

# Standard Operating Procedure of Institutional Review Committee, Kanti Children's Hospital

## Submitting the Application

Individuals or institutions desirous of conducting health research in Kanti Children's Hospital (KCH) are required to submit their health research proposal to IRC of KCH.

## Application Submission

1. The Principal Investigator (PI) and/or the one responsible for the health research will submit the health research proposal for review.

### Application Requirements Include

- a) Application: Application should be addressing to the Member Secretary of IRC
- b) Format for Application: Application should be submitted in the format provided by IRC. The prescribed format can be accessed from the website ([www.kantichildrenhospital.gov.np](http://www.kantichildrenhospital.gov.np)) of KCH or a hard copy can be obtained from IRC office.
- c) Application should include one hard copy and an electronic copy of the proposal to be sent via email to [irckanti@gmail.com](mailto:irckanti@gmail.com).
- d) Only those applications fulfilling the requirements will be accepted for review. Deficits in the application shall be informed to the applicants after administrative review. Incomplete applications will have to be resubmitted.
- e) Application Fee: Applications should be submitted along with processing fee as per IRC rule/ decision made by the Executive Board of IRC. The banking details are :-

Name of Bank: **Himalayan's Bank LTD**

SOP IRC KCH 2<sup>nd</sup> amendment 3 May 2020

Branch: Maharajgunj, Kathmandu

Account Holder's Name: Institutional Review Committee Kanti Children's Hospital

A/C No: 00203042970016

- f) Amendments: If any amendments are made in the proposal already submitted and approved, the researcher must submit in writing the changes made with reasoning. The proposal will be reviewed again in the IRC, taking the amendments into consideration during the re-approval process.
- g) Documentation Requirements for the Application- All the documents that are required by the IRC for a process of review and approval should be submitted along with the application. If any additional documents are required during the review process, the researcher will be notified by IRC.
- h) The application form should be submitted with the signature and date of submission using the IRC format.
- i) Application must include the most current version of the curriculum vitae of the Principal Investigator and co-investigators with special mention of academic qualification and research experiences
- j) Application must include the protocol of the proposed research project in the provided format together with the supporting documents. (A copy of research tools, questionnaires etc )
- k) A copy of informed consent form should be included in the application. This should include a detail description of the process of giving the information to the research participant and its content, process of obtaining the consent, the person responsible for obtaining the informed consent and documentation of the signature of the researcher/research participant and /witness if applicable.
- l) A signed statement by the researcher stating that he or she will abide by the ethical principles of research
- m) Information about any previous submission of this application to IRC of KCH or any other Institutional Review Committee and the result of such submission in the past

will have to be provided along with the application

### **Ethical Review Process**

The IRC will review all the submitted health research proposals in a timely manner and in accordance with the set review process

### **Meeting of the IRC**

The meetings of the IRC will be held on a regularly scheduled date that will be announced in advance. The General Secretary of IRC with the permission of the Chairman of the IRC will call the meeting. Meeting will take place at least once a month most preferably first week of the month.

1. Meeting will be chaired by chairperson . if chairperson has declared the conflict of interest , that meeting will be chaired by the eldest member who is present on that meeting.

The followings are considered as applicable for an IRC meeting:

- a) The meeting of IRC will be planned in accordance with the workloads and number of proposals received for review. Normally, IRC will meet once a month.
- b) IRC members will be informed about the meeting at least 72 hours prior to the scheduled date
- c) If felt necessary by the IRC, the applicant researcher or sponsor of the research can be invited to present the proposal or elaborate on specific issues of the proposal. Similarly, if necessary, experts can also be invited to the meeting for expert opinion about the research
- d) Minutes will be kept of all decisions and procedures of the meeting
- e) All the members and invitees present in the meeting should sign the minutes to indicate their presence

### **Elements of the Review Process**

1. After verifying the documents needed for the research proposal, Administrative Officer will give it to the general secretary of IRC.
2. General Secretary will allocate the reviewer for each proposal depending upon the subject of expertise. The reviewer can either be a member of IRC or an expert identified from outside IRC member.
3. After reviewing the proposal, the reviewer will submit it to the Administrative Officer.
4. Administrative Officer will take it to the IRC board.
5. Reviewer will brief about the research proposal. (If reviewer is from outside the IRC member, General secretary of IRC will brief about the research proposal )
6. The proposal will be discussed in full board IRC meeting for ethical review. IRC Board will decide on the acceptance of the paper for research.
7. The decision will be either –
  - acceptance,
  - conditional acceptance or
  - denial.
8. The IRC will make the decision only if the meeting has met required quorum
  - a) Normally the decision will be taken by consensus, (if consensus is not possible then a vote will be taken)
  - b) The IRC member should withdraw from the decision process when conflict of interests arises; the member should declare the conflict of interest.
  - c) The IRC may approve the proposal conditionally with specific suggestions to the researcher
  - d) The negative decision on a proposal should be supported by clearly stated reasons
9. If the applicant is the committee member, he/she can participate in the committee member but he will not have voting right in that particular agenda.
10. On behalf of the IRC, the Administrative officer will communicate its decision to the applicants in writing within two weeks after the meeting.
  - a. If the proposal is accepted by IRC meeting, an acceptance letter will be issued to the applicant.

- b. In case of denial/refusal, a letter will be issued to the researcher mentioning the reason behind the refusal of proposal.
  - c. In case of Conditional Approval, Administrative Officer will contact the concerned researcher and ask for the submission/modification of necessary documents. After the conditional criteria are fulfilled, AO will issue the letter of acceptance.
11. All letter related to ethical clearance will be issued with signature of general secretary. If General Secretary has declared the conflict of interest, that letter will be sign by the other member who is identified by the committee. This member will also serve as delegated role of general secretary in his absence.
12. Other administrative letter will be issued by the administrative officer with coordination with the general secretary.

**Processing time:**

Usually there will be at least one meeting in each month preferably first week of the month. The application will not be pending for more than a month except in special circumstances.

**Documentation and Archiving**

A Single file will be created for each proposal that was submitted to the IRC of KCH. All documentation and communication of IRC will be dated, filed, and archived in locked key board maintaining confidentiality. Office secretary is responsible for that. The documents will be archived for a minimum period of 5 years following the completion of a study.

Amendment Approved by: IRC Kanti Children's Hospital

Approved date: 3 May 2020