


APPLICATION FORM FOR INITIAL REVIEW

 Garissa University	APPLICATION FORM FOR INITIAL REVIEW ISERC Ref. No. (for office use):
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General Instructions: a) Tick one or more as applicable. Mark NA if not applicable
 b) Attach additional sheets if required

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

- (a) Name of Organization:
 (b) Name of the Ethics Committee:
 (c) Name of Principal Investigator:
 (d) Department/Division: (e) Date of Submission: [Click here to enter a date.](#)
 (f) Type of review requested:
 Exemption from Review Expedited Review Full Committee Review
 (g) Title of the study:
 Acronym/ Short title, (If any):
 (h) Proposal number(If any): Version number:
 (i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication
Principal Investigator/Guide			
Co-investigator/student/fellow			

- (j) Number of studies where applicant is a:

i) Principal Investigator at time of submission:

ii) Co-Investigator at time of submission:

(k) Duration of the study:

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget:

(b) Self-funding Institutional funding Funding agency
(Specify)

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH	
(a)	Summary of study (in simplest way possible for a common man) (300 words)
(b)	Type of study: Basic Sciences <input type="checkbox"/> Case study <input type="checkbox"/> Any others (Specify) <input type="checkbox"/>
4. METHODOLOGY	
(a)	Sample size/ No. of Participants (as applicable) Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation
(b)	How will the scientific quality of the study be assessed? Independent external review <input type="checkbox"/> Review by Sponsor/Funder <input type="checkbox"/> Review within PI's institution <input type="checkbox"/> Review within multi-centre research group <input type="checkbox"/> No Review <input type="checkbox"/> Date of review: _____ Click here to enter a date. Comments of Scientific Committee, if any(100 words)
SECTION C - PARTICIPANT RELATED INFORMATION	
5. RECRUITMENT AND RESEARCH PARTICIPANTS	
(a)	Who will do the recruitment? PI/ Co PI <input type="checkbox"/> Research team <input type="checkbox"/> Local/ institutional administration <input type="checkbox"/> Telephone <input type="checkbox"/> Others(Specify) <input type="checkbox"/>

(b)	i. Will there be vulnerable person/special groups involved? Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>					
	Children under 18 yrs <input type="checkbox"/>		Pregnant or lactating women <input type="checkbox"/>			
	Differently abled (Mental/Physical) <input type="checkbox"/>		Elderly <input type="checkbox"/>			
	Refugees/Migrants/Homeless <input type="checkbox"/>		Institutionalized <input type="checkbox"/>			
Any other (<i>Specify</i>) <input type="checkbox"/>						
ii. If yes, type of vulnerable person /special groups						
iii. Provide justification for inclusion/exclusion						
iv. Are there any additional safeguards to protect research participants?						
(c)	Are there any incentives to the participant? Yes <input type="checkbox"/>					
No <input type="checkbox"/>						
If yes, Monetary <input type="checkbox"/> Non-monetary <input type="checkbox"/> Provide details						
(e)	Are there any participant recruitment fees/ incentives for the study provided to the PI/ Institution? Yes <input type="checkbox"/>					
No <input type="checkbox"/>						
If yes, Monetary <input type="checkbox"/> Non-monetary <input type="checkbox"/> Provide details Yes <input type="checkbox"/>						
6. BENEFITS AND RISKS						
(a)	i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes <input type="checkbox"/> No <input type="checkbox"/>					
	<input type="checkbox"/> If yes, categorize the level of risk: Less than Minimal risk <input type="checkbox"/> Minimal risk <input type="checkbox"/> Minor increase over minimal risk or Low Risk <input type="checkbox"/> More than Minimal Risk or High Risk <input type="checkbox"/>					
ii. Describe the risk management strategy:						
(b)	What are the potential benefits from the study?	Yes	No	If yes,	Direct	Indirect
	For the participant	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

For the society/community	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
For improvement in science	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please describe how the benefits justify the risks				

7. INFORMED CONSENT

(a) Type of consent planned for:

Signed consent Verbal/ oral consent Witnessed consent Audio-Video (A/V) consent

For children <7 yrs parental consent Verbal assent from minor (7-12 yrs) along with parental consent Written Assent from Minor (13-18 yrs) along with parental consent

Other (specify)

(b) Who will obtain the informed consent?
 PI/Co-PI Research Staff Other (specify)

Any tools to be used (Describe)

(c) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

Simple language Data sharing Statement that consent is voluntary

Risks and discomforts Need to recontact Commercialization/benefit sharing

Alternatives to participation Confidentiality Right to withdraw

Return of research results Payment for participation Statement that study involves research

Benefits Use of photographs/ identifying data

Study Purpose Contact information of PI and Member Secretary of ISERC

Others(Specify)

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures?
 PI Institution Sponsor Other agencies(specify)

(b)	Is there a provision for free treatment of research related injuries? NA <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes, then who will provide the treatment?			

9. STORAGE AND CONFIDENTIALITY

(a) Identifying participant's Information: Study Involves samples/data. If Yes, Specify Yes
No NA

Anonymous/unidentified Anonymized: reversibly coded Irreversibly coded Identifiable

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited / data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.)

(b) Who will be maintaining the data pertaining to the study?

(c) Where will the data be analyzed (e.g. protected computer, data entry room) and by whom?

(d) For how long will the data be stored?

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? If yes, specify. Yes No
NA

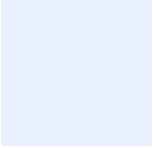
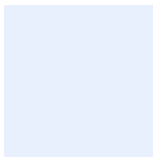
(b) Will you inform participants about the results of the study? Yes No
NA

(c) Are there any arrangements for continued provision of the compassionate intervention for participants, if effective, once the study has finished? If yes describe in brief (*Max 50 words*)
Yes No NA

- (d) Is there any plan for post research benefit sharing with participants? If yes, specify Yes No
 NA
- (e) Is there is any commercial value or a plan to patent/Intelectual Property Rights issues. If yes, Please provide details Yes
 No NA
- (f) Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide the details. Yes
 No

SECTION E: DECLARATION AND CHECKLIST

11. DECLARATION (Please tick as applicable)	
<input type="checkbox"/>	I/We certify that the information provided in this application is complete and correct.
<input type="checkbox"/>	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
<input type="checkbox"/>	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines including responsible.
<input type="checkbox"/>	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
<input type="checkbox"/>	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
<input type="checkbox"/>	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the ISERC approved protocol.
<input type="checkbox"/>	I/We declare that the expenditure in case of injury related to the study will be taken care of.
<input type="checkbox"/>	I/We confirm that we shall submit any protocol amendments, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.
<input type="checkbox"/>	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
<input type="checkbox"/>	I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples.
<input type="checkbox"/>	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.

<input type="checkbox"/>	I/We have the following conflict of interest (PI/Co-PI): 1. 2.
<input type="checkbox"/>	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.
Name of PI:	Signature:  Click here to enter a date.
Name of Co-PI:	Signature:  Click here to enter a date.

12. CHECKLIST

S.No	Items	Yes	No	NA	Enclosure No.	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1.	Cover letter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2.	Brief CV of all Investigators	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3.	Approval of Scientific Committee	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4.	ISERC clearance of other centers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5.	Agreement between collaborating partners	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
6.	Copy of contract or agreement signed with the sponsor or donor agency (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
7.	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ISERC for proposed study (whether in same location or elsewhere) and modification(s) to protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
PROPOSAL RELATED						
8.	Copy of the detailed protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
9.	Participant Informed Consent Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
10.	Assent form for minors (12-18 years)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

11.	Questionnaire / Interview guides/ Guides for Focused Group Discussions (FGDs)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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