## Application for Approval of Research Proposal

**IRC- NPH**

# Institutional Review Committee (IRC) Of Nepal Police Hospital (NPH)

### Maharajgunj, Kathmandu

##### **Tel: 977-1-4412630, e-mail:** **nphirc@nepalpolice.gov.np****,** **nphirc123@gmail.com**

#### Note:

#### Address all application to the member secretary IRC-NPH. Electronic submission is must. Please download the ‘word’ version of application form, complete (by inserting required information in the blank space, page number may increase) and submit via email (nphirc@nepalpolice.gov.np). Do not submit hard copies unless requested. You may attach separate file for photos if u have difficulty in putting the photos in required place.

#### Do not modify the form. Use attachments (files) when required.

1. **Checklist, ensure that following supporting information are included**

|  |  |
| --- | --- |
| **Supplementary documents enclosed (when applicable, in separate file)** | **Y/N/NA** |
|
| Approval letter from department/institution |  |
| Consent form |  |
| Questionnaires |  |
| Proforma |  |
| Timeline of study (proposal submission, data collection, analysis, writing, publication, e.g. Gantt Chart) |  |
| Budgeting and budget breakdown |  |
| Curriculum vitae of PI and co PI’s |  |
| Drugs and devices, including copy of DDA approval for unregistered drugs |  |
| Email of all co-investigators and signatories |  |
| If it is part of thesis, provide separate copy of **signed**(candidate, guide, co-guide)full proposal |  |
| Do you intend to publish your findings in scientific journal |  |

***For Official Use Only***

Registration No.:

Registration Date:

Approved: yes/no

Name of Internal Reviewer:

Name of External Reviewer:

# Part – I

## Administrative Information

1. Research Title:
2. Name and Title of Principal Investigator responsible for the proposed research:

Last (Surname) Middle (if any) First name

Signature:

Date:

Postal Address:

Telephone No.:

Mobile No.:

e-mail:

1. Name and Title of Co-investigators responsible for the proposed research

(Use the similar format if more than one):

Last (Surname) Middle (if any) First name Nationality:

1. Name and Title of Co-investigators responsible for the proposed research

(Use the similar format if required)

# Part – II

## Research Proposal Description

1. Research Title:
2. Proposal Summary (maximum 500 words):
3. Introduction:

Background of Study (maximum 500 words):

Statement of the Problem and Rationale / Justification (maximum 500 words)

Research Objectives / purpose / aim of the study:

General

Specific

1. Research Design and Methodology Research Method

Qualitative Quantitative Combined

Study Variables:

Dependent variables:

Independenet variables:

Type of Study (Specify):

Study Site and Its Justification:

Study Population (Specify):

Study Unit:

Sampling Methods / Techniques (Specify):

Sample size (with justification):

Criteria for Sample Selection:

Data Collection Technique / Methods (Specify):

Data Collection Tools: (please attached in annex)

Pre-testing the Data Collection Tools (if applicable):

Validity and Reliability of the Study Tools:

Potential Biases (if applicable):

Limitation of the Study:

1. Plan for Supervision and Monitoring:
2. Plan for Data Management and Analysis:
3. Expected Outcome of the Research:
4. Plan for Dissemination of Research Results:
5. Plan for Utilization of the Research Findings (optional):

How is the research project going to strengthen the research capability of the host institution: Nepali Researcher (if submitted from aboard):

1. Work Plan *(should include duration of study, tentative date of starting the project and work schedule / Gantt chart):*
2. Lists of references(Minimum 10):

# Part – III

## Ethical Consideration

1. Regarding the human participants:

Are human participants required in this research? If yes, provide justification.

Yes (*provide justification*) No

Are there any risks involved for the participants? If yes, identify clearly what are the expected risks for the human participants in the research and provide a justification for these risks.

Are there any benefits involved for the participants? If yes, identify clearly what are the expected benefits for the participants.

1. Informed Consent Form / Ethical Issues:

Statements required in the Informed Consent Form include:

A statement that the human participants can withdraw from the study at any time without giving reason and without fear. State clearly how the participants can opt out the study.

