Application for Approval of Research Proposal

(Revised September 2024)

IRC-PAHS

Institutional Review Committee (IRC) of Patan Academy of Health Sciences (PAHS)
P.O. Box: 26500, Lagankhel, Lalitpur, Nepal
Tel: 977-1- 5545112, e-mail: irc-pahs@pahs.edu.np

Instructions:

1. Read, especially the shaded area, and complete carefully all the sections of this form, if you have any queries write to IRC-PAHS. This form is compulsory even if you already have developed a full proposal and have obtained approval from another authorized body. **Do not delete or type inside the box with the shaded area in this proposal form below.**
2. Address all applications to the member secretary of IRC-PAHS. Please download the latest 'word' version of the application form, complete it (inserting the required information in the blank space, the page number may increase), and submit it via Google Form by clicking the "Application upload" from the IRC-PAHS homepage. Do not submit hard copies unless requested. Use Calibri font size 11 for English and Preeti font size 14 for Nepali.
3. Do not leave the information blank, write Yes, No, or NA (not applicable).
4. Do not modify the form. Use attachments (files) when required.
5. **When replying use word track change mode during the review process, answer all the comments within the comment box, and incorporate relevant revisions in the main text.** Save in the same file name, **do not modify.**
6. For the thesis proposal align all the changes made in the IRC-PAHS application form into your full proposal for the thesis.
7. **Align title, objective, methods, pro forma, and dummy table(s).**
8. Obtain approval for research from an authority above your position, e.g., faculty from the Head of the Department (HOD), HOD from the Hospital Director (HD) or Dean, HD from the Registrar, and so on; HD/Dean of PAHS and head of the respective Organization/community in case of NGO, INGO, community, etc.
9. **For an outside researcher to conduct a study in PAHS, at least a Co-Investigator from PAHS is mandatory.**

A. Checklist, ensure that the following supporting information is included (Y=yes, N=no, NA=not applicable)

	Enclosed supplementary documents (when applicable, in a separate file)	Yes/No/NA
1.	Approval letter from department/institution (detail see instruction above)	
2.	Information sheet	
3.	Consent form (as per IRC-PAHS format), plus assent form where applicable	
4.	Data Collection Tools	
5.	Timeline/work plan/Gantt Chart (submission, data collection, analysis, writing, publication)	
6.	Itemized detail budget breakdown, total budget, site budget	
7.	Updated curriculum vitae with a photo of PI and CV of Co-Is/Co-Researchers	
8.	Drugs and devices, including a copy of DDA approval for unregistered drugs	
9.	For the thesis, provide a 'full proposal' **signed** by the candidate, guide, and co-guide	
10.	A declaration that you will submit raw data to IRC-PAHS for monitoring and verification*	
11.	A declaration that you will submit a soft copy of final thesis/result by email to IRC-PAHS when requested	
12.	Declaration of conflict of interest	
13.	Valid Ethical Training Certificate of PI and Co-Is/Co-Researchers	
14.	Declaration of the research not conducted in the same place within 3 years or published as part of a thesis	
15.	A declaration that retrospective review of data contains at least 3 years data (except when justified)	
16.	A declaration that it is faculty research	
17.	A declaration that it is post-graduate thesis research	
18.	A declaration that it is student research, other than postgraduate thesis research	
19.	A declaration that the relevant fee will be paid before the proposal can be approved	
20.	cc email to all co-investigators and signatories	

*1. submit a password-protected document, 2. Send another email containing password

B. For Office use only

Submission Date:	Record number:
Approved: Yes / No	Date:

C. Applicant should provide all the details clearly

1. Name and title of principal investigator responsible for the proposed research:

Passport size photograph

Full name:
Title/Designation:
Department:
Institute/Organization:
Postal address Organization:
Office telephone: Email:
Researcher mobile: Email:
Country: Citizenship ID:

