



**STANDARD OPERATING PROCEDURE FOR
ESTABLISHMENT AND MANAGEMENT OF
EXTRAMURAL UNITS**

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ABBREVIATIONS

CEO	:	Chief Executive Officer
CV	:	Curriculum Vitae
EMC	:	Executive Management Committee
EMU	:	Extramural Unit
EMU ARR	:	Extramural Unit Annual Research Report
EOI	:	Expression of Interest
HDI	:	Historically Disadvantaged Institutions
IP	:	Intellectual Property
KIMS	:	Knowledge and Information Management Services
PMAO	:	Project & Management Accounting Office
R&D	:	Research and Development
RFA	:	Request for Application
SAMRC	:	South African Medical Research Council
SOP	:	Standard Operating Procedure
SPM	:	Senior Programme Manager
UD	:	Unit Director
VAT	:	Value Added Tax
VP	:	Vice President

DEFINITIONS

Term	Definition
Request for Applications (RFA)	A call for applications for the establishment of new EMUs publicly and disseminated to internal and external SAMRC stakeholders. The request for applications document describes the programme, purpose and the scope and topics covered in the call. It further lists the eligibility criteria, application requirements (application form and supporting documents), assessment criteria, conditions, and the timelines.
Expression of Interest (EOI)	An EOI is a formal document issued by the SAMRC to invite potential EMU Directors to express their interest in the establishment of new EMUs at their host institutions. It is typically used at the initial stage to gauge the interest and capabilities of potential applicants before they can be invited to submit a full application. It is made up of the following sections: proposed name of Unit, summary of proposed research including scientific rationale, research aims and objectives, expected contribution of proposed research, institutional Infrastructure, overview of key Unit members, collaborators, and capacity development plan.
Confidentiality agreement form	A confidentiality agreement form is a form signed by the reviewers as a way of protecting information from the Unit shared with the reviewers. It is an undertaking by the reviewers that they will not disclose confidential information to third parties or misuse the information to their benefit.
Declaration of interest form	A Declaration of Interest form is given to the review panel for any EMU review process to ensure none of the review panel members are conflicted prior to receiving the applications to review.
Quarterly publication outputs	The quarterly publication outputs are journal outputs from the EMUs which are submitted quarterly to the Knowledge and Information Management Services (KIMS) for the SAMRC to meet the statutory requirements to the National Department of Health.
Annual research report (ARR)	The ARR is a report that the EMUs complete annually on a template provided and submitted to the VP office, detailing the Unit's outputs/ activities from the previous year.
Peer Review	Evaluation of the proposed scientific work and applicants by individuals of equal or greater scholarly standing with expertise and experience in the same or similar scientific field to determine the quality, novelty and feasibility of the proposed research and the suitability of the applicant.
5-year review	A 5-year review is a review process that EMUs undergo during the fourth (4 th) or fifth (5 th) year of every 5-year cycle to determine whether the Unit is fulfilling its mandate as per the requirements by the SAMRC.
Scientometric analysis	Scientometric analysis is a report from KIMS that emanates from a list of research outputs submitted by the EMU undergoing a 5-year review. It details an analysis of scientific publications related to the author, h-index, journals, citations, and impact factor.
University representatives	University representatives are members of the host Institution senior management that are invited to the 5-year review meeting to provide information to the review panel about the overall role and standing of the UD at institutional, national, and international levels, the strategic direction of the EMU from a

Term	Definition
	University perspective, and the kind of support as per the EMU contract that the University is providing the EMU.
5-year review documents	The 5-year review documents are documents sent to the review panel inclusive of the following: framework for the review of EMUs, agenda/Order of Proceedings, UD five (5)-year report, 5 best publications from the Unit, UD CV, scientometric Analysis of UD and Unit’s publications record, minutes of Previous Review Meeting (if applicable); and scoring sheet for the reviewers.
Unit Deputy Director (UDD)	The UDD is an appointed individual by the EMU that is SAMRC approved for capacity development purposes and to assist the UD in ensuring that the necessary research infrastructure, and scientific output of the Unit continue past the tenure of the UD without additional funding from the SAMRC. The UDD is neither a replacement of the UD nor will they assume the role of the Unit Co-Director.
Unit Co-Director	A co-Director is an appointed individual by the EMU that is SAMRC approved to aid the UD with both administrative, leadership and strategic duties of the Unit In a rare circumstance when the UD is unable to fully immerse himself/ herself into the leadership duties of the Unit due to a higher Academic appointment. The co-Director is not a replacement of the UD.

