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

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| **SOP OWNER** | Executive Scientist for Research Strategy |
| **DEPARTMENT** | Office of the Executive Scientist |
| **STUDY**  | All studies  |
| **VERSION/ REVISION NUMBER**  | Version 2.0 |
| **SUPERCEDES** | Version 1.0 |
| **ELECTRONIC FILE NAME** | SOP for Scientific Review 2.0 |

**HISTORY:**

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| --- | --- | --- |
| **VERSION** | **IMPLEMENTATION DATE** | **CHANGES** |
| Version 1.0 | 1 April 2018 | Initial version |
| Version 2.0 | 8 July 2021 |  |
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## **INTRODUCTION**

### 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.

### 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.

### It is a requirement that proposals are subject to scientific review prior to having other aspects of the ethics of their design considered.

### This SOP outlines the procedures for submission of proposals for scientific review prior to review by the SAMRC Research Ethics Committee.

### 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.

##  PROCEDURES

## STAGE 1 OF SCIENTIFIC REVIEW CONDUCTED WITHIN UNITS

### 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.

### The Unit Director must also 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.

## STAGE 2 OF SCIENTIFIC REVIEW MANAGED THROUGH THE OFFICE OF THE EXECUTIVE SCIENTIST

### Submissions will enter the second stage of scientific review through submission to the email address scientificreview@mrc.ac.za accompanied by the completed Appendices in this SOP. Please take careful note of Appendix 3.

### Emails will be received by Dr. Bianca Dekel who will pre-screen the protocol for 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.

### 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 scientific review was not adequately conducted. Please note: Principal Investigators will need to resend protocols rejected at this stage for incomplete submission as a new submission.

### Dr. Dekel may flag obvious scientific issues for correction before external review is conducted. If there are no obvious problems, scientific reviewers will be approached by Dr. Dekel and the proposal sent to reviewers.

### Administrative action following up on reviews will be conducted by Dr. Dekel.

### Once two reviews are received, they will be collated and sent out to the Principal Investigator by Dr. Dekel.

### 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.

### 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.

### 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 (Adri.Labuschagne@mrc.ac.za).

### 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 as per the requirements stipulated in 2.2.8.

# 3.0. REVIEWER ELIGIBILITY, NOMINATION AND SELECTION

# 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.

# Research proposals that will be funded using SAMRC resources need to be reviewed by researchers external to the SAMRC, I.e. who are NOT SAMRC employees.

# Proposals not financially supported by the SAMRC may be reviewed by qualified employees of the SAMRC. Please note: proposals MAY NOT be reviewed by anyone employed in the same Unit as the Principal Investigator.

# Reviewers with conflicts of interest are ineligible. Conflicts include inter alia: Being colleagues within the same SAMRC Unit/academic department or similar; current doctoral supervisor to the PI or current doctoral student of the PI; close personal relationship (family or friend) with the PI; potential to receive any direct or indirect personal or financial benefit from the success of the proposal.

# All submissions should 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.

# Where the 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.

# The PI may request to exclude potential reviewers, but must provide an explanation for such requests. Such requests will be honoured when practical.

**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 is not a sufficient rebuttal in and of itself. The scientific reasoning underling the rebuttal must be sound enough to satisfy the scientific reviewer or the changes will be required.

**5. PROTOCOL AMENDMENTS REQUIRING SCIENTIFIC REVIEW**

### Major protocol amendments should be treated as per new proposals.

### 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.

### 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. EXPEDITATED SCIENTIFIC REVIEW**

6.1. In exceptional circumstances, the Office of the Executive Scientist can attempt to expedite the scientific review process. Requests for expedited scientific review must be accompanied by a motivational letter explaining the request for an expedited review. The normal grounds for approving such a request will be (A) The PI is proposing to respond to a suddenly-arising and time-sensitive opportunity to conduct research of high importance (for example, project on the health impact of the Covid-19 lockdown) or (B) The PI is facing external deadlines from a donor or similar authority that could not have been reasonably anticipated in advance or where the PI was unexpectedly delayed or impeded by an external party’s failure to deliver. The PI being late for a known or easily anticipated deadline is not a justification for expedited scientific review.

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. However, the Office of the Executive Scientist is unlikely to have full control over whether reviewers hold to their agreement. A request for expeditated review therefore does not guarantee that the review will be completed in time for the next REC meeting.

6.4. Requests for expedited review may be made in advance of protocol submission, with a date and time deadline for the receipt of the full and complete protocol agreed by the Office of the Executive Scientist and the PI. In this case Dr Dekel will attempt to arrange reviewers in advance and pre-book their time, 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. It is expected that the PIs requesting expeditated scientific review regard completion of the protocol as a top work priority. Thus, any revisions to the protocol required by the reviewers MUST be delivered with complete documentation by the date and time agreed as part of the expedited process, which will normally be 5 business 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.

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**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:**

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**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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Appendix 2: SAMRC Scientific Review Checklist**

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|  | Item No | Recommendation | PageNo |
| **Title and abstract** | 1 2 | Is the application labelled? |  |
| 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**

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| **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.  |