2. Approval of the head of the department/institution/university / NGO / INGO to conduct research

Full name:
Title/Designation
Department:
Institute/Organization:
Office telephone: Email:
Mobile:

Electronic Signature

3. List of Co-Investigators responsible for the proposed research (add as needed)

Electronic Signature

Full name:
Title/Designation:
Department:
Institute/Organization:
Mobile: Email:
Country: Citizenship ID:

Electronic Signature

Full name:
Title/Designation:
Department:
Institute/Organization:
Mobile: Email:
Country: Citizenship ID:

Electronic Signature

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Institute/Organization:
Mobile: Email:
Country: Citizenship ID:

Electronic Signature

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Title/Designation:
Department:
Institute/Organization:
Mobile: Email:
Country: Citizenship ID:

D. Research Proposal

1. Title

- Short, no waste words, no abbreviation, no full stop, should align with and reflect the objectives, method, and outcome of the study
- **Do not type in shaded areas, do not delete!**

2. Introduction (up to 250 words, citations 5-10 for the whole document, do not list out references here)

- Write in 'inverted triangle' format ideally in 3-paragraphs- 1) 'global, regional, and local' information about your study referring to the relevant literature; 2) What is known, controversies, and 3) Sum up with aim, rationale, and relevance of the study
- Citation in modified Vancouver, for details, see a recent issue of JPAHS
- Do not copy-paste the 'abstract' of a few randomly picked articles, avoid '**plagiarism**'
- **Do not type in the shaded areas, do not delete!**

3. Methods (details for reproducibility)

Detail enough for reproducibility, validity, and further extension

- Objectives- general, specific (number them e.g., 1,2,3…) do not use abbreviations in the objective, use measurable action verb;
- Study design, type of study, study site, study duration, sampling technique, sample size formula and calculation, study variables, inclusion and exclusion criteria, working definition;
- Procedure details-**who, where, when, how, whom**; data collection as per tools- user friendly pro forma and questionnaire (also in Nepali when relevant), dummy table(s) as per specific objectives (provide detailed tools at the end), data processing software, analysis tools; data management;
- Limitation of the study;
- Ethical consideration- Research participant safety, privacy, consideration for the vulnerable population, and conflict of interest.
- Provide citation where applicable, e.g., sample calculation
- **Do not type in the shaded areas, do not delete!**

4. List of cited references (total max 10)

- Ideally, ¼th within 2 years, ¼ within 3-5 years, modified Vancouver with **at least one workable hyperlink** (details as JPAHS style, e.g. Scherer RW, Meerpohl JJ, Pfeifer N, Schmucker C, Schwarzer G, von Elm E. Full publication of results initially presented in abstracts. Cochrane Database Syst Rev. 2018;11:MR000005 | DOI | PubMed | Google Scholar | Full Text | Weblink |
- Cited references may be more than 10 for multicentric and funded research
- **Do not type in shaded areas, do not delete!**

5. Additional information - provide detail of all items *a-j* individually, write NA if not applicable

a. Budget- itemized breakdown (e.g., generic given below, modify as necessary), funding - detail for approval, or if you plan to apply for it. Assure that you will provide the document of approval and fee to IRC-PAHS
b. Work plan, Gantt chart
c. Data storage, sharing, dissemination details
d. Multicenter - details of study sites, detailed proposal, and approval from the parent proposal site
e. Foreign researcher (institutional affiliation)
f. Details about vulnerable populations, the sensitivity of local culture and social values
g. Bio-sample taking out/bringing in the country
h. Equipment/materials to bring in/out of the country
i. The detailed proposal if any in addition to this IRC-Form
j. Conflict of interests, if yes provide details

- Do not type in shaded areas, do not delete!

a. Budget (generic guideline, may modify as necessary)

SN	Particulars	Qty	Unit cost NRs	Subtotal NRs
1.				
..				
..				
..	Miscellaneous (unseen, justifiable, max. 10% of aggregate subtotal)			
			Total NRs	

b. 'Work plan, Gantt chart (generic guideline, may modify as necessary; **Use AD**)

SN	Particulars	M Y	M Y	M Y	M Y
1	Proposal development				
2	Data collection after ethical approval				
3	Data analysis/ thesis/article writing				
4	Final thesis/article submission				

c. Data storage, sharing, and dissemination details (generic guideline, may modify as necessary): During study- data will be stored in a password-protected computer of the researcher/ department. After study- data will be deposited in a password-protected computer in the department/organization for at least 5 years, with access to IRC-PAHS/EC-PAHS when required.

