



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

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

SOP VERSION REVISED IN MARCH 2025

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1. INTRODUCTION

- 1.1.1. 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.
- 1.1.2. Further, SAMRC funded research normally has no external review process and so external scientific review prior to the Human-subjects Research Ethics Committee (HREC) submission is needed to assure quality of internally funded research.
- 1.1.3. It is a requirement that proposals are subject to scientific review prior to having other aspects of the ethics of their design considered.
- 1.1.4. This SOP outlines the procedures for submission of proposals for scientific review prior to review by the SAMRC HREC.
- 1.1.5. This 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. PROCEDURES

2.1. STAGE 1 OF SCIENTIFIC REVIEW CONDUCTED WITHIN UNITS

- 2.1.1. All proposals must be submitted to the Unit Director for review prior to submission to 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.
- 2.1.2. The Unit Director must also assure that should the proposal be approved by the HREC and funding be available, that the research work is a priority for the investigators and for the Unit.
- 2.1.3. It is acceptable for Unit Directors to assure their own proposals.

2.2. STAGE 2 OF SCIENTIFIC REVIEW MANAGED THROUGH THE OFFICE OF THE EXECUTIVE SCIENTIST

- 2.2.1. All Scientific Review submissions must be sent to the email address scientificreview@mrc.ac.za accompanied by the completed Appendices in this SOP. Please take careful note of Appendix 3.
- 2.2.2. Emails will be received by Dr. Dekel who will pre-screen the protocol for style and completeness against the checklist in the Appendix 2. This checklist needs to be submitted with the protocol as a separate file/document, i.e. not included in the pdf submission.
- 2.2.3. Incomplete proposals as per the checklist in Appendix 2 will be returned to the Principal Investigator with the email copied to the Unit Director indicating that the within Unit stage of review was not adequately conducted.

- 2.2.4. Scientific review will not accept proposals that have been written in the style required by a funder and have not been edited into the normal format of a proposal to be submitted for HREC approval, as shown in the HREC checklist. Attention should be paid to ensuring that all the necessary proposal sections are included and any special sections required by a funder that are non-standard in a proposal should be removed.
- 2.2.5. When initial screening has been completed satisfactorily, the proposal will be sent to the Executive Scientist, Prof. Rachel Jewkes. All Scientific Review protocols will be reviewed by Prof Jewkes. Protocols may proceed to the next stage after they have received Executive Scientist approval.
- 2.2.5 Feedback from the Executive Scientist review will be provided to Dr. Dekel, who will then communicate the necessary revisions to the PI. All resubmissions should include the following:
1. The updated protocol with revisions highlighted using tracked changes.
 2. A response letter detailing how the raised issues have been addressed, along with any rebuttals where applicable.
- 2.2.6 The Executive Scientist will review the resubmission and response letter to assess whether the issues have been sufficiently addressed for the proposal to proceed to scientific review. If further revisions are needed, the proposal will be returned to Dr. Dekel, who will send it back to the PI along with a letter outlining any remaining issues that must be resolved.
- 2.2.7 Dr. Dekel will be notified once Prof. Jewkes approves a submission/resubmission and will thereafter invite potential subject area-expert reviewers. Scientific reviewers will be approached by Dr. Dekel.
- 2.2.8 Once two reviews are received, they will be sent out to the Principal Investigator by Dr. Dekel.
- 2.2.9 If the reviewers require changes, the default deadline for providing a response to reviewers will be 7 working days. If the Principal Investigator is unable to meet this deadline, they must communicate this in writing and agree to a new deadline with Dr. Dekel.
- 2.2.10 The Principal Investigator must respond to all issues raised by reviewers, either through making changes to the proposal or by rebuttal. Resubmissions should be sent to scientificreview@mrc.ac.za, clearly marked as a resubmission and must include the following, submitted as 2 separate files:
- (a) point-by-point response letter clearly detailing how each point raised by the reviewers was addressed, or providing a detailed rebuttal,
 - (b) A complete protocol with all changes clearly marked in track changes.
- 2.2.11 If both reviewers are satisfied that all issues have been adequately addressed, Dr. Dekel will inform the PI. This will signal the end of the scientific review process, and the PI may then submit to ethics.
- 2.2.12 If one or both reviewers indicate that some scientific issues remain outstanding, the PI will be asked to make further revisions to the protocol and resubmit again.
- 2.2.13 Any disagreement between the PI and the scientific reviewer will be adjudicated by Prof. Jewkes.
- 2.2.14 Should a PI not respond to comments received from the Executive Scientist or scientific reviewers within 8 weeks (10 weeks will be allowed for comments received after 25th November each year) and not request an extension with a new agreed submission deadline, the proposal will be considered to have been withdrawn.

