

**Research Proposal Approval Format**

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| **Research Title:** |

# **Institutional Review Committee (IRC)**

**Institute of Science and Technology**

**Central Department of Microbiology**

**Tribhuvan University**

Kirtipur, Kathmandu

Phone: 01-4331869

Email: irc@iost.tu.edu.np

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| Name of Principal Investigator/Supervisor:Name of Student/ Investigator: Total budget of the Project:  Funding (if any):  Site for the research work:  Tentative date for the start of the Project:  Duration of the Research Project: |
| ***For Official Use Only***  ***(Please see the check list before Registration of the application form)*** |
| Registration No:  Date of registration:  Name of Reviewer:  Date of review:  Date of approval:  Signature & Seal of IRC: |

#### Part – I

###### Administrative Information

1. **APPLICANT’S DETAILS**
   1. **Student researcher:** *(if applicable)*

| **Passport size Photograph** | **Details** |
| --- | --- |
|  | Name:  Academic degree for which the student is admitted:  Affiliated Institution/Organization:  Mobile no:  Email address: |

* 1. **Principal Investigator OR Supervisor:**

*Note: This individual is responsible for effective oversight of the project in order to maintain proper ethical conduct and therefore must be appropriately qualified and experienced in carrying out the research process (i.e. in the case of a student project, the research supervisor or guide should be listed here.* ***Attach complete CV separately****.)*

| **Passport size Photograph** | **Details** |
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|  | Name:  Designation:  Qualification :  Affiliated Institution/Organization:  Office Address:  Office Telephone no.:  Mobile no:  Email address: |

* 1. **Co- Investigator(s)** *(if applicable)*

| **S.N** | **Passport size Photograph** | **Details** |
| --- | --- | --- |
| 1 |  | Name:  Designation :  Qualification :  Affiliated Institution/Organization:  Mobile no:  Email address: |
| 2 |  | Name:  Designation :  Qualification :  Affiliated Institution/Organization:  Mobile no:  Email address |

**\*In case of non- Nepali citizen, mention passport number and country of origin**

*(Use additional sheet if necessary)*

1. **Declaration of the head of the Institution (if applicable)**

If the proposed research is approved, we will allow him/her to conduct the research in this institution.

Signature:

Name:

Designation:

Name of the institution:

Contact/ Postal Address:

Telephone No.:

Fax No.:

Institutional E-mail:

Website:

1. **List the name(s) and institutional affiliation to the researcher(s) (other than co-investigator) to assist your project in Nepal and abroad (if any)**

*Name*  *Institution and Address*



*(Use additional sheet if necessary)*

1. **List the name(s) of Nepali researcher(s) (other than co-investigator) or Nepalese Institution/hospital/NGO(s) etc. from whom you may seek co-operation (if any)**

*(Use additional sheet if necessary)*

5. **List major equipment(s) in relation to your research project you plan to bring/import to Nepal (If applicable)**

(a)………………

1. ……

*(Use additional sheet if necessary)*

* 1. List details of all specimen(s) (if any) that you may transport from Nepal in relation to your research.

(a)

5.2Country of Destination:

Name of Institution:

5.3 Mode of Transportation of Specimen

5.4 How will you ensure duplicate specimens remain in the country?

……………………………………………………………………………

(If necessary, use additional sheet)

1. **Is this research part of student's thesis?**

Yes  No

If yes,

For what degree and in which subject?

From which department/campus/college?

#### Part – II

###### Financial Information

**Research Title:**

**Name of the funding organization:**

**Contact information of funding organization or agency**

Postal Address:

Telephone No.:

Fax No.:

Email address:

**Contact person at the funding organization or agency**

Name:

Designation:

Email address:

**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**

1. **Research Title:**

*(It should be informative, accurate, clear and concise with about 10-15 words. There should not be any acronyms. It should not include phrases like ‘a study of’ or ‘observations on’.)*

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1. **Proposal Summary(maximum 250 words):**

