



# **Institutional Research Committee**

**State Health Systems Resource Centre Kerala**

## **Standard Operating Procedure (SOP)**

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**STANDARD OPERATING PROCEDURES FOR  
INSTITUTIONAL RESEARCH COMMITTEE  
STATE HEALTH SYSTEMS RESOURCE  
CENTRE-KERALA**



**State Health System Resource Centre- Kerala  
2024**

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# STANDARD OPERATING PROCEDURES

## FOR INSTITUTIONAL RESEARCH COMMITTEE

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### **1. Scope**

The Institutional Research Committee (IRC) SHSRC-K has been constituted vide SHSRC-K order no: Admin/523/2016/SHSRC dated 04/03/2022 to put in place an effective and consistent scientific review mechanism for public health & biomedical research proposals submitted by various research investigators in their area of interest.

### **2. Functions**

The IRC SHSRC-K has the overall responsibility of reviewing, approving and monitoring of all the research projects submitted for review by the investigators and discuss all the scientific and methodological issues related to it.

The main aim of the committee is to review the scientific merit, rationale of the study and feasibility, scientific design and methodology, data quality and security, safety & progress of each proposal from the perspective of the welfare of human participants involved.

### **3. Composition**

The Executive Director, SHSRC-K who is the Chairperson of IRC shall constitute IRC with a minimum strength of 8 members. The IRC shall be multi-institutional in nature and shall adequately represent age, gender etc.

The Chairperson is responsible for the conduct of the IRC meeting. The Convener, drawn from SHSRC-K itself, shall organize the meeting, maintain the records and communicate with all the concerned. At least 50% of the members shall be from outside SHSRC-K, preferably from the local premier institutions like Government Medical College(s), Sree Chitra Thirunal Institute of Medical Sciences and Technology etc., to ensure a fair and scientific evaluation of the proposals submitted by the investigators. A minimum of one biostatistician and one epidemiologist shall be included in the IRC.

#### **4. Term of office**

Once constituted, the term of office of the IRC shall be for a period of three years from the date of constitution.

#### **5. Membership duration and responsibilities**

- a. The duration of the membership of each IRC member shall be for a maximum of three years.
- b. There will be no bar on the members serving for more than one term with the condition that 25% of IRC members shall be fresh members.
- c. A member can be replaced in the event of absence in three consecutive IRC meetings. Authority to replace a member shall vest with the Chairperson of IRC.
- d. All members shall furnish their Curriculum Vitae (CV) immediately after the formation of IRC (see Annexure I).
- e. The members shall maintain confidentiality of documents submitted to them for review.
- f. Conflict of interest, if any, shall be declared by members of the IRC at the beginning of every meeting.
- g. Each member attending an IRC meeting is eligible for a sitting fee as decided by SHSRC-K

#### **6. Quorum requirements**

Half the strength of the IRC is required for conducting every meeting. All decisions should be taken in the meeting and not by the circulation of project proposals via e-mail or other modes of communication. Only in cases of unavoidable circumstances, virtual meetings shall be conducted.

#### **7. Independent consultants**

The IRC may call upon subject experts as special invitee for the review of selected research proposals. These experts may be from outside the institute and have sufficient expertise on the concerned research proposals submitted to them. They will not take part in the decision-making process but are eligible for consultation fee as decided by SHSRC-K.

## **8. Application procedure**

When submitting a research proposal to the State Health Systems Resource Centre - Kerala (SHSRC-K), it is essential to adhere to the outlined application procedure.

- a. All the proposals shall be submitted in the prescribed format, available on the SHSRC-K website and send to [irc.shsrc@shsrc.kerala.gov.in](mailto:irc.shsrc@shsrc.kerala.gov.in)
- b. All relevant documents should be enclosed with the proposal as per the check list (see annexure II).
- c. The date of IRC meeting will be intimated to the Principal Investigator via e-mail.
- d. Each research proposal shall be accompanied by the applicable fee as prescribed by SHSRC – K periodically.
- e. The decision of IRC will be communicated via e-mail within two weeks to the Principal Investigator. If any revision is to be made, the revised proposal shall be submitted by the PI within the time stipulated by the Research Committee.