3.0. REVIEWER ELIGIBILITY, NOMINATION AND SELECTION

- 3.1.1 Scientific reviewers will be selected according to the relevance of their expertise. All nominated reviewers must hold a PhD qualification. The exception will be in the case of statisticians, who may be asked for statistical review without holding a PhD.
- 3.1.2 Research proposals funded using SAMRC resources must be reviewed by researchers external to the SAMRC.
- 3.1.3 Proposals for research with external funding may be reviewed by employees of the SAMRC. Proposals may not be reviewed by anyone currently or formerly employed in the same Unit as the Principal Investigator.
- 3.1.4 Potential reviewers will be asked to disclose any conflicts of interest as soon as they become aware of them. Any information that subsequently comes to light to render a reviewer ineligible will result in a review being disregarded. Conflicts include inter alia:
- i) Co-authoring a publication or grant proposal with the PI or the Co-PI in the last 3 years;
 - ii) Being a current co-investigator on a project with the PI;
 - iii) Being colleagues within the same SAMRC Unit/academic department or similar in the past 3 years;
 - iv) Current or former Doctoral supervisor or mentor to the PI or current or former Doctoral student, or mentee, of the PI;
 - v) Close personal relationship (family or friend) with the PI;
 - vi) Potential to receive any direct or indirect personal or financial benefit from the success of the proposal;
 - vii) Anything else that might reasonably be considered to compromise review independence.
- 3.1.5 Should it be difficult to find eligible reviewers due to 3.1.4 (1), a Principal Investigator may motivate for this to be disregarded in respect of co-authors or co-applicants on a grant or publication. Dr Dekel and Prof Jewkes' decision will be final.
- 3.1.6 All submissions must include a nomination of at least 4 potential scientific reviewers who are eligible per the above criteria. Nomination of ineligible reviewers will be grounds to consider an application incomplete. When it is hard to identify reviewers without a COI, Dr Dekel's advice should be sought.
- 3.1.7 Where a multi-country project has at least one research site within South Africa, at least half of the nominated reviewers must be either based in South Africa or be South African scholars currently working abroad but with a track record of publications from work in South Africa.
- 3.1.8 The PI may request to exclude potential reviewers, but must provide an explanation for such requests.
- 3.1.9 All decisions are at the discretion of Prof. Jewkes and Dr. Dekel.

4. MULTI-COUNTRY STUDIES

- 4.1. All multi-country studies require ethical approval in the individual countries in which the research is being implemented.
- 4.2. SAMRC PIs on such studies are required to address feedback from the scientific review process and make relevant protocol revisions with track changes. Such PI's are welcome to rebut suggestions if there is a disagreement, but such rebuttals must be scientifically grounded – the existence of an international consortium and/or approval from another ethics committee is not grounds for rebuttal in and of itself. The scientific reasoning underling the rebuttal must satisfy the scientific reviewers and Prof. Jewkes or the changes will be required.
- 4.3. Where there is a difference in style between the proposal as approved by international ethics committees and the requirements of the SAMRC HREC, and there are concerns that changing the proposal would triggering repeated review in other settings, it is acceptable to address the specific requirements of the SAMRC HREC in a 'jacket' with the proposal as approved elsewhere contained within and unchanged. For example, the HREC-style cover sheets, executive summary and list of investigators may be included as part of the jacket. Scientific Review does not provide assurance that this will be accepted in the circumstances where a reviewer identifies material matters that should be changed in the proposal.

5. PROTOCOL AMENDMENTS REQUIRING SCIENTIFIC REVIEW

- 5.1.1. Major protocol amendments should be treated as new proposals.
- 5.1.2. 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.
- 5.1.3. Amendment submissions should be sent to scientificreview@mrc.ac.za, clearly marked as an amendment to previously approved protocols and must include the following, submitted as 3 separate files: (A) A cover letter detailing the amendments which require review and any additional detail about the motivation for the amendments that is not obvious from the protocol, (B) A complete protocol, including appendices, with all changes clearly marked in track changes, and (C) a clean copy of the protocol.

6. EXPEDITED SCIENTIFIC REVIEW

- 6.1. In exceptional circumstances, the Office of the Executive Scientist can agree to make efforts to expedite the scientific review process. Requests for expedited scientific review must be accompanied by a motivation. The normal grounds for approving such a request will be that the PI is proposing to respond to a time-sensitive opportunity to conduct research of high importance (for example, project on the health impact of the Covid-19 lockdown).
- 6.2. The request for expedited review will be considered and the PI will be informed whether the request was successful or unsuccessful.