*The summary should stand on its own without the need for the reader to refer to the project description. It should be one paragraph and must include: A brief statement of the purpose, objectives, research methodology including research design, study population, research setting, measurement tools, time frame and expected outcomes.*

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1. **Introduction:**
   1. Background of Study (maximum 500 words):

*(Relevant to the topic, preferably recent evidences to drive the need of the study)*

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* 1. Statement of the Problem and Rationale / Justification (maximum 500 words)

***(Rationale should demonstrate the literature gap and what is intended to do to address the gap.*** *It should strive to answer the question of why the research needs to be done and what will be its relevance. )*

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* 1. Conceptual framework
  2. Research Objectives / purpose/aim of the study:

General

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Specific

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1. **Research Design and Methodology**

Research Method

Qualitative Quantitative  Combined

Study Variables:

Type of Study (Specify):

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Study Site and Its Justification:

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Study Population (Specify):

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Study Unit:

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Sampling Methods/Techniques (Specify):

Sample size (with justification):

Criteria for Sample Selection:

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Data Collection Technique / Methods (Specify):

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Data Collection Tools: (please attached in annex)

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

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Validity and Reliability of the Study Tools:

Potential Biases (if applicable):

Limitation of the Study:

1. **Plan for Supervision and Monitoring:**
2. **Plan for Data Management and Analysis:**
3. **Expected Outcome of the Research:**
4. **Plan for Dissemination of Research Results:**
5. **Plan for Utilization of the Research Findings (optional):**

How is the research project going to strengthen the research capability of the host institution: Nepali Researcher (if submitted from aboard)?

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

**Part – IV**

**Ethical Consideration**

1. **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.

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What is the frequency of the participant’s involvement in the research? Explain.

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Clearly indicate the participant's responsibilities in the research. What is expected of the research participants during the research?

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Are vulnerable members of the population required for this research? If yes, provide justification.

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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.

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Are there any benefits involved for the participants? If yes, identify clearly what are the expected benefits for the participants.

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1. **. Informed Consent Form / Ethical Issues:**

*(Ethical principles are based on Declaration of Helsinki. Please refer to explanations of the ethical consideration in the Declaration of Helsinki)*

**2.1 Clearly indicate the participant’s responsibilities in the research. (Mention clearly as what is the role of the participants during research For e.g. Any performance ; any preparation for the task, etc.)**

2.2 **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?

…………………………………………..………………………………

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.

……………………………………………………………………………

Is health insurance *(if applicable )*being made available to the research participants? If yes, please provide the necessary insurance data.

……………………………………………………………………………

(**Include in consent form)**

(Informed consent form should be submitted in English and Nepali language and also in the language of the research participants if s/he does not understand Nepali and English)

(Information required in the informed consent form includes but is not limited to:

* 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.
* Declaration that participants have understood all the information in the consent form and are willing to volunteer/participate in the research.
* Participants can withdraw from the study at any time without giving reason and without fear. State clearly how the participants can opt out the study.
* Guarantee of confidentiality of the research participants.
* Any compensation that might be given to the research participants and or their community (if applicable).
* Signature space for the research participants, a witness, and the date.)
* 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.
* If the study uses database or archival data the use of informed consent is not applicable.

**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), IoST, TU 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.

**Signature of Principal Investigator:………………………….**

**Date:** …………………

Co-investigator(s):

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| **S. N.** | **Name** | **Signature** |
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**CONFIDENTIALITY OF DATA: *Confidentiality of data MUST be addressed 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. Electronic version should be submitted to irc@iost.tu.edu.np.
4. Curriculum Vitae of the Principal Investigator/Supervisor Student/Investigator &Co-Investigators of the study team should be submitted.
5. Source of funding for the proposed project.
6. 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.
7. Consent form should be in Nepali & local language (if necessary).
8. Data collection tools should be in Nepali & local language (if necessary) including interview guideline, observation checklist, questionnaires etc.
9. Style of referencing should be in Harvard style.
10. List of abbreviations / acronyms should be provided.

**For students' applicants**

1. Recommendation letter from Academic Supervisor along with above all lists.