Agriculture and Forestry University

Institutional Review Board (AFU-IRB)

STANDARD OPERATING PROCEDURE (SOP) FOR
NON-MEDICAL HUMAN AND ANIMAL SUBJECTS RESEARCH

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Background

Ethical issues in biological and social research are the serious and fundamental issues influencing behaviors related to customs and moral values of the public. Ethics relies on determining right and judicious activities and guided by moral principles existing in society. It is guided by the concept of human and animal right, social and professional responsibilities and beyond. In social and biological researches, it is concerned with the activities proposed in the research is ethical or not. It is primarily concerned with safeguarding the interest of researchers and aims to promote their rights, dignity, values, and responsibilities.

This standard operating procedure (SOP) is based on the following guidelines

i. National Ethical Guidelines for Health Research in Nepal and Standard Operating Procedures, published by National Health Research Council, 2011
ii. National Health Care Waste Management Guidelines, 2002

Purpose

- To streamline the process of receiving, reviewing and making appropriate decisions towards the proposals submitted to AFU–IRB by researcher so that their tasks can be executed free from bias and from any influence of those conducting the researches in the University.
- To safeguard the dignity, rights, safety, and well-being of research participants, involvement of animals, and promote scientific and ethical issues by guiding researchers through standard procedure.

Scope

The SOP is a valuable guideline for students, faculties, external researchers who want to conduct research within and in collaboration with AFU, AFU-IRB members, academic heads, along with administrative and assistance staff involved in AFU–IRB

Research units in different academic programs such as

- Thesis committee: Faculty of Agriculture
- Thesis committee: Faculty of Animal Science, Veterinary Science, and Fisheries
- Thesis committee: Faculty of Forestry
- Thesis committee: Center for Biotechnology
- Directorate of Research and Extension
- Externally funded researches which are executed in collaboration with AFU

Ethical clearance application process

A. Ethical clearance application

This section outlines the process for receiving ethical clearance for research. The forms that are required for seeking approval are located at: **Error! Reference source not found.**

A.1. Submission of application for ethical clearance

A.1-1. Any researchers, who want to do study/data collection/research in AFU, must get ethical clearance from AFU-IRB.

A.1-2. Principal investigator or correspondent researcher should submit the application on behalf of whole research team with given standard format.

A.1-1.2. Application should be addressed to member secretary of AFU-IRB

A.1-1.3. External researchers who are going to conduct the research in collaboration with any unit of AFU must apply for ethical clearance from AFU-IRB

A.1-3. Applicant should submit one electronic and one hard copy of research proposal along with application and processing fee as per the AFU-IRB decision. The researchers asked for presentation will have to submit additional designated copies of his/her printed ppt slides.

A.1-4. Only those applications fulfilling the requirements will be accepted for review.

A.1-5. Deficits in the application will be informed to the applicants within one week of submission.

A.1-5.1. Incomplete applications must be resubmitted duly completed.

A.1-6. If any amendments/corrections are made in the proposal already submitted and approved, the researcher must submit in writing the changes made with reasoning to the committee AFU-IRB. The proposal will be reviewed again in the IRB, taking the amendments into consideration during the re-approval process.

A.1-7. Application should include the Informed Consent Form as a separate copy which is to be used while undertaking the research. In addition, this may include a translation copy, in a local language if that is applicable.

A.2. Documents required for the ethical clearance application

A.2-1. Filled application form with signature and date in AFU-IRB format.

A.2-2. Latest version of curriculum vitae of principal investigator and co-investigators with academic qualification and work experiences.

A.2-3. The protocol of the proposed research in the given format with the supporting documents. (A copy of valid and reliable research tools, questionnaires etc)

A.2-4. Consent format if data collection in the field

A.2-5. A signed statement by the researcher stating that he or she will abide by the ethical principles of research.

A.2-6. Ethical clearance letter from the parent institution if the researcher is from other institution.