- 6.3. In expedited reviews, reviewers are asked to complete the review in 5 working days from receipt of the protocol, and SAMRC may be asked to conduct the review in a shorter timeframe if they have appropriate expertise and the work is externally funded. It should be noted that the Office of the Executive Scientist is does not have full control over the speed of reviews. A request for expedited review therefore does not guarantee that the review will be completed in time for the next HREC meeting.
- 6.4. Requests for expedited review may be made in advance of protocol submission, in this case Dr Dekel will attempt to arrange reviewers in advance, although the success of these efforts cannot be guaranteed. Failure to deliver a complete protocol by the agreed deadline will delay these processes and may constitute grounds to remove the protocol from the expedited review process.
- 6.5. When an expedited scientific review has been agreed, it is expected that any revisions to the protocol required by the reviewers will be delivered within 5 days from the receipt of the scientific reviewer comments. Failure to deliver a revised protocol by the agreed deadline will be grounds to remove the protocol from the expedited review process.

7. EXEMPTIONS FROM SCIENTIFIC REVIEW

- 7.1. Proposals for research that does not involve HREC approval do not require scientific review
- 7.2. There are no other grounds for exemption from the Scientific Review process.



Appendix 1: SAMRC Scientific Review Submission Cover Sheet

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: _____

Certification by the Unit Director:

I have reviewed the above proposal and am satisfied that it meets acceptable scientific standards and is complete and ready for scientific review. 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: _____

Name of funder (if known): _____

Will SAMRC funds be used: _____

Recommended reviewers:

* Please ensure nominated reviewers meet the reviewer criteria*

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: _____

Appendix 2: SAMRC Scientific Review Checklist

	Item No	Recommendation	Page No
Title and abstract	1	Is the application labelled?	
	2	Provide in the abstract an informative summary of what is planned.	
Are details of the investigators provided?	3	Provide name, title, and e-mail address of principal investigator and co-investigators from each collaborating organisation.	
Introduction			
Background/rationale	4	Has the research been adequately contextualized and has relevant previous work been reviewed?	
Objectives	5	Is the research goal and objectives clearly stated?	
Methods			
Data collection	6	Present key elements of the data collection plan	
Participants	7	Give the eligibility criteria, and the sources and methods of selection of participants	
Data analysis	8	Present key elements of the data analysis plan	
Time chart	9	Present the study's timeline	
Management details			
Management approach	10	Discuss the overall management of the project. Where is managerial responsibility? Consider specific functions such as reporting, financial management, procurement of equipment and research supplies, and management of field activities.	
Staff and scientific collaboration	11	Who will do what, when and where?	

Facilities	12	Describe the facilities and resources available for the proposed research.	
Budget			
Budget	13	Provide full detailed budget for each year. The following headings can act as a guide: Salaries, equipment, its repair and maintenance, materials and supplies, training, consultation, travel, other, indirect costs/overheads.	
Budget justification	14	Explain how the individual items of the budget were calculated. Justify major or unusual expenses.	
Details of researchers	15	CVs (Health Professionals) (non-Health Professionals) and publication lists of all senior personnel involved in the project. NOTE: Only provide qualifications and scientific experience, e.g. publications, projects, presentations. A one-page biosketch with the ten most important references will suffice. Please use the ethics CV template on the SAMRC website.	
Ethical considerations	16	This must address all relevant ethics issues including: details of possible negative consequences to the study participants, information to be given to participants, reporting back procedures to the community/authorities and an example of the consent form to be used.	
Other information			
Are all attachments and appendices included as per Appendix 3?	17		
Is the final submission one document entitled "Protocol" in PDF format?	18		
Have 4 reviewers meeting reviewer criteria been nominated?	19		

Appendix 3: Explanation of Appendices/Attachments

Attachments	Mandatory	Location
Appendix 1: SAMRC Scientific Review Submission Cover Sheet	Yes	Included in the initial submission to scientificreview@mrc.ac.za but not included in the protocol pdf submission. Please send as a separate document.
Appendix 2: Scientific Review Checklist	Yes	Included in the initial submission to scientificreview@mrc.ac.za but not included in the protocol pdf submission. Please send as a separate document.
Appendix 3: Explanation of Appendices/Attachments	No	Do not include in the submission. For your information purposes only.
Researcher CV's	Yes	Included in the initial submission to scientificreview@mrc.ac.za – please insert into the pdf protocol submission labelled as an appendix.
Budget	Yes	Included in the initial submission to scientificreview@mrc.ac.za – please insert into the pdf protocol submission labelled as an appendix.
Information Sheet	Yes	Included in the initial submission to scientificreview@mrc.ac.za – please insert into the pdf protocol submission labelled as an appendix.
Consent Form	Yes	Included in the initial submission to scientificreview@mrc.ac.za – please insert into the pdf protocol submission labelled as an appendix.