**Research Proposal Approval Format**

| RESEARH TOPICS |
|---|

Passport size photograph

**Institutional Review Committee (IRC)**

**Civil Service Hospital of Nepal**
**Minbhawan, Kathmandu, Nepal**
***Tel: +977-4107000, 4107002***
***Email: irc.csh@gmail..com***

***For Official Use Only***
***(Please see the check list before Registration of the application form)***

| |
|---|
| Registration No: |
| Date of registration: |
| Date of approval: |
| Name of Principal Investigator: |
| Total budget of the Project: |
| Site for the research work: Civil Service Hospital Kathmandu,Nepal |
| Tentative date for the start of the Project: |
| Duration of the Research Project: |
| Name of Internal Reviewer: |
| Name of External Reviewer: |
| Signature & Seal of IRC: |

**Part – I**

**Administrative Information**

1. Research Title:

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

   Last (Surname) Middle (if any) First name

   Nationality:

   Citizenship Number with the name of the district 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):

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

   Telephone No.:

   Fax No.:

   e-mail:

   Website:

4. Name and title of the Co-Investigator responsible for the proposed research:

   Last (Surname) Middle (if any) First name

   Nationality:

   Citizenship Number with the name of the district 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:

5. Full name of the Institution associated with the Co- Investigator (if applicable):

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

   Telephone No.:

   Fax No.:

   e-mail:

   Website:

6. Declaration of the head of the Department.

   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:

7. Declaration of the head of the institution .

   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:

8. Is this research part of your Thesis?

   Yes No

   If yes,

   For what degree and in which subject?

   From which university?

From which country?

**Financial Information**

9. Research Title:

10. Name of the funding organization:

Contact information of funding organization or agency:

Postal Address:

Telephone No.:

Fax No.:

E-mail:

Contact person at the funding organization or agency:

Last (Surname) Middle (if any) First name

Designation:

Total amount of funds (in NRs / US $) allocated for the proposed research project:

Itemized budget (in detail) and justify the resources required for the proposed research work (*use additional sheet*)

**Part – III**

**Research Proposal Description**

11. Research Title:

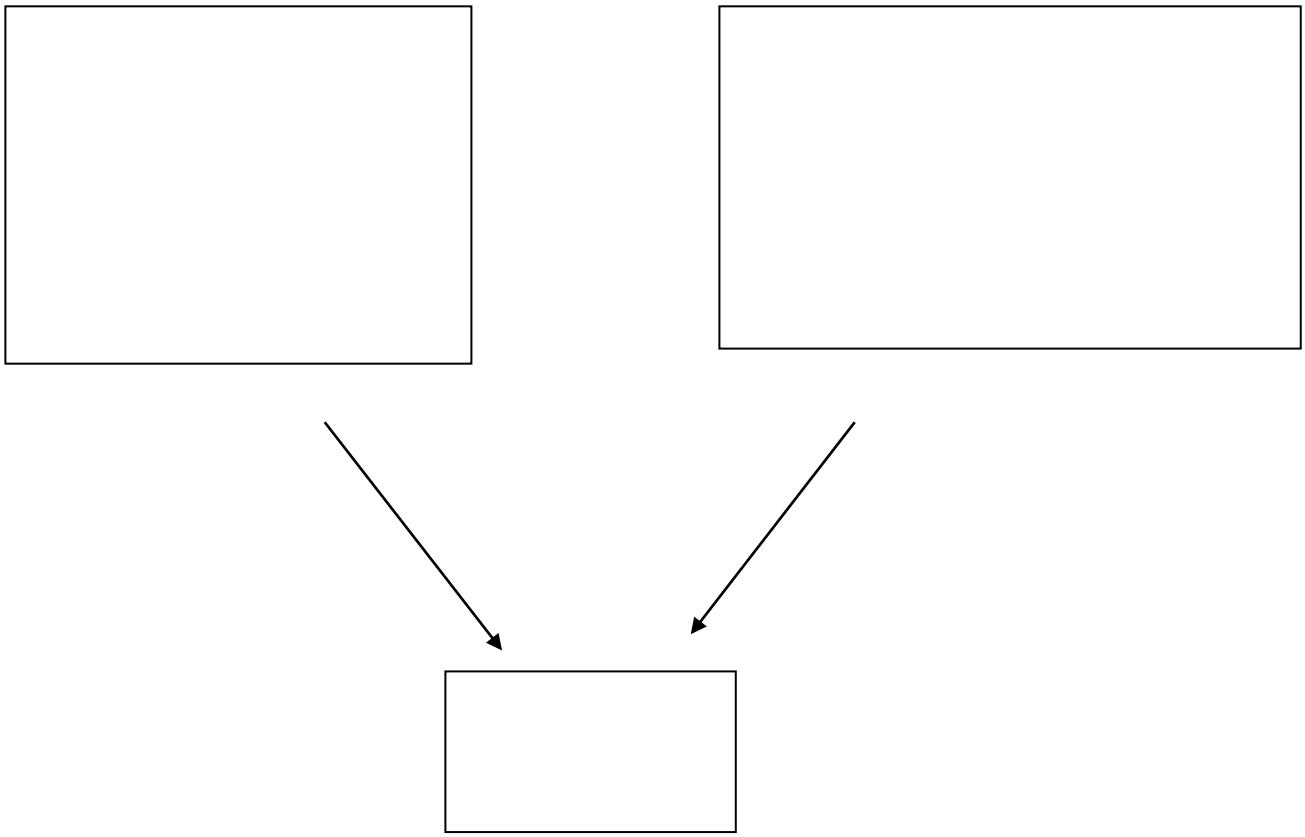
12. Proposal Summary(maximum 500 words):