B. Ethical review process

B.1. Identification of reviewer

B.1-1. Ethical approval of research is mandatory for all research conducted at AFU:

B.1-1.1. It is mandatory to submit thesis proposal for all Graduate and Post Graduate Students to AFU-IRB for ethical approval.

B.1-1.2. Faculties, staffs and/or external researchers must submit proposals for AFU-IRB ethical approval.

B.1-1.3. The AFU-IRB committee can ask for presentation if required to get ethical approval.

B.1-1.4. It is the responsibility of assigned AFU-IRB member to get consent from the head/in charge of the concerned departments for further processing of ethical approval.

B.1-2. The AFU-IRB member secretary in consultation with coordinator will decide the reviewer for a particular proposal. Depending upon the nature of the proposal, it can be reviewed by more than one reviewer.

B.1-3. Some of the minor reviews can pass reviewer and approved without convening a meeting of the AFU-IRB.

B.1-4. Proposals passed through minor changes in the past meeting of AFU-IRB and minor changes in previously approved research can be approved by coordinator and member secretary.

B.1-5. Under an expedited review procedure, review of the research may be carried out by the AFU-IRB co-ordinator or by one or more experienced members of the committee designated by the co-ordinator. If required can ask for expert/peer review.

B.1-6. The reviewer(s) may exercise all the authorities except disapproval. Research may only be disapproved following review by the full committee. The review committee will adopt a method of keeping all members advised of research studies that have been approved by the expedited review process.

B.1-7. A checklist will be sent to the reviewer in order to maintain the consistency and objectivity of the review process.

B.1-8. Depending upon the nature of research proposal, the committee can invite the researcher to present the proposal to the panel of experts and its members. This will help the committee to understand the proposal in a better way and guide the researcher appropriately.

B.1-9. AFU-IRB will prepare a list of potential experts who are capable and interested to review the research proposals. These experts could be a specialist in specific diseases, in health systems, health research methodologies or legal or ethical aspects or member of special interest groups so that they can provide special expertise in the review and finalization process to the research proposals submitted to AFU-IRB.

B.2. Ethical concerns during the review process

B.2-1. Potential research related risks to the participants are reasonable in relation to the anticipated benefits that might be expected from participating in research study and to the importance of the knowledge that may result and attempts will be made to minimize those risks.

B.2-2. Informed consent will be provided

B.2-3. There will be adequate provisions to protect the privacy of participants and confidentiality of data will be maintained.

B.2-4. The research plan will make adequate provisions for monitoring the data collected to ensure the safety of participants.

B.2-5. The AFU-IRB will receive periodic and final report on the research

C. Decision on ethical application

C.1. Making decision

The committee members will consider the following before making the decision:

C.1-1. Withdrawal from the process if there is a 'conflict of interest'.

C.1-2. Decisions can only be made by a meeting that has a proper Quorum.

C.1-3. All relevant documents must be present before a decision can be made.

C.1-4. Only members who participate in the review should be involved in the decision.

C.1-5. The committee members should arrive at a pre-defined method for arriving at a decision on the basis of evidence.

C.1-6. The IRB will respond with one of the following decisions to the research applicant:

- **Approved:** either with or without comments or questions addressed to the applicant; any replies to a committee's comments or questions to be forwarded in due course;

- **Approved subject to conditions:** subject to recommended revisions of the proposal and/or satisfactory answers to questions asked of the applicant. The applicant's reply and/or revised proposal will be forwarded to consider the revisions that have been made and to provide final approval;
- **Approval deferred:** pending substantial revisions of the proposal/study and/or satisfactory answers to questions asked of the applicant. The applicant's reply and/or revised proposal will be forwarded to the committee for reconsideration and final approval, and
- **Approval declined:** reasons for declining approval to be forwarded to the applicant, either with or without an invitation to submit a substantially revised protocol for reconsideration.

C.2. Communicating a decision

C.2-1. A decision will be communicated in writing to the applicant according to the AFU-IRB procedures.

C.2-2. Approval will be given for maximum of **three years** at a time.

C.2-3. Projects, which have not been commenced within two years of original approval, must be resubmitted to AFU-IRB.

