## **Application for Approval of Research Proposal**

**(Form B)**

**Revised on September 2017**

**IRC-PAHS**

# **Institutional Review Committee (IRC) Of Patan Academy of Health Sciences (PAHS)**

### **Lagankhel, Lalitpur, P.O. Box: 26500, Kathmandu, Nepal**

##### Tel: 977-1- 5545112, Fax: 977-1- 5545114, e-mail: irc-pahs@pahs.edu.np

#### Note: Address all application to the member secretary IRC-PAHS. Electronic submission is must. Please download the ‘word’ version of application form, type in and email. You may attach separate file for photos if you have difficulty in putting the photos in required place. Please allow us at least one month time for review. Please do not change the format.

**The investigator should ensure that the application form includes all supporting information**

|  |  |
| --- | --- |
| **Documents** | **Enclosed****Yes/No** |
|
| Study protocol |  |
| References |  |
| List of abbreviation |  |
| Declaration by PI |  |
| Consent form for participants |  |
| Information sheet for participants |  |
| Data collection instruments including questionnaires |  |
| Curriculum vitae of principal investigator |  |
| Drugs and devices, including copy of DDA approval for unregistered drugs |  |
| Institution/university approval letter (in case of students) |  |

**For Office Use Only**

Submission Date: Record number:

Approved by research committee: yes / no

Expedited review: yes / no Full house review: yes / no

Approved: yes / no Date:

**Part I**

###### Administrative Data Sheet

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

 Last (Surname) Middle (if any) First name Title (e.g. Mr. Ms. Dr.)

*(Please attach a copy of your curriculum vitae and list of publications relevant*

Passport size photograph (Compulsory)

 *to the proposed research)*

Electronic Signature

Designation:

Postal Address:

 Telephone No.: Fax No.: E-mail:

1. Full name of the Institution / University / NGO / INGO associated with the Principal Investigator (if applicable) :

Postal Address (if different from the address given above):

Telephone No.: Fax No.: E-mail:

1. Declaration (own institution-1 and study site-2) of the head of the Department / Institution / University / NGO / INGO to allow him/her to conduct the research

Electronic Signature-2

Electronic Signature-1

Last (Surname) Middle (if any) First name

Title (e.g. Mr. Ms. Dr.) Designation:

Name of the Institution / University / NGO / INGO:

Postal Address:

 Telephone No.: Fax No.: E-mail:

Last (Surname) Middle (if any) First name

Title (e.g. Mr. Ms. Dr.) Designation:

Name of the Institution / University / NGO / INGO:

Postal Address:

Telephone No.: Fax No.: E-mail:

1. Name and Title of Co-Investigator (if any) responsible for the proposed research:

Passport size photograph

(Optional)

Electronic Signature

 Last (Surname) Middle (if any) First name

Title (e.g. Mr. Ms. Dr.) Designation:

*(A copy of the curriculum vitae and list of publications relevant*

 *to the proposed research should be annexed)*

Postal Address (if different from the address given above):

Telephone No.: Fax No.: E-mail:

1. Name and Title of Co-Investigator (if any) responsible for the proposed research:

Passport size photograph

(Optional)

Electronic Signature

 Last (Surname) Middle (if any) First name

Title (e.g. Mr. Ms. Dr.) Designation:

*(A copy of the curriculum vitae and list of publications relevant*

 *to the proposed research should be annexed)*

Postal Address (if different from the address given above):

Telephone No.: Fax No.: E-mail:

1. Name and Title of Co-Investigator (if any) responsible for the proposed research:

Passport size photograph

(Optional)

Electronic Signature

 Last (Surname) Middle (if any) First name

Title (e.g. Mr. Ms. Dr.) Designation:

*(A copy of the curriculum vitae and list of publications relevant*

 *to the proposed research should be annexed)*

Postal Address (if different from the address given above):

Telephone No.: Fax No.: E-mail:

*(Note: If the Principal Investigator is a foreigner, at least one Co-investigator should be a Nepali researcher and the proposal should have institutional ethical clearance from his/her own country)*

7. Is the research responsive to the health priorities and needs of Nepal?

Yes ( ) No ( ) Explain.

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

Yes ( ) No ( ) Explain.

