**Agriculture and Forestry University**

Institutional Review Board (AFU-IRB)



STANDARD OPERATING PROCEDURE (SOP) FOR

**NON-MEDICAL HUMAN SUBJECTS RESEARCH**

Publisher

Directorate of Research and Extension

Agriculture and Forestry University (AFU)

Rampur, Chitwan, Nepal

# Form for Request for Ethical Approval of Non-Medical Human Subjects Research

**Agriculture and Forestry University (AFU)**

**Institutional Review Board (IRB)**

Bharatpur, Nepal

E-mail: afu.irb@afu.edu.np | Website: [www.afu.edu.np](http://www.afu.edu.np)/irb

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| **Research Title:**  |

***For Official Use Only***

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| --- | --- |
| Registration No.: |  |
| Registration Date: |  |
| Approved Date: |  |
| Name of PI: |  |
| Project Budget Total |  |
| IR Processing Fee: |  |
| Research Site: |  |
| Project Initiation Date |  |
| Project Duration: |  |
| Name of Internal Reviewer: |  |
| Name of External Reviewer: |  |
| Signature & Seal of IRB: |  |

1. **Administrative Information**
	1. **Primary Investigator Information***All student researchers must have a faculty member sign-off as the primary investigator*

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| 1. Date:
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| 1. Research Title:
 |  |
| 1. Name of Principal Investigator:
 |  |
| 1. Designation/Title:
 |  |
| 1. Nationality
 |  |
| 1. Citizenship Number & place of issue (*Nepali citizens*):
 |  |
| 1. Passport Number & country (N*on-Nepali citizens*):
 |  |
| 1. Telephone No./ Mobile No:
 |  |
| 1. Email:
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* 1. **Co-Investigator Information** *(Use additional sheet if necessary)*

|  |  |
| --- | --- |
| 1. Name of Co-Investigator
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| 1. Designation/Title:
 |  |
| 1. Nationality
 |  |
| 1. Citizenship Number & place of issue (*Nepali citizens*):
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| 1. Passport Number & country (N*on-Nepali citizen*):
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| 1. Telephone No./ Mobile No:
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| 1. Email:
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* 1. **Non-AFU Researchers**

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| 1. Name of Institution associated with Principal Investigator:
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| 1. Institutional e-mail
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| 1. Telephone No:
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| 1. Contact/Postal Address:
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| 1. Website:
 |  |
| 1. Declaration of the head of the Institution
 | If the proposed research is approved, we will allow him/her to conduct the research.Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

* 1. **Research Assistants** *(Use additional sheet if necessary)*

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| 1. Name
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| 1. Institution
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| 1. Name
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| 1. Institution
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* 1. **Cooperating Institutions** *(Use additional sheet if necessary)*

List the name(s) of Nepali researcher(s) or Institution(s) from whom you may seek co-operation

|  |  |
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| 1. Name
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| 1. Institution
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* 1. **Equipment** *(Use additional sheet if necessary)*

List major equipment in relation to your research project you plan to bring/import to Nepal

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1. **Financial Information**

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| 1. Name of funding organization:
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| 1. Contact person:
 |  |
| 1. Designation/Title of contact:
 |  |
| 1. Total amount of funds
2. (*in NRs / US $*)
 |  |
| 1. Nationality
 |  |
| 1. Citizenship Number & place of issue (*Nepali citizens*):
 |  |
| 1. Passport Number & country (N*on-Nepali citizens*):
 |  |
| 1. Telephone No./ Mobile No:
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| 1. Email:
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1. **Research Proposal**
	1. **Proposal Summary (maximum 500 words)**

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

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* 1. **Research Objectives**

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1. **Population and Sampling**
	1. **Study Population, Site and Its Justification**

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* 1. **Sampling Methods / Techniques**

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* 1. **Sample Size and Justification**

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1. **Data Collection**
	1. **Data Collection Methods**

Describe all data collection methods including the purpose and sample.

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* 1. **Data Collection Instruments**

List all data collection instruments. Provide a copy of all instruments for review by AFU-IRB.

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* 1. **Data Sensitivity**

Do any of the study instruments include sensitive questions? This may include questions that are culturally sensitive, questions to which the answers could put the participant in danger or at risk of persecution/prosecution, and others. For each instrument that includes sensitive questions provide information on a) the population to which the instrument will be given; b) why it is necessary to ask the sensitive question(s); c) why it is appropriate to ask the question(s) to the population; and d) how the identity of the participants will be protected.

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* 1. **Data Management Plan**

Provide information on how you will manage data including any sensitive materials, security of data files, and other relevant information.

