INSTITUTIONAL ETHICS COMMITTEE KHPT

APPLICATION PROCEDURES

1. All proposals will be submitted on any working day (**Monday- Friday 9 AM-5 PM IST**) in the Department of Health Research (DHR), Government of India (GoI) prescribed **KHPT IEC Application Form** (refer *F1_KHPT IEC Application Form*), the details of which are given depending on type of study such as academic/investigator initiated etc. Please note that only the **PI of the Study** should write a mail to the Member Secretary, IEC KHPT at khpt.ecsecretary@khpt.org attaching all relevant documents and clearly mentioning in the subject line – "Application for EC Review- Short Study Title"

2. All research proposals (2 hard copies and 1 soft copy) shall be submitted along with the information and documents as specified in the KHPT IEC Application Format. **Hard Copies should reach** KHPT office addressed to the **Member Secretary-IEC KHPT** within **Seven days of applying online/mail**.

3. Copy of SOP of KHPT -IEC will be given on request to PI/Co-investigators (Co-PI)/Guide if he/she has applied for review for the first time will who in turn bring it to the notice of investigating team.

4. All relevant documents will be enclosed with application form by PI as per DHR checklist and guidelines for PI. Following are documents to be sent as part of the initial application to IEC KHPT for review.

   a) Covering Letter (on institutional letterhead and signature)
   b) F1_KHPT IEC Application Form
   c) F2_Participant Information Sheet (PIS) & Informed Consent Form (ICF)*
   d) Brief CV of the PI and Co PI (refer Annexure-13 F1_KHPT IEC Application Format)
   e) Copy of an email from the donor on the confirmation of the study
   f) Copy of a detailed Study Proposal
   g) Study Tools
   h) GCP Training Completion Certificates for PI and Co-PIs.

   [*PI can prepare and have their own institutional PIS and ICF referring the KHPT's format recommended in F2_PIS and ICF]

5. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the (PI) and Collaborators/Research Sposnorships to be submitted to the office of IEC KHPT and the same will be acknowledged.

6. Every application will be allotted an IEC registration number to be used for all future correspondence and reference.

7. The date of KHPT -IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation using power point slides of the proposal and to clarify the points raised by the members.

8. Applicants are required to mention specific ethical issues separately in their application to be approved by the IEC.

9. The decision of the committee on the proposal will be communicated in writing through a decision letter within a maximum of **six weeks from the date of application**.

10. If revision is to be made, the revised document in required number of copies will be submitted within a stipulated period as specified in the communication on/or before the next meeting.

11. All research proposals/studies involving human subjects funded/sponsored etc., will be charged an administrative fee/processing fee/as specified by the Office of IEC KHPT. This will be intimated to the PI by the member secretary in response to the application. Waiver of these fees is permissible for studies funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, WHO etc. A total of approximately 15-20% of total IEC administrative fees needs to be paid as institutional service charges for maintenance. In general, **waiver of administrative fee will be at the discretion of KHPT-IEC/CEO KHPT**.

REVIEW PROCEDURES

1. The meeting of the KHPT-IEC will be held at periodic intervals or every quarter. Additional review meetings can also be held on short notice as and when required. Meetings will be scheduled in accordance with the needs of the workload.
2. Virtual meeting will be conducted if felt necessary for expedited review or due to COVID-19 or any other public health emergencies.
3. The IEC's member-secretary/secretariat shall screen the proposals for their completeness and, depending on the risk involved, categorise them into three types, namely:
   a] exemption from review, b] expedited review and c] full review
   [PI will be intimated the reasons/justification for such categorisation and necessary steps required thereafter**]**
4. Decisions will be taken by consensus after discussion and voting when necessary.
5. Investigators/researchers may be invited to offer clarifications if need be.
6. The PI will present the proposal in person at the IEC meeting. When the PI is not available due to unavoidable reasons, the Co-PI will present the proposal.
7. Independent consultants/subject matter experts may be invited to offer their opinion on specific research proposals whenever needed.

PLEASE MAKE USE OF FOLLOWING **ANNEXURES** in the **F1_KHPT IEC APPLICATION Form**

Annexure-1 Application for Expedited Review
Annexure-2 Application form for Exemption from Review
Annexure-3 Continuous Review/Annual Report Format
Annexure-4 Application form for Amendments
Annexure-5 Protocol Violation/Deviation Reporting Form
Annexure-6 Serious Adverse Event Reporting Form
Annexure-7 Premature Termination/Suspension/Discontinuation Report
Annexure-11 Application form for Socio-Behavioural Public Health Research
Annexure-12 Study Completion/Final Report Form
Annexure-13 PI/Co-PI CV Format