13. Introduction:

13.1 Background of Study (maximum 500 words):

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

## 13.3 Conceptual framework



13.4 Research Objectives / purpose/aim of the study:

General

Specific

14. Research Design and Methodology

Research Method:

Study Variables:

Type of Study (Specify):

Study Site and Its Justification:

Study Population (Specify):

Study Unit:

Sampling Methods/Techniques (Specify):

Sample size (with justification):

Data Collection Technique / Methods (Specify):

Data Collection Tools: (please attached in annex)

Pre-testing the Data Collection Tools (if applicable):

Validity and Reliability of the Study Tools:

Limitation of the Study:

15. Plan for Data Management and Analysis:

Expected Outcome of the Research:

.

16. Plan for Dissemination of Research Results:

17. Plan for Utilization of the Research Findings (optional):

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

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

**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?

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:

Statements required in the informed consent form include:

- ✓ A statement that the human participants can withdraw from the study at any time without giving reason and without fear.
- ✓ A statement guaranteeing the confidentiality of the research participants.
- ✓ If required a statement on any compensation that might be given to the research participant and their visitors.
- ✓ A statement indicating that the participants have understood all the information in the consent form and is willing to participate in the research.

- ✓ Signature space for research participants, a witness and the date.

*(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?

The principal investigator.

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.

Research shows that majority of the patient cannot perform the inhalation technique correctly resulting the management of COPD is going on bad condition The study doesn't contain any vulgar questionnaires which may sensitive or can cause the effect to their culture and values but patient becomes benefited.

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:

**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 Institutional Review Committee (IRC), on the approval 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 IRC of this decision and provide the reasons for such actions. I will provide 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 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 IRC 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 on NHRC (Nepal Health Research Council) web site.
- 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 Member secretary indicating the submission of the approval of proposal.
2. Proposal will only be accepted if submitted in 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. Source of funding for the proposed project.
7. 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.
8. Consent form should be in Nepali & local language (if necessary).
9. Data collection tools should be in Nepali & local language (if necessary) including interview guideline, observation checklist, questionnaires etc.
10. Style of referencing should be in Harvard style.
11. List of abbreviations / acronyms should be provided.

**For students' applicants**

Recommendation letter from Academic Supervisor along with above all lists