C.2-4. If the project is not complete within three years' validation period, the researcher will be required to write to AFU-IRB to request an extension of approval or will need to reapply.

C.2-5. The communication of the decision should include, but not be limited to the following:

i. The exact title of the research proposal reviewed.
ii. The potential research participant information sheet/material and informed consent form.
iii. The name and title of the research applicant.
iv. The name of the site(s) for the research.
v. The date and place of the decision.
vi. A clear statement of the decision reached.
vii. Any advice by the AFU-IRB concerning the research study.
viii. In the case of a conditional decision, any requirements by the AFU-IRB, including suggestions for revision and the procedure for having the application re-reviewed.
ix. The schedule/plan for the ongoing review by the AFU-IRB
x. In the case of a negative decision, clearly stated reason(s) for the negative decision should be mentioned.
xi. Signature and date of the authorized person of the AFU-IRB

C.3. Suspension or discontinuation of research

C.3-1. When the AFU-IRB is feels the circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved protocol and that, as a result, the welfare and rights of participants are not or will not be protected, the IRB will take the following steps:

i. Withdraw approval
ii. Recommend that the research project be discontinued, suspended, or that other necessary steps be taken
iii. A research must not continue if ethical approval has been withdrawn and the researches didn't comply with any special conditions required by the AFU-IRB.

D. Supervision and monitoring of research

D.1. AFU-IRB have the responsibility to ensure that the conduct of all research approved by AFU-IRB is carried out with the given ethical and technical standard.

D.2. The ongoing lines of communication between the AFU-IRB and the researcher should be clearly specified.

D.3. The frequency and type of monitoring determined by the AFU-IRB should reflect the degree of risk to participants in the research project.

D.4. To maintain standard of researches being conducted by associated researchers, the AFU-IRB should:

D.5-1. Provide guidelines to the researcher and help the researcher to follow those guidelines

D.5-2. Ensure relevance of the research to national and scientific needs.

D.5-3. Monitor the progress of the research and compliance on the proposed activities of the proposal accepted by AFU-IRB through periodic review process.

D.5-4. Review the proposed revision in the original research proposal (if necessary) and approve or disapprove it.

D.5-5. Immediate and continuous reporting by the researchers in order to warrant additional review of ethical approval of the protocol including:

i. Serious or unexpected adverse effects on participants.
ii. Proposed changes in the protocol; and
iii. Unforeseen events, that might affected the continual ethical acceptability of the project.

E. Right to Appeal/Complaint

E.1. An investigator who receives an unfavorable review by the committee has the right of appeal. This appeal is initiated by filing a notice of appeal in writing to the head of the institution within thirty (30) days from the date of notice he/she received.

E.2. The head of the institution may request the AFU-IRB for re-review of the proposal if he/she gets an appeal for the same.

E.3. The AFU-IRB shall notify the investigator for rehearing, and the investigator shall have the right to appear at the rehearing to defend the proposal.

E.4. Any research participants involved in a research project has the right to voice complaints or concerns directly to the Co-ordinator of IRB.

E.5. In case of an appeal to the committee by a research participant, the committee will determine the validity of the complaint and notify the principal investigator of its judgment in the matter. The latter will abide by the decision of the committee.

Formation of AFU-IRB

F. Composition of AFU-IRB

F.1. The AFU-IRB will consist of members from diverse disciplines. Potential candidates should be from faculties having at least postgraduate qualification in a related scientific discipline, preferably having training in ethics and the ethical review process.

F.2. The committee will have minimum of 7 and maximum of 15 members.

F.3. The committee should include at least three members who is not affiliated to the university.

F.4. Persons with expertise in following disciplines will be eligible for AFU-IRB member:

i. Agriculture
ii. Animal Science
iii. Veterinary Science
iv. Social Science
v. Public Health
vi. Biostatistics
vii. Law/teaching/Journalism/Community Leaders
viii. Environmental scientist/Ecologist

G. Membership of AFU-IRB

G.1. The Vice-Chancellor of the university will appoint AFU-IRB coordinator

G.2. The executive committee (EC) members of AFU-IRB will be appointed by the Vice-Chancellor in consultation with AFU-IRB coordinator.