1. PURPOSE

- 1.1. This Standard Operating Procedure (SOP) describes the general SAMRC procedures for the establishment, extension/reestablishment, reporting and review of Extramural Research Units (EMU) funded by the SAMRC and hosted at different institutions in South Africa.
- 1.2. EMUs address numerous strategic goals of the SAMRC, and they make valuable contribution to the SAMRC mandate of delivering relevant and responsive health research.
The objective of this SOP is to ensure that the entire process from the establishment of the EMUs to their termination is done in the most effective, fair, transparent, and consistent manner possible and in accordance with all funder and legislative requirements.

2. SCOPE

- 2.1. Approval of EMUs for funding must be in accordance with the SAMRC Delegation of Authority Framework Policy, Collaborative Research Policy, and Supply Chain Management Policies and SOPs, as amended, and all contracting must follow the Contract Management Policy and Framework.

3. ELIGIBILITY CRITERIA FOR APPLYING FOR A NEW EMU

- 3.1. Investigators from South African public universities, science councils and other national public health institute for South Africa. whose responsibility is to coordinate, and where appropriate conduct, disease and injury surveillance, as well as provide for specialised public health services, public health interventions, training and research directed towards the major health challenges affecting the population of the country.
- 3.2. Members of the SAMRC Board of Directors may apply for an EMU, provided they have not participated either directly or indirectly in the EMU selection process as described in this SOP and have declared their conflict of interest.
- 3.3. Application(s) that address(es) relevant priority area(s) as outlined in the RFA.
- 3.4. Any employee of the SAMRC, including EMC members are not eligible to apply for an EMU.
- 3.5. Should an existing EMU holder join the SAMRC as an employee, the incumbent should cease the EMU directorship. In this case, the SAMRC EMC will, in consultation with the hosting institution, decide on the future of the EMU.

4. NEW EMU AWARDING PROCEDURES

4.1. Priority Setting

- 4.1.1. The VP will submit to the EMC recommendations on priority areas for setting-up new EMU(s).
- 4.1.2. The priority areas will among others include, addressing gender and race inequalities, SAMRC strategic objectives, country research needs, building research capacities in the HDIs, etc. or any combination of the priority areas.
- 4.1.3. The EMC-approved areas will serve as the basis for the new EMU call.

4.2. **Request for Applications**

- 4.2.1. Standardized/adapted RFA template relevant to the priority area of the call will be used.
- 4.2.2. Some RFAs may involve a two-step process, namely:
 - a) Submission of full proposal only, or
 - b) Submission of EOI in the first instance and followed by full proposal by those who passed the EOI stage.
- 4.2.3. RFAs are published on the SAMRC website and sent directly to all relevant stakeholders.

4.3. **Responses to the advertised Request for Applications**

- 4.3.1. Completed application forms with required supporting documents will be received by the SPM to screen for eligibility, completeness and capturing on the database.
- 4.3.2. The SAMRC reserves the right to verify any information provided by applicants through any legal channels.
- 4.3.3. Only eligible and complete applications received by the due date (or as extended) will be submitted for EOI review (where applicable) and/or independent peer review process(es).

4.4. **EOI Review Process**

- 4.4.1. This review process is conducted by an Internal review committee inclusive of selected senior SAMRC staff members, VP-ERIP, and the SAMRC President/CEO.
- 4.4.2. The committee base their selection on the alignment of the proposed research areas with the SAMRC's strategic objectives, and potential impact of research in addressing the country's research needs in line with the SAMRC mandate.
- 4.4.3. All applicants are notified of the outcomes of the initial review process, and successful applicants are invited to submit a full proposal for the independent peer review process.