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* 1. **Work Plan**

Provide a planned schedule of activities including the duration of the study, tentative date of starting the project and work schedule.

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1. **Human Subjects**
	1. **Research Participants**

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| 1. Are participants required for this research?
 |  □ Yes □ No |
| 1. How many participants are required for this research?
 |  |
| 1. What will be the age range of the participants?
 |  |
| 1. Are vulnerable populations required for this research? *Check all that apply.*
 | □ No □ Minors (*Under 18 years of age*) □ Pregnant Women □ Fetuses or neonates□ Minorities □ Cognitively impaired persons  | □ Persons with disabilities □ AIDS/HIV+ subjects □ Terminally ill subjects□ Prisoners□ Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. If you answered *yes* to Question 6.1D above, provide a justification for conducting research with the vulnerable population.

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1. 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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1. 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**

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| 1. How will informed consent be obtained?
 |  □ Written □ Verbal |
| 1. Who will be responsible for obtaining consent?
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1. Will any information be withheld from the participants at the time the informed consent will be sought? Explain and justify.

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All research must include written or verbal informed consent from participants. All written consent documents and scripts for obtaining verbal consent must be provided to the Institutional Review Board. *All informed consent forms must be submitted to the review board in English. All the informed consent documents must include*:

1. A statement that the human 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.
2. The document must give a statement guaranteeing the confidentiality of the research participants and how the researcher will protect the data being collected.
3. A statement on any compensation that might be given to the research participant and or their community, if applicable.
4. A statement indicating that the participant has understood all the information in the consent form and is willing to volunteer / participate in the research.
5. Signature space for the research participants (for written consent), a witness, and the date.
6. **Sensitivity to Culture**

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| 1. Is the research sensitive to the Nepali culture?
 |  □ Yes □ No |
| 1. Explain your response to 7A.
 |  |

1. **Obligations of the Study Sponsor**

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| 1. Is there any risk of mental, physical, emotional, or other forms of injury to the study participants?
 |  □ Yes □ No |

If you answered *Yes* to question 8.A:

1. Describe how you will respond to any issue that occurs while collected data, including how you will obtain and provide medical or mental health services.

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1. How will your study provide for capacity building of the national research institutions in the host country?

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1. **Checklist for Submission to AFU-IRB**

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| **Did you include in your Ethics Review Packet:** | **Yes** | **No** | **Not Applicable** |
| 1. Information on the Primary Investigator, Co-Investigators and/or Non-AFU Investigators?
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| 1. Information on any research assistants who will participate in data collection or analysis activities?
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| 1. The name of any cooperating institutions within or external to Nepal?
 |  |  |  |
| 1. A complete list of equipment that will be imported into Nepal?
 |  |  |  |
| 1. Financial information including your source of funding?
 |  |  |  |
| 1. A summary of your proposal including rational, justification, and research objectives?
 |  |  |  |
| 1. A complete description of your sampling methods?
 |  |  |  |
| 1. A complete description of your data collection methods?
 |  |  |  |
| 1. A copy of all data collection instruments in English?
 |  |  |  |
| 1. A copy of all data collection instruments in the appropriate native language?
 |  |  |  |
| 1. An explanation of how you will manage data to protect the identify of participants?
 |  |  |  |
| 1. An overview of your work plan schedule?
 |  |  |  |
| 1. A complete description of who will be targeted as participants and how they will be recruited?
 |  |  |  |
| 1. A complete description of how consent will be obtained from participants?
 |  |  |  |
| 1. A copy of all consent forms and/or consent scripts in English?
 |  |  |  |
| 1. A copy of all consent forms and/or consent scripts in the appropriate native language?
 |  |  |  |
| 1. A clear description of the risks and benefits to participating in the study?
 |  |  |  |
| 1. A clear plan for how the study PI will handle any mental, physical, emotional, or other form of injury to the participant.
 |  |  |  |
| 1. A clear description of how the research will benefit the host country, particularly in terms of capacity development
 |  |  |  |

1. **Acceptance of Conditions and Declaration by the Investigator(s)**

I hereby certify that the above-mentioned statements are true, I have read and understood the regulation of the AFU-IRB on the approval of the 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 AFU-IRB of this decision and provide the reasons for such actions. I will provide AFU-IRB 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 AFU-IRB and submit at least one copy of any such articles to AFU-IRB.

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| Name of Principal Investigator |  | Signature of Principal Investigator |  | Date |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Co-Investigator |  | Signature of Co-Investigator |  | Date |