- G.2-1. At least 33% of the member must be from different gender.
- G.2-2. The tenure of AFU-IRB EC will be for a period of 3 years.
- G.2-3. Member Secretary will be fixed by the first meeting of AFU-IRB.

G.3. AFU-IRB EC member should sign the acceptance of appointment and confidentiality agreement regarding the meeting deliberation, applicant's information's on research participants and related issues. The AFU-IRB administration staff should also sign the confidential agreement.

G.4. While revising the AFU–IRB EC, at least 33% of the members of the existing IRB members will be retained in order to ensure continuity of experience and smooth continuity of AFU–IRB.

- G.4-1. A member who does not want to continue as member of the AFU–IRB, he/she can submit resignation to AFU-IRB.
- G.4-2. Membership on the IRB will cease when resignation is accepted by the AFU–IRB.
- G.4-3. Replacement of the vacant membership can be initiated through the upcoming AFU–IRB meeting.
- G.4-4. For any voluntary resignation a prior notice of at least one month should be given to the AFU–IRB coordinator.

G.5. The membership will automatically expire if the member:

- G.5-1. Continuously absent in the meeting for more than 3 times without prior notice
- G.5-2. Deviates from the norms and standards of the committee
- G.5-3. Non-compliance or resignation from the position
- G.5-4. Is convicted by a court of law for a criminal offence

H. Functions and Responsibilities of the AFU-IRB

H.1. The AFU-IRB will be the apex body for ethical approval of research activities conducted within AFU. It will cover up undergraduate and post-graduate academic research through subsequent thesis committees (already existed and forth coming) in different academic programs. The charge to the AFU-IRB is to:

- H.1-1. To review research proposals according to the SOP conducted by the students as well as faculties of AFU with a view to approve, amend or reject the proposal.
- H.1-2. To organize research workshop/trainings within AFU.
- H.1-3. To organize orientation program for new members and reviewers of IRB on the ethical review process along with continuing education for existing members regarding ethical review process. Education will be linked to cooperative arrangements with other IRB's in the area, country or region.

H.2. Responsibilities of AFU-IRB towards the University

- H.2-1. The AFU-IRB will submit the following information to DOREX, AFU:
  - List of all the approved research proposals.
  - Progress report (Annually) on all research being conducted under the IRB's.
- H.2-2. IRB will notify any approved health research projects that was subsequently suspended or terminated to DOREX, AFU
- H.2-3. The AFU-IRB will report annually to DOREX, AFU information relevant to its procedures including:
  - i. Membership/membership changes
  - ii. Numbers of meetings
  - iii. The number of protocols presented, the number approved, and the number rejected
  - iv. Monitoring procedures in place and any problems encountered; and
  - v. Complaints procedures and number of complaints handled.

Management of the AFU-IRB

I. Office Management

I.1. It will have a separate AFU-IRB secretariat to carry out regular administrative work. It will be equipped with filing cabinet, locker for confidential, computer, printer and communication facilities (internet, telephone).

I.2. A fully furnished seminar room with LCD projector should be available for research related review meetings, education and training

I.3. The office will be managed by a full-time office assistant and part-time account officer including support staff for transport and communication.

J. Fund management

J.1. It will have its own fund management process and fund disbursement mechanism. Despite the 'research fund' granted by the institute, revenue will be generated through research proposals registration and review process.

J.2. An institutional overhead charge of up to 5% of AFU-IRB ethical review process charge can be levied on researches involving human subjects and hospital data base.

J.3. Each proposal submitted to AFU-IRB will be charged for ethical review process as per the AFU-IRB rule.

J.4. External donations, university grants could also be the source of revenue.

K. Recording and Reporting/Documentation and Archiving

K.1. Copies of all research proposals reviewed, scientific evaluations (if any) that accompany proposals, approved sample 'informed consent' documents, progress reports and other related documents including:

- K.1-1. Minutes of meetings.
- K.1-2. Records of continuing review activities.
- K.1-3. Copies of all correspondence between the IRB and investigators.
- K.1-4. A list of all members, reviewers and experts.

