Guide Lines and Application Forms
Institutional Review Committee for Biomedical Research
University of Veterinary and Animal Sciences
Lahore, Pakistan

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APPLICATION FORM

Checklist

This checklist is prepared in order to aid investigators in preparing a complete application and to help expedite review by the Institutional Review Committee. Your cooperation in completing it will be greatly appreciated. Do not attach unnecessary pages such as instructions to fill the form and sample of consent form.

PRINCIPAL INVESTIGATOR/SUPERVISOR NAME:

_____

TITLE OF RESEARCH:_____

_____

DESIGNATION: _____

DEPARTMENT: _____

☐ A copy of IRC Application form with checklist.

☐ A copy of Research Proposal/ synopsis.

☐ A copy of Drug Brochure or any supplementary information enclosed (if applicable).

☐ A copy of informed consent both in English and Urdu or any other local language of the study's population.

☐ A copy of Questionnaire (in English or Urdu or any other local language of the study's population) being administered during the study (if applicable).

☐ I have made a copy of this entire application for my files.

☐ I have submitted the application form, research protocol and informed consent with Urdu translation by e-mail at www.uvas.edu.pk

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Name & Signature of student (where applicable) Date

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Signature of Supervisor/PI: Date

Institutional Review Committee for Biomedical Research
University of Veterinary and Animal Sciences, Lahore

Instructions / guidelines for researchers:

1. Please answer all questions. It is the responsibility of researcher to fill the application form appropriately. Incomplete and inappropriately filled form will not be accepted for review and discussion in the committee. This may result in delay in approval of the proposal.

2. In case of urgency, a strong justification should be provided for an expedited review and approval such as meeting a deadline for funding etc. Even in case of expedited review, it may take 7-10 days in granting approval if there is no ethical issue.

3. Application must be signed by PI. In case of student's/ resident's application, it should be signed by supervisor also.

4. In response to Q.1, please give a brief background of the study indicating the need for the study.

5. In response to Q.3, please don't give details of laboratory or scientific procedures. Only mention the procedures to be carried out on human subjects such as withdrawal of blood or collection and storage of other samples, treatment to be provided to study subjects, observations, interviews, focus group discussions etc.

6. In response to Q.8, only direct compensations should be mentioned. Travelling in connection of studies and presentation should not be included here.

7. In response to Q.9, all possible adverse events likely to occur as a result of the study should be included, with a plan to help the patient get appropriate treatment.

8. Consent form must be attached. Separate guidelines are given for drafting consent form which should be strictly followed. In case of improperly drafted consent form or its absence on preliminary scrutiny, no application will be considered for discussion in the committee.

Introductory Questionnaire

Title of protocol: _____

Principal Investigator/Supervisor/ Student:

1. _____ _____ _____
   NAME DESIGNATION SIGNATURE

2. _____ _____ _____
   NAME DESIGNATION SIGNATURE

3. _____ _____ _____
   NAME DESIGNATION SIGNATURE

Project involves the use of:
(Check all pertinent ones)

a)	☐	Experimental drug(s)/Non-approved use or non-approved dose for approved drugs
b)	☐	Radioactive agents
c)	☐	Behavioral research/Observational studies
d)	☐	Stem cells /Cloning experiments
e)	☐	Microbial Research
f)	☐	Molecular biology and genomics research
g)	☐	Fetal research
h)	☐	Nutritional trials
i)	☐	Blood sampling
	☐	Other (please specify):

Please provide details in case of **a, b**, **c** or **d** if checked

1. What is the purpose of the study? (Please give a brief background of the study)

2. Enumerate the objectives of the study

3. Brief description of methods used in protocol.

4. a) Expected duration of the study period (to completion).

   b) Expected duration of study on each individual subject.

5. Please indicate source of funding.

6. Subject information.

a) Group: ☐ Patients ☐ Public ☐ Others

b) Records: _____

c) Age range: _____

d) Sex: ☐ Male ☐ Female ☐ Both

e) If subjects are children, pregnant women, mentally retarded, or prisoners, or if it includes foetal research, give brief explanation of need to use these particular individuals.

7. Criteria for inclusion and exclusion of **patients and controls** (type separate).

8. Compensation:

a) To Research Subject:

Monetary: Yes ☐ No ☐ Amount: _____

Other: Yes ☐ No ☐ Specify: _____

Reimbursement of expenses: Yes ☐ No ☐ Type & amount: _____

b) To Investigators: Yes ☐ No ☐

If yes, then:

Monetary: ☐ Travel: ☐ Gifts: ☐ Amount: ☐

Other Specify: _____

9. Adverse effects:

a) Describe adverse effects/risks expected to the subjects involved in the investigation during the study?

b) What is the provision for managing these effects?

c) Who will pay for them?

