**Agriculture and Forestry University**

Institutional Review Board (AFU-IRB)



STANDARD OPERATING PROCEDURE (SOP) FOR

**ANIMAL SUBJECTS** **RESEARCH**

Publisher

Directorate of Research and Extension

Agriculture and Forestry University (AFU)

Rampur, Chitwan, Nepal

#

# Form for Request for Ethical Approval of Animal 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

|  |
| --- |
| **Research Title:**  |

***For Official Use Only***

|  |  |
| --- | --- |
| Registration No.: |  |
| Registration Date: |  |
| Approved Date: |  |
| Name of PI: |  |
| Project Budget Total |  |
| IRB 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*

|  |  |
| --- | --- |
| 1. Date:
 |  |
| 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:
 |  |

* 1. **Co-Investigator Information** *(Use additional sheet if necessary)*

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

|  |  |
| --- | --- |
| 1. Name of Institution associated with Principal Investigator:
 |  |
| 1. Institutional e-mail
 |  |
| 1. Telephone No:
 |  |
| 1. Contact/Postal Address:
 |  |
| 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)*

|  |  |
| --- | --- |
| 1. Name
 |  |
| 1. Institution
 |  |
| 1. Name
 |  |
| 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

|  |  |
| --- | --- |
| 1. Name
 |  |
| 1. Institution
 |  |

* 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. **Specimens** *(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

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|  |
| * + 1. Name of Institution
 |  |
| 1. Country of Destination
 |  |
| 1. Mode of Transportation of Specimen(s)
 |  |

1. **Financial Information**

|  |  |
| --- | --- |
| 1. Name of funding organization:
 |  |
| 1. Contact person:
 |  |
| 1. Designation/Title of contact:
 |  |
| 1. Total amount of funds

(*in NRs / USD, Euro…*) |  |
| 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:
 |  |

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

Describe all data collection methods including the purpose and sample.

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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. **Animal Subjects**
	1. **Research Participants**

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| --- | --- |
| 1. Are human participants required for this research?
 |  □ Yes □ No |
| If you answer “Yes” to 6.1A above, please fill out the Form “Request for Ethics Approval of ***Human*** Subjects Research. This form is for ***animal*** subjects research. |

* 1. **Sampling**

|  |  |
| --- | --- |
| * + 1. How many animals will be used for this research?
 |  |
| * + 1. Provide a justification for the number of animals required for the research.
 |   |

* 1. **Housing Plan**

Describe your plan, processes, and procedures for housing animals including the conditions in which they will be kept.

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* 1. **Medical Records Plan**

Describe your plan and procedures for keeping medical records of animals.

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* 1. **Waste Management Plan**

Describe your waste management plan and how you will document waste management.

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1. **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**

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-Ethics Review**

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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?
 |  |  |  |
| 1. Information on any research assistants who will participate in data collection or analysis activities?
 |  |  |  |
| 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. A complete list of specimens that will be removed from 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. An explanation of how you will manage data files?
 |  |  |  |
| 1. An overview of your work plan schedule?
 |  |  |  |
| 1. A complete description of how many animals will be used in the study, for what purpose, and a justification?
 |  |  |  |
| 1. A description of your animal housing plan?
 |  |  |  |
| 1. A description of your medical records plan?
 |  |  |  |
| 1. A description of your waste management plan?
 |  |  |  |
| 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 Principal Investigator**

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

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

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

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# Resources for Primary Investigators

## Cage card

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Cage card** |   | **Cage No:** |  |  |  |  |  |
| Strain |   | Responsible person/Tel. No. |  |  |  |  |  |
|   |  |  |  |  |  |
| Number of Animals | ♂ : | Project Leader: |  |  |  |  |  |
| ♀: |  |  |  |  |  |
| Animal ID | DOB | Ear Mark/identification | Genotype/Sex | (Not needed if animals are not in exp) | Experimental Group | Comment |
|   |   |   |   | Start of Exp | End of Exp |   |   |
|   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |
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## Daily activity record sheet of Laboratory Animal Facility

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SN** | **Date** | **Temperature & Humidity** | **Water** | **Feed** | **Cleaning** | **New pups** | **Health Condition** | **Signature** |
| 1 |   |   |   |   |   |   |   |   |
| 2 |   |   |   |   |   |   |   |   |
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