.2.11 The Executive Scientist will determine if the proposal requires further revisions or is quality assured for the REC and communicate this in writing.

3.0 Covering letter for scientific review

3.1 All submissions for scientific review must have a covering letter which outlines:

- a) Name of any other ethics committees that have scientifically reviewed the proposal
- b) Name of any other review processes, including those of the funder
- c) Brief summary of revisions recommended and remedial action (if a) or b) are applicable)

3.2 All documentation related to prior reviews including details of the name(s) and position of the committee or reviewers conducting the review, reviewers comments and any final letters of scientific acceptance should be submitted with the scientific review application.

3.3 A proposal is not exempted from Scientific Review just because there has already been a prior review process, however the nature of this review is pertinent to the scientific review process. Rigorous previous external scientific review of a complete research proposal may be accepted by the Executive Scientist as a reason not to repeat external scientific review.

3.4 This decision will be at the discretion of the Executive Scientist. Any concerns about methods, or major protocol changes post-review, will result in submission for full scientific review, notwithstanding and prior review processes.

4.0 Submission

4.1 Scientific review must be completed within 15 working days of an Ethics Committee meeting for proposals to be submitted to the REC.

4.2 Normally review will take a month. The dates by which proposals for Scientific Review should be submitted will be on the MRC website. There will be no Scientific Review in December.

4.3 Major protocol amendments should be treated as per new proposals

4.4 Minor protocol amendments will not normally be sent for external scientific review and need not be submitted, unless the REC disagrees that they are minor

4.5 Requests for expedited scientific review may be made to the Executive Scientist accompanied by motivations of urgency. Agreement to an expedited scientific review does not guarantee that the review will be completed in time for the next REC meeting.

5.0 Quality assurance in scientific review

5.1 Overall quality assurance for scientific review will be provided by the Executive Scientist for Research Strategy

5.2 All scientific reviewers will be identified according to the relevance of their expertise, as demonstrated by research publications, and all will be researchers who hold a PhD or equivalent qualification. Please only nominate reviewers who hold a PhD or equivalent qualification.

5.3 Reviewers may be employees of the SAMRC, staff of extramural Units or external to the organisation (please refer to 5.8)

5.4 The exception will be in the case of statisticians, who may be asked to review without holding a PhD

5.5 Quantitative research proposals will be reviewed by a statistician focusing on overall study design, sample size and data analysis

5.6 Scientific reviewers may be nominated by the PI or Unit Director and they also have an opportunity to name any individuals who they feel should not be asked to review.

5.7 The final decision on who is asked to conduct scientific review rests with the Executive Scientist

5.8 All research proposals that will be funded using SAMRC resources need to be reviewed by at least two researchers who are not employees of the SAMRC. If your study is funded using SAMRC resources, please nominate reviewers who are not employed by the SAMRC.



**EXECUTIVE SCIENTIST
RESEARCH STRATEGY OFFICE
OF THE PRESIDENT**

The **SAMRC pre-Research Ethics Committee scientific review** should proceed as smoothly and rapidly as possible. In order to enable this we require that all proposals are reviewed by the Unit Director prior to submission to for Scientific Review. This form must be completed with every submission:

Name of Principal Investigator(s): _____

Title of research proposal: _____

I have reviewed the above proposal and am satisfied that it meets acceptable scientific standards. I agree that undertaking this research is a priority for the investigator(s) and the Unit.

I am aware of any previous external scientific review and have checked that details of this are included in the covering letter for the application.

Name: _____

Unit: _____

Signature: _____

Date: _____

Recommended reviewers:

1. Name, position, email: _____

2. Name, position, email: _____

3. Name, position, email: _____

4. Name, position, email: _____

Names of researchers who should not be asked to review (if any):

1. Name, position, email: _____

2. Name, position, email: _____

3. Name, position, email: _____