4.5. **Independent Peer Review**

- 4.5.1. SAMRC will appoint a panel of experts relevant to the (combination of) priority area(s).
- 4.5.2. All parties participating in any of the review process(es) will be required to sign confidentiality agreement and declaration of interest form.
- 4.5.3. Reviewers will be expected to evaluate applications based on agreed review criteria and timelines given to submit their results/reports.
- 4.5.4. Recommendation of the panel will be submitted to the EMC.

4.6. **Approval for setting up a new EMU**

- 4.6.1. A selection committee inclusive of selected Senior members of the SAMRC, VP as well as the President/CEO of the SAMRC will deliberate on the peer review outcomes to make their final recommendation to the EMC.
- 4.6.2. EMC is responsible for the first approval of the panel's recommendation.
- 4.6.3. Subsequent approval will be by the R&D committee of the SAMRC Board
- 4.6.4. Final approval of the EMU will be given by the SAMRC Board
- 4.6.5. SAMRC decision should be communicated to all applicants irrespective of the outcome.
- 4.6.6. Once approved, the SAMRC may award:
 - a) Full EMU, in case where submissions score at least 3.5 out of 5 or
 - b) Partial EMU, in case where submissions score at least 3.0 out of 5.

5. REPORTING

- 5.1. EMU UD's must timeously submit quarterly publications outputs and the EMU ARR as and when requested by the Knowledge Information Management Services (KIMS) and VP office of the SAMRC respectively.
- 5.2. The SAMRC requires all EMUs to list their SAMRC affiliation, either as primary or secondary affiliation, in all outputs (publications, presentations, posters and reports).
- 5.3. All relevant outputs should acknowledge SAMRC funding as follows: "Research reported in this [publication/press release] was [partly] supported by the South African Medical Research Council."
- 5.4. Any outputs that do not affiliate with- and/or acknowledge the SAMRC cannot be accepted for reporting and incentivized performance allocation purposes.

6. EMU 5-YEAR REVIEW PROCESS

- 6.1. Planning Phase
 - 6.1.1. Reviews normally take place in the fourth or fifth year of each funding cycle and EMU UD's will be notified at least 6 months before the review date.
 - 6.1.2. Review panel will comprise a of mixture of local and international reviewers sourced by the SAMRC and some recommended by the EMU UD.
 - 6.1.3. For the period under review, the EMU UD should submit a list of UD's and EMU's publications record (at least 3 months before the review date), UD's CV and a review report (at most 1 month before the review date).
 - 6.1.4. KIMS will do verification and Scientometric analysis on the UD's publications record and Units publications.
 - 6.1.5. EMU hosting institution representatives are invited to the meeting to provide information to the panel about the overall role and standing of the UD and EMU at the institutional, national and international levels, the strategic direction of the EMU from a University perspective, and the support as per the EMU contract that the University is providing to the EMU.
 - 6.1.6. The review panel comprises a chairperson, three or four external experts in the field (at least one of whom should be an international expert) and representatives from the SAMRC.
 - 6.1.7. The VP is an ex-officio member of the panel, while the SPM and other SAMRC staff are responsible for organising the review.
 - 6.1.8. The SAMRC makes all the necessary arrangements and supports all the costs regarding travel and accommodation for the Chairperson, SAMRC staff and reviewers.
 - 6.1.9. Review documents are sent to external reviewers at most a month prior to the review date.
- 6.2. Meeting Phase
 - 6.2.1. The UD is required to present the major successes of the Unit over the reporting period and highlight those with the most significant health/scientific impact.
 - 6.2.2. Other researchers in the EMU are also expected to present their specific research activities and findings to the committee.
 - 6.2.3. Minutes of the review proceedings are taken by the secretariat.
 - 6.2.4. Panel members will submit their score sheets to the Chairperson and the secretariat.
 - 6.2.5. Post the review, the Chairperson will compile a comprehensive Draft Review Report and shares the same with the review panel for concurrence, and thereafter discuss it with the office of the VP before finalization.
 - 6.2.6. The final Review Report detailing the recommendations from the review panel is submitted to the EMC for approval, and to R&D committee and the Board for noting.