K.2. The AFU-IRB will maintain a record of all research protocols received and reviewed including the following:

- K.2-1. Name and responsible institution or organization or group or individual
- K.2-2. Project identification number(s)
- K.2-3. Principal researcher(s)
- K.2-4. Title of the project
- K.2-5. Ethical approval or non-approval with date
- K.2-6. Approval or non-approval of any changes to the protocol
- K.2-7. The terms and conditions, if any, of approval of any protocol
- K.2-8. Whether approval was by expedited review
- K.2-9. Action to be taken by the AFU-IRB to monitor/supervise the conduct of the research

K.3. For multi-center research proposals, the AFU-IRB will also record information provided by the researcher:

- K.3-1. Details of other centers involved.
- K.3-2. The approval status of the study at each centers, and
- K.3-3. Details of any amendments required at other centers
- K.3-4. Records will be kept at least for ten years even after the completion of the research. The records shall be accessible for inspection and copying by authorized representatives of the institutions.
- K.3-5. All documentations and communication of the AFU-IRB will be dated, filed and archived according to written procedures. Proper storage space should be provided for this in the institute. The co-ordinator and the person/s authorized by him can have access and retrieval of the various documents, files and archives.
- K.3-6. Documents that should be filed and archived include, but are not limited to:
  - K.3-6.1. The constitution, written standard operating procedures (SOP) of the AFU-IRB, and regular (annual) reports.
  - K.3-6.2. The CV of all the AFU-IRB members.
  - K.3-6.3. A record of all expenses (including allowances and reimbursements) of the AFU-IRB.

K.3-6.4. Agenda of the AFU-IRB meetings.
K.3-6.5. The minutes of the AFU-IRB meetings.
K.3-6.6. Copy of all research proposal documents.
K.3-6.7. All correspondence of the AFU-IRB.
K.3-6.8. A copy of all decisions and advice given by the AFU-IRB
K.3-6.9. Notification of the completion, premature suspension or termination or all research proposals.
K.3-6.10. Final summary or final report of all research studies.

L. Revision of SOP

This SOP document is subject to continuous change, review and update in accordance to constitutional, national and international perspectives.

AFU-IRB Meetings and Quorum Requirements

M. Meeting

M.1. AFU-IRB will organize a regular meeting each month.
M.2. An extra meeting might be called if number of proposals submitted to AFU-IRB will be five or more.
M.3. The coordinator will decide and assign a member or expert to evaluate the proposal submitted. The member will lead the discussion on that particular proposal in the meeting.
M.4. Member Secretary of AFU-IRB will prepare the agenda for the meeting in consultation with the coordinator of AFU-IRB. The Member Secretary will also keep minutes of the meeting and notify decisions to the researcher. The Member Secretary will be assisted in his or her tasks by an administrative secretary.
M.5. Applications should be submitted to the IRB secretariat at least two weeks before the next upcoming scheduled meeting that the applicants want their applications to be reviewed.
M.6. The secretariat should prepare and distribute a tentative agenda based on the applications received and matters arising from the previous meeting.
M.7. The facility and allowances of the members in the meeting will be as per the university rule
M.8. Secretariat will be facilitated by AFU-DOREX

N. Ad hoc /extraordinary meeting

N.1. Ad hoc/extraordinary review meeting will be held if there is an urgent issue (s) that do not qualify for expedited review but require a full review committee meeting.
N.2. The secretariat should circulate notice mentioning the date, venue, time and agenda of the ad hoc or extraordinary meeting at least 48 hours before the day of the meeting.

O. Quorum requirement

O.1. The minimum number of members required to compose a quorum will be more than 51 percent of the total.
O.2. Invited experts will not be considered for quorum requirement.
O.3. At least one member from different gender must be present in the meeting
O.4. At least one legal or non-affiliated member must be present in the meeting.