Provide details individually for each item, and write NA if not applicable for the following:

d. Multicenter:

e. Foreign researcher (institutional affiliation):

f. Details about vulnerable populations:

g. Bio-sample taking out/bringing in the country:

h. Equipment/materials to bring in/out of the country:

i. The detailed proposal if any in addition to this IRC-Form:

j. Conflict of interests, if yes provide details:

E. Declaration by the principal investigator

I hereby declare that the above-mentioned statements are true. I/we will commence research after the approval from IRC-PAHS (and NHRC- Nepal Health Research Council when suggested) and will comply fully. 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 a final summary of the research upon completion. For publication in a journal, I shall acknowledge the IRC-PAHS approval and shall provide the committee copy of such publication.

Full name:

Date (AD):

Electronic Signature

F. Annex. Information sheet and Consent form: Both in English and Nepali

1) **Information sheet** (write detail about study/research, the responsibility of organization/researcher/ participants) Research Ethics Online Training

The Information Sheet should contain the following contents:
- Details about the study/research: Self Introduction, title, aim and description of the study
- Voluntary Participation; Risk/Benefit to self and community; Alternative Treatment, if applicable; Vulnerability; Sensitivity (culture, tradition, custom, gender, etc.); Confidentiality; Information on what the participants should do in case of experiencing adverse effects and how they will be dealt with; For data collection through telephone, a separate consent with recording declaration; For photographs a separate consent form to use and publish; Queries or Concerns; Contact Information of the Researcher and the Ethical body
- The write up must be simple for an easy understanding by a layperson
- **Do not type in shaded areas, do not delete!**

2) **Consent form** (this is a generic consent form, add similar assent form where applicable)
Research title -
Researcher -
Research site -

I hereby give my voluntary consent for myself / Mr. / Ms. …….. to participate in the research. I have been fully informed about the nature, risks, and benefits of participation. I am aware that I have the right to accept/withdraw from participating in the above-mentioned research whenever I wish to do so.

Rt. thumb	Lt. thumb	Signature…… Participant (preferred) Guardian…… Relation…… Contact number…… Date……	Signature…… Witness name …… Date……

dGh'/Lgfdf

cg';Gwfgsf] laifoM
cg';Gwfgstf{M
cg';Gwfg :ynM

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		;xL gfd gfdf 7]ufgf ldlt	;flfL ;xL gfd ldlt

G. Data Collection Tools / Pro forma

The Pro forma should contain the following contents:

- Title, Document ID number, Inclusion and Exclusion Criteria, Study variables, Data Collection Tools
- **Do not type in shaded areas, do not delete!**

H. Dummy Table:

List dummy table as per **EACH** specific objective

- Write the complete title of each dummy table to reflect the contents of the table
- **Do not type in the shaded areas, do not delete!**

Note: The researcher will be required to submit the copy of voucher (Laxmi Sunrise Bank, Account Number: 01811000295 in the name of PAHS) as required to the IRC-PAHS office as follows-

IRC Processing Fees

1. Non-funded research

1.1 IRC will charge NRs. 1000/-

1.2 The processing fee for the research proposal of staff and/or students of PAHS will be waived

2. Funded research

2.1 For national funding, 2% of the site (PAHS) budget and not less than NRs. 3000/-

2.2 For international funding, 2% of the site (PAHS) budget and not less than NRs. 10,000/-