- 6.2.7. The final report and EMC decision should be communicated to the host institution and the UD within six (6) months after the review.

7. APPOINTMENT OF UNIT DEPUTY DIRECTOR/CO-DIRECTOR

- 7.1. The proposal for appointment of UDD/ Co-Director will be motivated by the UD.
- 7.2. EMC will assess whether the proposed candidate is suitable to be appointed as the UDD/CO-Director within the EMU.
- 7.3. The UD will still be the ultimate authority in charge of the EMU and accountable to the SAMRC.

8. REQUEST FOR EXTENSION / RE-ESTABLISHMENT OF EXISTING EMUS

- a. EMUs will be closed down at the end of 15-year lifespan.
- b. Continuation beyond a 15-year lifespan, either as an extension or re-establishment of existing EMU, may only be considered in exceptional circumstances.
- c. The SAMRC or hosting institution could propose either extension or re-establishment of existing Unit.
- d. However, there will be no open RFA, applications will be by invitation.

8.1. Process for extending existing EMUs

- 8.1.1. Should the EMU be invited to submit an application for Extending the existing Unit, the proposed research direction should clearly link back to the original research mandate of the Unit, show progress, not a duplication of the previous aims, and clearly describe the significance of the renewal in the larger science and health context.
- 8.1.2. The application is sent for an independent peer review.
- 8.1.3. EMC is responsible for the first approval of the panel's recommendation.
- 8.1.4. Subsequent approval will be by the R&D committee of the SAMRC Board
- 8.1.5. Final approval of the EMU will be given by the SAMRC Board
- 8.1.6. The SAMRC decision should be communicated to all applicants irrespective of the outcome.
- 8.1.7. If the application is approved, the SAMRC will approve the extension for a maximum of 5 years (i.e. only one term).
- 8.1.8. All other SAMRC administrative and governance rules for EMUs apply during this period.

8.2. Process for the re-establishment of existing EMUs

- 8.2.1. Re-establishment of existing EMUs is intended for Units that performed extraordinarily over time and may wish to continue with the SAMRC status with a significantly expanded or amended research mandate post the initial 15-year lifespan.
- 8.2.2. Should the EMU be invited to submit an application for re-establishing the existing EMU, a new application in the 14th year or as advised by the SAMRC is submitted, clearly articulating the expanded research scope or deviation from the original mandate when the Unit was initially applied for.
- 8.2.3. The application is sent for an independent peer review.
- 8.2.4. EMC is responsible for the first approval of the panel's recommendation.
- 8.2.5. Subsequent approval will be by the R&D committee of the SAMRC Board
- 8.2.6. Final approval of the EMU will be given by the SAMRC Board
- 8.2.7. If the application is approved, the SAMRC will approve the extension for a maximum of 15 years (i.e. three (3) terms) subject to satisfactory performance.
- 8.2.8. The SAMRC decision should be communicated to all applicants irrespective of the outcome.
- 8.2.9. All other SAMRC administrative and governance rules for EMUs apply during this period.

9. TERMINATION OF THE SAMRC EMU STATUS BEFORE REACHING 15-YEAR LIFESPAN

Termination of SAMRC EMU status may take place under the following circumstances:

- 9.1. When the research conducted in the Unit is in breach of the regulations that apply to research integrity or research ethics, or any regulatory, legislative and institutional guidelines governing research;
- 9.2. When the Unit fails to deliver on its mandate or to demonstrate satisfactory productivity, as judged by the first, second or any other review process; and
- 9.3. Due to non-availability of funding from the SAMRC.
- 9.4. If at any time during the contract term the SAMRC decides the contract should be terminated, the SPM in consultation with the VP must submit a recommendation to EMC for final decision making.
- 9.5. Contracts may only be terminated in accordance with the termination provisions set out in the contract and in consultation with Legal Services.
- 9.6. If during the term of the contract the UD leaves the institution for whatever reason, the UD must inform the SAMRC in writing to initiate the way forward and/or to nominate a possible successor through a detailed succession plan.
- 9.7. The EMC will evaluate the succession plan/ proposed way forward and determine if an interim UD needs to be appointed, the nominated person meets the minimum requirements to submit a full application for peer review, or if the grant needs to be terminated.
- 9.8. The rotation of Directors or automatic handover of the EMU to a Unit Deputy Director or any other scientist is not permitted by the SAMRC, unless the handover is approved by the SAMRC EMC based on the scientific status of the nominated person.
- 9.9. The Unit will also be terminated when the UD retires (at age 65, or according to the retirement policy of the institution involved), resigns, or is unavailable to work for any other reason for an extended period. In this case, the SAMRC-associated funding shall terminate within 6 months of such an event unless the UD or institution present a proposal and succession plan that is satisfactory to and approved by the SAMRC.