1. Is health insurance being made available to the research participants? If yes, please provide the necessary insurance data.
2. List the name(s) and institutional affiliation of foreign researcher(s) (other than co-investigator) to assist your project in Nepal and abroad (if any)

|  |  |  |  |
| --- | --- | --- | --- |
| S.No. | *Name* | *Institution* | *Email* |
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1. List the name(s) of Nepali researcher(s) (other than co-investigator) or Nepalese Institution/hospital/NGO(s) etc. from whom you may seek co-operation (if any)

(a)

12. List major research equipment(s) (if any) that you may bring to Nepal.

(a)

13. List details of all specimen(s) (if any) that you may take away from Nepal in relation to your research (if relevant).

(a)

(c)

(d)

How will you ensure duplicate specimens remain in the country?

1. How are the external sponsors going to strengthen the research capability of the host institution? (if relevant)

15. Is this research part of your Thesis? Y/N ( )

If yes,

 For what degree and in what subject?

 From which university?

####  From which country? Part II

###### Financial Data Sheet

1. Which funding organization or agency is going to fund your research project?

Contact information of funding organization or agency:

Postal Address:

Telephone No.: Fax No.: E-mail:

Contact person at the funding organization or agency:

 Last (Surname) Middle (if any) First name Title (e.g. Mr. Ms. Dr.)

Total amount of funds (in US $) allocated for the proposed research project:

Overall gross budgetary breakdown of the research project:

Personnel:

Equipment:

Major:

Minor:

Operational Expenses:

 Laboratory/Office Expenses:

 Clinical Expenses:

 Field Expenses:

 Data Analysis:

 Others: **Part III**

**Research Proposal Description Sheet**

1. Title
2. Objectives

General

Specific

1. Summary (Not more than 200 words)
2. Introduction

1. Statement of the Problem

1. Literature Review
2. Rationale / Justification
3. Research Questions (if relevant)

25. Research Hypothesis (if relevant)

1. Research Design and Methodology

Research Method: Y/N Qualitative ( ), Quantitative ( ), Combined ( )

Study Variables

Type of Study

 Descriptive Study Y/N ( )

Specify:

 Analytical Study Y/N ( )

Specify:

 Experimental Study Y/N ( )

Specify:

Other:

Study Site and its Justification

Target Population

Sampling Methods

Non-probability Sampling Y/N ( )

Specify:

Probability Sampling

Sample Size

Sampling Frame (if relevant) and Sampling Process including Criteria for Sample Selection

Tools and Techniques for Data Collection

 Pre-testing the Data Collection Tools (if relevant)

 Validity and Reliability of the Research (if relevant)

 Biases (if relevant)

 Limitation of the Study (if relevant)

27. Plan for Supervision and Monitoring

28. Plan for Data Management

29. Plan for Data Analysis

30. Expected Outcome of the Research

31. Plan for Dissemination of Research Results

32. Plan for Utilization of the Research Findings (optional)

33. Work Plan *(should include duration of study, tentative date of starting the project and work schedule / Gantt chart)*

**Part IV**

**Ethical Consideration**

34. Regarding the human participants:

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

How many participants are required for the research? Explain.

What is the frequency of the participant’s involvement in the research? Explain.

Clearly indicate the participant’s responsibilities in the research. What is expected of the research participants during the research?

Are vulnerable members of the population required for this research? If yes, offer justification.

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.

35. 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 is informed consent obtained from the research participants ?

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?

No ( ) Yes ( )

If yes, explain

36. Regarding Clinical Trial:

 In case of a clinical trial address the following:

 The trial treatment

A detailed explanation of the trial procedures including all invasive procedures.

 The potential or direct benefits (if any) for the research participants.

Alternative procedure(s) or treatment(s) that may be available.

The risks, discomforts, and inconveniences associated with the study

Provisions for management of any adverse reactions

 The provisions of insurance coverage for any permanent disability or death caused directly by the investigational treatment or procedure.

The provision of including the name and address, including telephone numbers of person to be contacted in case of adverse events or for any information related to the trial.

Is there going to be a transfer of any biological materials from the country? Explain.

**Part V**

**Annexes**

37. Annexes should include

1. References
2. Data collection instruments including questionnaires
3. Information sheet for participants and informed consent form (if relevant)
4. List of abbreviations
5. Recently updated curriculum vitae of principal investigator
6. Drugs and devices, including approval from DDA for unregistered drugs in Nepal
7. For Students- Institution/university approval letter, name of academic supervisor

**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 of Patan Academy of Health Sciences (IRC-PAHS) 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-PAHS of this decision and provide the reasons for such actions. I will provide IRC-PAHS 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-PAHS and shall provide the IRC-PAHS with three copies of any such articles.

Electronic Signature of the applicant

Date:

