

Application for Approval of Research Proposal

(yyyy-mm-dd)

IRC-NAPFH

Institutional Review Committee (IRC) of Nepal APF Hospital
Balambu, Kathmandu, Nepal

Tel: 977-1- 4315224, Fax: 977-1- 4313600, e-mail: ircapfhospital@gmail.com

INSTRUCTIONS TO THE INVESTIGATOR:

- *All sentences/words in Italics (including these) are for the information to the applicant/investigator and should be deleted before submitting the proposal.*
- *The research proposal should be submitted in Microsoft Word structured around following layout to fulfill criteria for successful submission. The proposal should be submitted in English, and should be a maximum of 10 pages (excluding cover page and references).*
- *All entries should be done in Times New Roman, font size 12, citation in Vancouver referencing style, Citation should be done in Vancouver superscript style, Line spacing should be 1.5.*
- *Submit Additional Information/supporting documents in separate file.*
- *Electronic signature can be used in electronic submission.*
- *Use word track change mode during the review process, answer to all the comments within the comment box and incorporate relevant revision in main text.*
- *If any section is not applicable, write “Not Applicable (NA)”.*

A. Research Proposal

1. **Title:** *Short, no waste words, no abbreviations, should align and reflect the objectives, methods, and outcome of the study*
2. **Proposal summary:** *The summary should be one paragraph (upto 500 words) and must include: A brief statement of the purpose, objectives, research methodology including research design, participants and procedures, research setting, measurement tools and significance of the study.*

3. **Introduction:** *Up to 500 words.*

Write ideally in three paragraphs, avoid 'plagiarism.

- I. *'Global, Regional, Local' information about your study referring to the relevant literature;*
- II. *What is known, controversies;*
- III. *Sum up with aim, rationale, and relevance of the study.*

4. Objectives:

- 4.1 General objectives: *Specify the research hypothesis and concrete objectives that you aim to achieve.*
- 4.2 Specific objectives: *Outline very specific objective(s) that will be met with this specific project (number them e.g., 1,2,3...).*

Do not use abbreviations in the objective(s), use measurable action verbs.

5. Methodology:

- 5.1 Study design: *Provide a description of type of study design; e.g. Cross-sectional, Cohort, Case control, Interventional, Others.*
- 5.2 Type of study: *e.g. Qualitative, Quantitative, Mixed (If applicable, describe).*
- 5.3 Study sites: *Indicate where the sample (e.g., medical records or stored specimens) were obtained or the data collection will take place. Permission letter from study site is compulsory for proposal submission.*

5.4 Study duration:

5.5 Study population: *Describe the participant characteristics whether healthy individuals, or patients from outpatient department or hospital wards or community.*

5.6 Sampling technique:

5.7 Sample size: *Mention appropriate number of participants or participant units required for your study. Provide reference if your prediction of number is based on previous studies. Include the calculation if you used formula to predict the sample size.*

5.8 Study variables: *Provide a description of type of variables in the study*

5.9 Inclusion and exclusion criteria:

5.10 Pre-testing/Pilot testing: *if applicable*

5.11 Validity and Reliability of tool:

5.12 Data collection technique:

5.13 Data collection tools:

5.14 Data processing, analysis and management: *Explain how the specimen/data will be managed, where will be the specimen/data be stored, how will the confidentiality of the specimen/ data be maintained.*

Software that will be used for data analysis

Specify the most probable statistical tests that will be used to analyze the data depending on the predicted nature of data.

5.16 Plan for Dissemination of Research Results:

6. Potential biases: *If applicable*

7. Ethical consideration:

7.1 Research participant safety, privacy.....

7.2 Conflict of interest.....

7.3 Are vulnerable members of the population required for this research. If yes, provide justification..... (e.g. *Pregnant, Child, Prisoners, Mentally ill person, Terminally ill patients*)

7.4 Are there any risk 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.....

7.5 Are there any direct benefits for the participants? If yes, clearly mention.....

8. Limitations of the study:

9. References:

The references should follow the Vancouver referencing style. Number of references should not be more than 15. The references must be part of the document, but does not count towards the 10-page restriction.

10. Budget:

Self-funded

Funding organization

Name of funding organization if any.....

SN	Particulars	Amount
1		
2		
3		
4		
	Total	

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

SN	Particulars	Jan	Feb	March	April	May	June	July	August	Sept	Oct	Nov	Dec
1	Research Committee application												
2	Prepare for data collection												
3	Data collection												
4	Prepare for data analysis												
5	Writing the first draft of the manuscript												
6	Writing the final draft of the manuscript												
7	Submission of the final report												

B. Applicant details

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:

Mobile:

Email:

Country/citizenship ID:

Signature:

2. Name and title of Co-Investigators responsible for the proposed research: *(add as needed)*

Full name:

Title/designation/department:

Institute/organization:

Mobile:

Email:

Country/citizenship ID:

Signature:

Full name:

Title/designation/department:

Institute/organization:

Mobile:

Email:

Country/citizenship ID:

Signature:

Full name:

Title/designation/department:

Institute/organization:

Mobile:

Email:

Country/citizenship ID:

Signature:

C. Declaration by the Principal Investigator

I hereby certify that the above-mentioned statements are true. I/we will commence research after the approval from IRC-NAPFH (and NHRC- Nepal Health Research Council when suggested) and will comply fully. If the research is terminated, for any reason, I will notify IRC-NAPFH 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-NAPFH approval and shall provide the copy of such publication.

Full name:

Date:

Signature:

ADDITIONAL INFORMATION

Information sheet:

Information sheet: *Write in detail about study/research, the responsibility of organization/researcher/participants.*

Performa:

Consent form: *Consent form can be modified as per the need of the study and can be drafted in local language*

Consent form

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.....
Guardian.....
Relation.....
Contact No.....
Date

Signature.....
Witness Name.....
Contact No.....
Date

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Checklist/ supporting documents (Y=yes, N=no, NA=not applicable)

Checklist/ Supplementary documents enclosed (when applicable, in a separate file)		Y/N/NA
1.	Approval letter from the institution (Study Site)	
2.	Covering letter addressed to chairman for submission of approval of proposal	
3.	Consent form in Nepali, English and local language when applicable	
4.	Information sheet (In addition to consent form)	
5.	Questionnaires/tools	
6.	Proforma	
7.	Timeline/work plan/Gantt Chart (submission, data collection, analysis, writing, publication)	
8.	Budget	
9.	Updated curriculum vitae with a photo of Principal Investigator and Co-Investigator/Co-Researcher	
10.	cc email to all co-investigators and signatories	
11.	Both electronic version and printed version of proposal should be submitted	
12.	Declaration of conflict of interest	
13.	For thesis, provide the 'full proposal' signed by candidate, guide, co-guide	
14.	Declaration of the original work not conducted in the same place within 3 years or published or part of a thesis	
15.	A declaration that it is a post-graduate thesis research	
16.	A declaration that it is student research, other than postgraduate thesis research	
17.	Training Related to Ethics –Principal Investigator	
18.	Training Related to Ethics -Co-Investigator	

Note: The IRC processing fee for the research will be applicable as follows:

- i) *The processing fee will be free for all staff of Nepal APF Hospital and students*
- ii) *The processing fee will be NRs. 2000 for all other applicants (other than staff of Nepal APF Hospital and students)*
- iii) *The processing fee for research with national and/or international funding will be 2 % of the total research funding (also applicable to Nepal APF Hospital staff and students)*