10. CONTINUATION/ NO-COST EXTENSION AFTER THE LIFESPAN OF EMUS

- 10.1. A continuation/ no-cost extension will be given to allow the continuation of high performing EMUs post their 15-year term as an EMU.
- 10.2. The continuation/ no-cost extension will only be by EMC invitation for high performing Units (*who have reached their 15-year lifespan, or those that are at a point of closure due to the UD having reached retirement age prior to reaching their 15-year term*) that have demonstrated one or all of the following criteria:
 - Public health significance of the EMU research in the lifespan of the Unit;
 - Scientific excellence and research stature of the UD demonstrated by national and international recognition for his/her scientific contributions;
 - Demonstrated research innovation in the lifespan of the Unit;
 - Outstanding quantity and quality of research outputs in the lifespan of the Unit;
 - Diverse team members who have appropriate training and experience and have contributed to advances in their field;
 - Impact of the Unit on capacity development imperatives with a focus on diversity and gender parity;
 - Ability to leverage external funding relative to SAMRC baseline funding which is more than 50 million in the Unit's last 5 years of existence.

10.2.1. Special conditions for a no-cost extension

- The no-cost extension will be for a further 5-year period only without any funding.
- The Unit will continue to be recognised as an SAMRC EMU.
- The Unit will continue to benefit from all other EMU related funding such as the EMU Postdoc funding and continue to have close proximity to funding from other SAMRC funding structures.
- The EMU will continue to have all other administrative support afforded to all the EMUs and continue to remain part of the SAMRC community.

10.2.2. Special conditions for a continuation

- The continuation of an EMU will be for a further 5-year period only.
- The EMU will receive half the baseline funding (R500 000) per annum only for a period of 5 years.
- The Unit will continue to be recognised as an SAMRC EMU.
- The Unit will continue to benefit from all other EMU related funding such as the EMU Postdoc funding and continue to have close proximity to funding from other SAMRC funding structures.
- The EMU will continue to have all other administrative support afforded to all the EMUs and continue to remain part of the SAMRC community.

11. RESOLUTION OF DISPUTES, OBJECTIONS, COMPLAINTS AND QUERIES

- 11.1. The SPM is responsible for resolving any complains failing which the matter must be officially escalated to the VP.
- 11.2. Should the VP not be able to resolve the dispute or complaint, the matter must officially be escalated to the EMC.
- 11.3. The President may appoint an independent and impartial person(s)/organisations not directly involved in the specific grant making and management process, to resolve disputes between the contracting parties.
- 11.4. The President, or another official designated by him/her, is responsible for assisting the appointed person(s)/organisations to perform his or her functions effectively.
- 11.5. The person(s)/organisations so appointed must strive to resolve promptly all disputes, objections, complaints or queries received and report to the President on such.
- 11.6. Outcomes of the resolution must be formally communicated with the EMU concerned.

12. MONITORING AND REVIEW OF THIS SOP

- 12.1. The SPM in consultation with the VP is responsible for monitoring and reviewing the implementation of this SOP and making recommendations for changes to minimise risks to the SAMRC's operations and reputation.
- 12.2. This SOP shall be reviewed and updated/amended from time-to-time, as required.

13. SOP APPROVAL/VERSION CONTROL

Drafted by: Dr Refiloe Eunice Zwane

EMC Approval: Prof Liesl Zühlke

Date: 26 March 2024