**Agriculture and Forestry University**

Ethical REVIEW Board (AFU-IRB)



STANDARD OPERATING PROCEDURE (SOP) FOR

**NON-MEDICAL HUMAN AND ANIMAL SUBJECTS RESEARCH**

Publisher

Directorate of Research and Extension

Agriculture and Forestry University (AFU)

Rampur, Chitwan, Nepal

## Form: Review of the Research Proposal for Ethical Clearance of Non-medical Human Subjects Research

|  |  |
| --- | --- |
| Project Title: |  |
| Registration No.: |  |
| Registration Date: |  |
| Name of Internal Reviewer: |  |
| Name of External Reviewer: |  |

| **Categories for Review** | **Review Questions** | **Review Ranking** |
| --- | --- | --- |
| ***Accept-able*** | ***Unaccep-table*** | ***Not Applicable*** |
| 1. **Admini-stration**
 | 1. Is *Section 1: Administrative Information* of the ethics form fully completed?
 |  |  |  |
| 1. Do the researchers have adequate qualifications and competencies?
 |  |  |  |
| 1. Do student researchers have an appropriate faculty member identified as the study Primary Investigator?
 |  |  |  |
| 1. **Finances**
 | 1. Is *Section 2: Financial Information* of the ethics form fully completed?
 |  |  |  |
| 1. Are there any demonstrable conflicts of interest?
 |  |  |  |
| 1. **Research Proposal**
 | 1. Is *Section 3: Research Proposal* of the ethics form fully completed?
 |  |  |  |
| 1. Is the study essential to accomplish the goal?
 |  |  |  |
| 1. Is there no other way to obtain the information?
 |  |  |  |
| 1. **Population & Sampling**
 | 1. Is *Section 4: Population and Sampling* of the ethics form fully completed?
 |  |  |  |
| 1. Is the target population and the sampling method appropriate for the study?
 |  |  |  |
| 1. Is the sample size appropriate for the study?
 |  |  |  |
| 1. **Data Collection**
 | 1. Is *Section 5: Data Collection* of the ethics form fully completed?
 |  |  |  |
| 1. Are the data collection methods appropriate for the study goals?
 |  |  |  |
| 1. Are the data collection methods appropriate for the study population?
 |  |  |  |
| 1. Are all data collection instruments provided in English?
 |  |  |  |
| 1. Are all data collection instruments provided in the local language?
 |  |  |  |
| 1. Are sensitive data being collected?
 |  |  |  |
| 1. The population to which the sensitive questions will be given is described?
 |  |  |  |
| 1. A justification of use of sensitive questions is provided and appropriate for the research context?
 |  |  |  |
| 1. A justification for asking sensitive questions to the specific study population is provided and appropriate for the research context?
 |  |  |  |
| 1. A clear description of how the identity of the participants will be protected is provided?
 |  |  |  |
| 1. A data management plan is provided including a clear description of how data will be protected?
 |  |  |  |
| 1. A work plan is provided with a realistic timeline?
 |  |  |  |
| 1. **Human Subjects**
 | 1. Is *Section 6: Human Subjects* of the ethics form fully completed?
 |  |  |  |
| 1. Are the number of participants required appropriate for the study?
 |  |  |  |
| 1. Are any vulnerable populations required for the study?
 |  |  |  |
| 1. Vulnerable populations: A justification is provided for conducting research with the population and is acceptable given the research goals and context
 |  |  |  |
| 1. The protocol includes a description of any benefits to the participants and how these benefits will be disseminated?
 |  |  |  |
| 1. The protocol includes a description of any risks to the participants and how these risks will be mitigated?
 |  |  |  |
| 1. Do the benefits outweigh the risks?
 |  |  |  |
| 1. Are the risks reasonable and not excessive?
 |  |  |  |
| 1. Description of consent process is provided and is appropriate for the study context and participant sample (*such as provisions for special populations*)
 |  |  |  |
| 1. Consent form includes: A clear description of the study topics
 |  |  |  |
| 1. A clear description of the role of the participant
 |  |  |  |
| 1. A statement that participants can withdraw from the study at any time without giving reason
 |  |  |  |
| 1. A statement that describes the process by which participants can opt out of the study
 |  |  |  |
| 1. A statement guaranteeing protection of the confidentiality of the research participant and the data collected
 |  |  |  |
| 1. A statement that describes any risks to the participants
 |  |  |  |
| 1. A statement that describes any benefits to the participants
 |  |  |  |
| 1. A statement that asks the participants if they understand the information in the consent and are willing to participate in the research
 |  |  |  |
| 1. The consent does not induce the participant to participate through coercion, money or other inappropriate incentives.
 |  |  |  |
| 1. The consent includes a mechanism to ensure consent from special populations, if needed
 |  |  |  |
| 1. The consent does not mislead or trick participants into participation
 |  |  |  |
| 1. **Sensitivity**
 | 1. Is the study appropriate within the Nepali culture?
 |  |  |  |
| 1. **Obligations of the Sponsors**
 | 1. Assurance of medical services related to research for study participants is provided?
 |  |  |  |
| 1. Reasonable mechanisms for care and compensation in case of injury, resulting from research is described?
 |  |  |  |
| 1. Provision of mechanism for capacity building of the national research institutions in the host country is described?
 |  |  |  |
| 1. **Reviewer Comments:**
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