##

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

**(Revised Jan 2021)**

**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 and complete carefully all the sections of this form, if you have any query write to IRC-PAHS. This form is compulsory even if you already have developed a full proposal, and have obtained approval from other 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 (by inserting required information in the blank space, page number may increase), and submit via email (irc-pahs@pahs.edu.np). Do not submit hard copies unless requested. You may attach a separate file for photos if you have difficulty in putting the photos in the required place. Use Calibri, font size 11.

1. Do not leave 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 ‘review-track change mode’ of word processors, save in same file name, **do not modify**.
2. For the thesis proposal align all the changes made in the IRC-PAHS application form into your full proposal for thesis.
3. Align title, objective, methods, and dummy table (results).
4. **Use word track change mode during the review process, answer to all the comments within the comment box, and also incorporate relevant revisions in the main text.**
5. **Checklist, Y-yes, N-no, NA-not applicable, ensure the supporting information/document is included**

|  |  |
| --- | --- |
| **Supplementary documents enclosed (when applicable, in a separate file)** | **Y/N/NA** |
| 1 | Approval letter from department/institution  |  |
| 2 | Consent form (as per IRC-PAHS format) |  |
| 3 | Information sheet (In addition to consent form) |  |
| 4 | Questionnaires/tools |  |
| 5 | Proforma |  |
| 6 | Timeline/work plan/Gantt Chart (submission, data collection, analysis, writing, publication) |  |
| 7 | Total budget, site budget, detail breakdown |  |
| 8 | Updated curriculum vitae with the photo of PI and co-PI’s/researcher co-researcher |  |
| 9 | Drugs and devices, including a copy of DDA approval for unregistered drugs |  |
| 10 | cc email to all co-investigators and signatories |  |
| 11 | For thesis, provide ‘full proposal’ **signed** by candidate, guide, co-guide |  |
| 12 | The full proposal included for multicentric/multicounty/funded study/approval of parent organization  |  |
| 13 | Will submit raw data to ‘irc-pahs@pahs.edu.np’ for monitoring and verification\*  |  |
| 14 | Will submit final thesis/manuscript together with approved proposal soft copy by email to IRC-PAHS |  |
| 15 | Declaration of conflict of interest |  |

\*submit the password-protected document to IRC-PAHS by email, send another email containing password only

1. **For Office Use**

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 (for thesis do not list guide, go-guide here) for the 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:

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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 200 words, citations 5-10 only)**
* Write in ‘inverted triangle’ to introduce the topic based on relevant literature review – 1. ‘global, regional, local’ information; 2. What is known, controversies, and; 3. Sum up with aim, rationale, and relevance of the study
* Citation in modified Vancouver, superscript after full stop, for details, see the recent issue of [JPAHS](https://jpahs.edu.np/index.php/jpahs)
* Do not copy-paste the ‘abstract’ of a few randomly picked article, 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, mention ethical issues- consent, ethical approval etc.

* Objectives- general, specific (number them e.g., 1,2,3…) do not use abbreviations in 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,
* Procedures detail-where, when, how, whom; data collection as per tools- proforma, questionnaire, dummy table as per specific objectives (provide detail tools at the end), data processing software, analysis tools; data management.
* Ethical consideration- Research participant safety, privacy, consideration for vulnerable population, conflict of interest.
* Provide citation where applicable, for 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 hyperlink 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) )
* **do not type in shaded areas, do not delete!**
1. **Additional information - provide detail of all items a-j**
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 population, the sensitivity of local culture and social values
8. Bio-sample taking out/bringing in the country
9. Equipment/materials bringing in/out country
10. Detail 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, 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, 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** (where applicable- write detail about study/research, the responsibility of organization/researcher/ participants)
3. **Consent form** (must, this is generic 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 (preferred) ………………..

Guardian………………………………………

Relation…………………………............... Contact number…………………..........

Date……………………………..................

Signature..………………………..............

Witness name ……….....………………..

Date……………………………..................

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1. **Proforma**

