## 

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

**(Revised May 2023)**

**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

#### Instruction:

#### 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.

#### Address all applications to the member secretary IRC-PAHS. Electronic submission is a must. Please download the ‘word’ version of the application form, complete it (by inserting the required information in the blank space, the page number may increase), and submit it via email google form by clicking the “Application form” from the IRC-PAHS homepage. Do not submit hard copies unless requested. You may attach a separate file for photos if you have difficulty putting the photos in the required place. Use Calibri, font size 11.

1. Do not leave the information blank, write Yes, No, or NA (not applicable). **Do not type in to or delete the shaded area.**

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

1. When replying please use the ‘review-track change mode’ of word processors, save in the same file name, **do not modify**.
2. **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.**
3. For the thesis proposal align all the changes made in the IRC-PAHS application form into your full proposal for the thesis.
4. **Align title, objective, methods, and dummy table (results).**
5. 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), HD from the dean, and so on; head of the organization/community in case of NGO, INGO, community, etc.
6. **Do not delete or type inside the box with the shaded area in this proposal form below.**
7. **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** |
|  | Approval letter from department/institution (detail see instruction above). |  |
|  | Consent form (as per IRC-PAHS format), plus assent form where applicable |  |
|  | Information sheet (In addition to consent form) |  |
|  | Questionnaires/tools |  |
|  | Proforma |  |
|  | Timeline/work plan/Gantt Chart (submission, data collection, analysis, writing, publication) |  |
|  | Itemized detail budget breakdown, total budget, site budget |  |
|  | Updated curriculum vitae with a photo of PI and co-PI’s/researcher co-researcher |  |
|  | Drugs and devices, including a copy of DDA approval for unregistered drugs |  |
|  | cc email to all co-investigators and signatories |  |
|  | For the thesis, provide a ‘full proposal’ **signed** by the candidate, guide, and co-guide |  |
|  | The full proposal included for multicentric/multicounty/funded study/approval of parent organization |  |
|  | A declaration that you will submit raw data to ‘irc-pahs@pahs.edu.np’ for monitoring and verification\* |  |
|  | A declaration that you will submit a final thesis and approved proposal soft copy by email to IRC-PAHS |  |
|  | Declaration of conflict of interest |  |
|  | Declaration of the original work not conducted in the same place within 3 y or published or part of a thesis |  |
|  | A declaration that retrospective review of data contains at least 3 y data (except when justified) |  |
|  | A declaration that it is a faculty research |  |
|  | A declaration that it is a post-graduate thesis research |  |
|  | A declaration that it is student research, other than postgraduate thesis research |  |
|  | A declaration that the relevant fee will be paid before the proposal can be approved |  |

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

1. **For Office use only**

Submission Date: Record number:

Approved: Yes / No Date:

###### 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:

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

Full name:

Title/designation/department:

Electronic Signature

Institute/organization:

Office telephone: Email:

Mobile:

1. 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:

Full name:

Electronic Signature

Title/designation/department:

Institute/organization:

Mobile: Email:

Country/citizenship ID:

Full name:

Electronic Signature

Title/designation/department:

Institute/organization:

Mobile: Email:

Country/citizenship ID:

Full name:

Electronic Signature

Title/designation/department:

Institute/organization:

Mobile: Email:

Country/citizenship ID:

1. **Research Proposal**
2. **Title**
3. Short, no waste words, no abbreviation, should align and reflect the objective, method, and outcome of the study—**do not type in shaded areas, do not delete!**
4. **Introduction (up to 250 words, citations up to 5-10 only, 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](https://jpahs.edu.np/index.php/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!**

1. **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, study design, type of study, study site, study duration, sampling technique, sample size and sample size formula and calculation, study variables, inclusion and exclusion criteria, working definition,
* Procedure details-where, when, how, whom; data collection as per tools- proforma and questionnaire, dummy table as per specific objective (provide detail tools at the end), data processing software, analysis tools; data management.
* 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!**

1. **List of cited references (total max 10)**

* Ideally, ¼th within 2 y, ¼ within 3-5 y, modified Vancouver with hyperlinks as many as available (details as [JPAHS](https://www.nepjol.info/index.php/JPAHS) style, e.g.- 6. 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](https://doi.org/10.1002/14651858.mr000005.pub4) | [PubMed](https://pubmed.ncbi.nlm.nih.gov/30480762/) | [Google Scholar](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C5&q=Scherer+RW%2C+Meerpohl+JJ%2C+Pfeifer+N%2C+Schmucker+C%2C+Schwarzer+G%2C+von+Elm+E.+Full+publication+of+results+initially+presented+in+abstracts.+Cochrane+Database+Syst+Rev.+2018%3B11%3AMR000005&btnG=) | [Full Text](https://www.ncbi.nlm.nih.gov/pmc/articles/pmid/30480762/) | [Weblink](https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.MR000005.pub4/full) |
* Cited references may be more than 10 for multicentric and funded research
* **do not type in shaded areas, do not delete!**

1. **Additional information - provide detail of all items a-j individually, write NA if not applicable**
2. 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.
3. Work plan, Gantt chart
4. Data storage, sharing, dissemination details
5. Multicenter - details of study sites, detailed proposal, and approval from the parent proposal site
6. Foreign researcher (institutional affiliation)
7. Details about vulnerable populations, the sensitivity of local culture and social values
8. Bio-sample taking out/bringing in the country
9. Equipment/materials to bring in/out of the country
10. The detailed proposal if any in addition to this IRC-Form
11. Conflict of interests, if yes provide details

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

* 1. **Budget** (generic guideline, may modify as necessary)

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

* 1. **‘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 |  |  |  |  |

* 1. **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.

***d-j***. **provide details individually for each item, and write NA if not applicable**

1. **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-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:

Electronic Signature

Date:

1. **Annex. Information sheet and Consent form**
2. **Information sheet** (write detail about study/research, the responsibility of organization/researcher/ participants)
3. **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……………………………..................

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1. **Proforma**
2. **Proforma**

(Please prepare the proforma in the following format. Please add any sections that are relevant to this study)

Document ID number:

Title of the study:

|  |  |
| --- | --- |
| Inclusion Criteria | Exclusion Criteria |
|  |  |

Demographic Variables:

Study Variables:

Outcome Variables (If relevant):

1. **Dummy Table:**

(Please list dummy table as per EACH specific objectives)