## **9. Review procedure**

- a. When sufficient number of proposals is submitted for review, the process for convening the IRC meeting shall be initiated. A minimum of 5 proposals are needed for conducting an IRC meeting.
- b. The agenda & proposals shall be sent to the members at least two weeks in advance.
- c. The Principal Investigator shall present the proposal before the IRC. In case, PI is not available during the meeting, he/she can authorize one of the Co- investigators to present the proposal before the committee.
- d. The decisions of the meeting shall be recorded in the minutes book and shall be confirmed during the next meeting with the signature of the Chairperson on each page or by acknowledging the information mailed.
- e. IRC shall review the rationale, aim, methodology and the robustness of each of the proposal in detail.
- f. After discussion the committee shall take a decision regarding approval of the proposal. The decision may be any of the following:-



- i. Approve as submitted
- ii. Approve with minor modification.
- iii. Resubmit after major modifications.
- iv. Reject the proposal.

The decision shall be made irrespective of whether the Principal/ Co-investigators are present or not.

- g. In case modifications are suggested, specific recommendations shall be communicated to the PI mentioning the time line within which the modified proposal shall be resubmitted.
- h. In case a proposal is rejected by IRC, the reasons for rejection shall be communicated to the PI by the Convener of the IRC.
- i. Each IRC member shall follow-up studies which are specifically allotted to them for further corrections and monitoring.
- j. Soft copy of final approved proposal along with the tools, consent forms etc. shall be sent to **irc.shsrc@shsrc.kerala.gov.in**. A spiral bound hard copy of the same shall be submitted to the Convener, IRC. The hard copy shall also include the IRC approval letter.
- k. Flow chart for submission of research proposal is attached as Annexure III.

## **10. Procedures of resubmitted proposal**

For proposal resubmitted with minor modifications for approval, the modified proposal shall be submitted to the IRC Convener, who shall accord sanction after verifying that all necessary modifications are made.

For proposal resubmitted with major modifications for approval, they shall be submitted to the IRC convener and to the member who is in charge of reviewing that particular proposal, after necessary modifications made. The Convener shall issue sanction after obtaining the approval from the concerned IRC member.

## **11. Record keeping and archiving**

The Convener of the IRC shall be responsible for the safe custody of the following records.

- a. Curriculum vitae (CV) of all members of IRC
- b. Minutes of all the meetings duly signed or acknowledged via mail by the Chairperson.

- c. Copy of all the correspondence with members, investigators etc.
- d. Copy of all the existing relevant documents of the IRC norms and research proposals.
- e. Copy of manuscript, accepted/published reprints of the research papers.



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## 12. Annexures

### I. CV For Members of the Research Committee

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1	Name			
2	Sex			
3	Date of Birth (mm/dd/yyyy)			
4	Email Address (Personal & Official)			
5	Telephone (Office)			
6	Mobile Number			
7	<b>Academic Qualifications (Most current qualification first)</b>			
	<b>Degree/Certificate</b>	<b>Year</b>	<b>Institution/University</b>	
a.				
b.				
c.				
d.				
8	<b>Professional Experience</b>			
	<b>Month and Year</b>	<b>Title</b>	<b>Institution/University</b>	
a.				
b.				
c.				
d.				
9	<b>Publication Experiences</b>			
	<b>Month and Year</b>	<b>Title</b>	<b>Journal</b>	
a.				
b.				
c.				
d.				

Signature:

Date:

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## *II. Format of proposal submission*

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When preparing and submitting research proposals, researchers are advised to adhere to the following guidelines to ensure a thorough and successful submission, and to facilitate a systematic process for proposal review.

1. Title of the proposed research
2. Problem Statement with rationale of the proposed study
3. Research question
4. Study Objectives (both primary and secondary)
5. Methodology including
  - i. Study design
  - ii. Study setting
  - iii. Study population (inclusion and exclusion criteria)
  - iv. Sample size estimation and sampling strategy (detailed justification of sample size)
  - v. Study duration
  - vi. Study tools and instruments
  - vii. Method of data collection
  - viii. Project implementation plan
  - ix. Design of statistical analysis
6. Expected outcome (both primary and secondary expected outcomes should be mentioned)
7. Ethical considerations
8. Timelines with achievable targets -Include Gantt chart
9. Budget (expected expenditure under different heads)

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### III. *Flow chart for submission of projects by the Principal Investigators*

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