Research Proposal Endorsement Requirement

Research Title (Capital Letter):

Purbanchal University School of Health Sciences-

Institutional review Committee (PUSHS-IRC)

Gothgaun- 9 , Morang, Nepal, Tel: 021-425009

E-mail: pushsirc@pushs.edu.np

For Official Use Only

(Please see the check list before Registration of the application form)

Registration No.:
Registration Date:
Approved Date:
Name of PI:
Total Budget of the Project:
PUSHS-IRC Processing Fee:
Research Site:
Tentative Date of Initiating the Project:
Duration of the Research Project:
Name of Internal Reviewer:
Name of External Reviewer:
Signature & Seal of PUSHS-IRC:

Part – I

Passport size photograph

Administrative Information

1. Research Title:

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

   Last (Surname) Middle (if any) First name

   Nationality:

   Citizenship Number with district name from where it was obtained (only for Nepali)

   Passport Number (only for non Nepali citizen):

   Signature: Date:

   Postal Address:

   Telephone No.:

   Mobile No.:

   Fax No.:

   E-mail:

   Alternate e-mail:

3. Full name of the Institution associated with the Principal Investigator (if applicable) :

   Designation:

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

Telephone No.:

Fax No.:

e-mail:

Website:

4. Declaration of the head of the Institution (if applicable)

   If the proposed research is approved, we will allow him/her to conduct the research in this institution.

   Signature: Date:

   Last (Surname) Middle (if any) First name

   Designation:

   Name of the Institution

   Contact/Postal Address:

   Telephone No.:

   Fax No.:

   Institutional e-mail:

   Website:

5. Name and Title of Co-investigators responsible for the proposed research (Use the similar format if more than one):

   Passport size photograph

   Last (Surname) Middle (if any) First name

   Nationality:

   Citizenship Number with district name from where it was obtained (only for Nepali)

Passport Number (only for non Nepali citizen):

Affiliated Institution (if applicable):

Designation:

Signature: Date:

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

Telephone No.:
Fax No.:

e-mail:

(Use additional sheet if necessary)

6. List the name(s) and institutional affiliation to the researcher(s) (other than co-investigator) to assist your project in Nepal and abroad (if any)

	Name	*Institution and Address*
(a)		
(b)		

(Use additional sheet if necessary)

7. 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)

(b)

(Use additional sheet if necessary)

8. List major equipment(s) in relation to your research project you plan to bring/import to Nepal (If applicable)

(a)

(b)

(Use additional sheet if necessary)

8.1 List details of all specimen(s) (if any) that you may transport from Nepal in relation to your research.

(a)

(b)

(c)

(d)

8.2 Country of Destination:

Name of Institution:

8.3 Mode of Transportation of Specimen

8.4 How will you ensure duplicate specimens remain in the country?

(If necessary use additional sheet)

9. Is this research part of your Thesis?

Yes ☐ No ☐

If yes,

For what degree and in which subject?

From which university?

From which country?

Part – II

Research Proposal Description

10.Research Title:

11.Proposal Summary (maximum 500 words):

12.Introduction:

12.1 Background of Study (maximum 500 words):

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

12.3 Conceptual framework

12.4 Research Objectives :

General

Specific

13.Research Design and Methodology

15.1 Design

Qualitative ☐ Quantitative ☐ Combined ☐

Study Type (Describe)

Study Site and Its Justification:

Study Population (Specify):

Sampling Methods / Techniques (Specify):

Sample size (with justification):

Sampling Unit:

Criteria for Sample Selection (Inclusion and Exclusion Criteria)

Study of operational definition

Study of conceptual framework definition

Data Collection Technique / Methods (Specify):

Data Collection Tools: (please attached in annex)

Validity and Reliability of the Study Tools (including pre-testing (if applicable

Potential Biases (if applicable):

Limitation of the Study:

14.Plan for Supervision and Monitoring:

15.Plan for Data Management and Analysis:

16.Expected Outcome of the Research:

17.Plan for Dissemination of Research Results:

18.

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

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

Research Plan	**Year**								
Research proposal writing									
Ethics application and Approval									
Data collection									
Literature review									
Data coding and entry									
Data Analysis									
Data interpretation									
Manuscript preparation									

Part – IV

Ethical Consideration

22. Regarding the human participants:

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

☐ Yes (*provide justification*) No ☐

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?

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

23. Informed Consent Form / Ethical Issues:

Instruction for the Informed Consent Form includes:
(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?
Investigators……..……

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)

24. Regarding Clinical Trial (intervention)

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.

……

Is there a Data Safety Monitoring Board?
If Yes, Mention
……

Is this trail internationally registered?
……..

Part – V

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 Purbanchal University, College of Medical and Allied Sciences- Institutional Review Committee (PUSHS-IRC) on the endorsement 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 PUSHS-IRC of this decision and provide the reasons for such actions. I will provide PUSHS-IRC 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 PUSHS-IRC and shall provide the Committee with three copies of any such articles.

……

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 IRC 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 IRC 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 IRC 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. Covering letter addressed to the Chairperson PUSHS-IRC indicating the submission of the proposed proposal.
2. Proposal will only be accepted if submitted in PUSHS-IRC format.
3. Both printed and electronic version of the proposal should be submitted.
4. Curriculum Vitae of the Principal Investigator & Co-Principal Investigator of the study team should be submitted.
5. If the Principal Investigator is a non Nepali citizen, at least one Co-investigator should be a Nepali citizen.
6. Submission of the application processing fee to PUSHS-IRC.(According to CMC-IRC rules and regulations)
7. Source of funding for the proposed project.
8. The proposal should have institutional ethical clearance from PUSHS-IRC.
9. If the research study is to be conducted in any hospitals/organization or institution/community, a letter of approval from the related hospital/organization or institution/district authority should be provided.
10. 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 Department/School/Institute/University.
2. Recommendation letter from Academic Supervisor.

Processing Fee

Researcher has to pay the processing fee as per the rules and regulations of PUSHS-IRC.