A statement guaranteeing the confidentiality of the research participants.

If required, a statement on any compensation that might be given to the research participant and or their community.

A statement indicating that the participants has understood all the information in the consent form and is willing to volunteer / participate in the research.

Signature space for the research participants, a witness, and the date.

*(Informed Consent form should be submitted in English and in the language appropriate to the research participants)*

Obtaining the Consent

How informed consent is obtained from the research participants?

Verbal Written

Please indicate who is responsible for obtaining informed consent from the participants in this research study?

…………………………………………..………………………………

Is there anything being withheld from the research participants at the time the informed consent is being sought?

If yes, explain

……………………………………………………………………………

Is the research sensitive to the Nepali culture and the social values?

Yes No Explain.

……………………………………………………………………………

Is health insurance *(if applicable)* being made available to the research participants? If yes, please provide the necessary insurance data.

…………………………………………………………………………… (Include in consent form)

# Part – IV

### ACCEPTANCE OF GENERAL CONDITIONS AND DECLARATION BY THE PRINCIPAL INVESTIGATOR

I hereby certify that the above mentioned statements are true, I have read and understood the regulation of the Institutional Review Committee- Nepal Police Hospital(IRC-NPH) on the approval of research proposal and will act in conformity with the said regulation in all respects.

If the research is terminated, for any reason, I will notify IRC-NPH of this decision and provide the reasons for such actions. I will provide IRC-NPH with a written notice upon the completion of the research as well as a final summary/full report of the research study. If I publish the results in a journal, I shall acknowledge the IRC-NPH and shall provide the Council with one copy of any such article.

…………………………

### Signature of Applicant Date: …………………

**INFORMED CONSENT:**

 Describe the manner in which informed consent will be obtained.

 Indicate what kind of consent (e.g. parental, child, adult, etc) will be used.

 If the subjects are children/adolescents ages 7-18 years, an Assent Form must be included with the IRB application. The signed Assent Form along with the Parental/Guardian Consent Form must be retained on file for at least three years after completion of the research project.

 If prisoners / pregnant women, or fetuses are to be included in the research sample, it is likely that a full IRB review will be required and additional human subjects' protections will be expected.

 If the subjects do not read or comprehend English, you must provide a consent form in their language as well as in English for IRB review and approval.

 If you are requesting a waiver of written consent (i.e. a signature on an informed consent form) from the subjects, you MUST justify this request by providing an explanation of why obtaining written consent would add additional risk to the subjects and your alternative provisions for informing them about the study.

 If consent documents from another site will be used, you will have to indicate this and provide a copy of the authorized consent document and IRB approval with your application.

 You will have to provide any other relevant information if necessary. Please be aware that the PI is legally required to retain all signed Informed Consent forms for at least three years after the project terminates

 The Informed Consent form must be written at a level that the subjects will understand.

Please use simple language, and avoid clinical jargon.

 Attach a copy of the written informed consent form (assent or parental consent where applicable). Consent documents MUST be in format requested. See examples on line.

 If the study uses database or archival data the use of informed consent is not applicable.

**CONFIDENTIALITY OF DATA: *Confidentiality of data MUST be address for all studies.***

 Indicate the extent to which confidentiality of records identifying subjects will be maintained.

 Describe the storage and disposal of information where applicable.

**Check List**

### For all applicants

1. Approval letter from hospital director.
2. Covering letter addressed to the Member secretary indicating the submission of the approval of proposal.
3. Proposal will only be accepted if submitted in NPH- IRC format.
4. Both printed and electronic version of the proposal should be submitted.
5. Curriculum Vitae of the Principal Investigator & Co-Principal Investigator of the study team should be submitted.
6. Source of funding for the proposed project.
7. Consent form should be in Nepali & local language (if necessary). 11.Data collection tools should be in Nepali & local language (if necessary)

including interview guideline, observation checklist, questionnaires etc.

12.Style of referencing should be in Vancouver style. 13.List of abbreviations / acronyms should be provided.

### For students' applicants

1. Approval letter from concern Institute/University.
2. Recommendation letter from Academic Supervisor.