10. In cases where therapeutic need of the research subject is identified during the course of the study:

a) What is the provision for managing these cases?

b) Who will pay for them?

11. Laboratory and Radiological studies:

a) Will any tests be performed which are not routinely included as part of the work-up for these types of patients?

b) Who or what agency will pay for these tests?

12. Location of study:
UVAS Department: _____

Other than UVAS (please specify the location): _____

13. What are the actual potential benefits, if any, to be obtained?

a) By participants?

b) By society as a result of this study?

c) Please specify benefit of the study to the funding agency or sponsors.

d) Please specify benefit of the study to institution where study is being conducted.

14. How will confidentiality of the subjects be ensured?

15. How will the study findings be shared with?

a) Study subjects

b) Community at large

16. Discuss **ETHICAL ISSUES** involved in the study.

17. Any other information relevant to the study in context to Pakistan?

18. Has this study been conducted elsewhere earlier? If yes, where? Please give references.

Guidelines for drafting an informed consent form

Although a sample of informed consent form is attached, additional guidelines are given here in order to help and facilitate the researchers in drafting a proper, acceptable consent form.

1. All studies involving human subjects should have a properly drafted consent form. No study should be done on human subjects without obtaining informed consent and sufficiently before the start of the study, at an appropriate time, and not at a time when s/he is under stress such as surgical procedure, and is unable to understand the study.
2. Consent may be written or verbal or telephonic. In case of unwritten consent, it should be signed by the person taking the consent and witnessed by a second person.
3. In case of children, an assent form from children and consent from guardian / parents is needed.
4. In case of mentally or physically incapacitated subject, consent should be obtained from immediate guardian or relative such as, wife or husband, father or mother, brother or sister etc.
5. In case of community studies, community leaders, elders, local political leaders, religious leaders (in certain cases), and governmental officials should be taken into confidence, and a written consent should be obtained.
6. In case of doing a study in other locations such as other hospitals and clinics, permission from appropriate authority or physicians should also be obtained.
7. The consent form should be in English, Urdu or other local language if needed. These should be identical in such a way that the translation of one into other is similar. The language should be easy which can be understood by study subjects (uneducated or primary passed). Use of technical terms should be avoided.
8. It should be written in "second or third person" and not in "first person". For example, "You will be asked to give 10 cc blood" or "you will be asked few questions" etc.
9. A properly drafted consent form should contain the following important points.
    a) Information sheet. There should be one paragraph or page giving information about the nature of study, its purpose and need, possible benefits of the study, and procedures to be carried out on the study subjects.
    b) Possible risks and benefits to the study subjects
    c) Availability of alternate treatment in case of therapeutic trials
    d) Voluntary participation without any compulsion, moral or otherwise and without any financial incentive or coercion. However, financial assistance or reimbursement for time and traveling may/should be provided to study subjects; which should commensurate with the time spent, and should not be too high.
    e) Right to withdraw from the study at any time without affecting their rights and treatment.
    f) Confidentiality
    g) If any specimen is to be stored, its time of storage and permission to use it in further research.
    h) Name and contact number of the investigator in case the study subject wants further clarification or information about study.
    i) Authorization from study subjects with their signature, thumb impression, signature of witness etc.

Important Notes

1. Studies shouldn't be done on patient's expenses.
2. If any new or additional tests are to be done as a requirement of study, their cost should be supported by the study.
3. If a new treatment is compared with an existing and established one OR two treatment modalities are being evaluated and compared, cost of treatment or difference in cost of treatment should be borne by the study. In addition any expected or unexpected complication arising as a result of new treatment should also be supported by the study.
4. Studies which are unlikely to produce any significant results because of faulty design are often considered not to be ethical as such studies cause wastage of time and resources. These should be avoided unless there is strong justification.

Sample Informed Consent

This is a generic sample form to help you address most situations. Please adapt as appropriate for your research protocol and institution. *Pending rulemaking for classified human subject research will require additional elements of consent.*

Project Information	
Project Title:	
Principal Investigator:	
IRC Ref No:	Organization:
Address:	Phone:
Other Investigators:	Organization:
Address:	Phone:

Consent document must be clearly written and understandable to subjects. The language must be non-technical (comparable to the language in a newspapers or general circulation magazine), and scientific, technical or medical terms must be plainly defined.

Informed Consent, whether oral or written, may not include language that appears to waive subjects' legal rights or appears to release the investigators or anyone else from liability for negligence.

It must begin with the introduction of the person seeking consent. For example: "I am Dr [SAK] from Department of _ _ _,University of Veterinary and Animal Sciences, Lahore and doing a research on _ _ _."
It must also include some background information on the topic of study. For example: "Disease X (Malaria) is a common disease in Pakistan, Asia and Africa, caused by a germ (parasite) spread by mosquito. It causes high grade fever. Some patients may have complications and even die. The commonly used drugs are losing their effectiveness and germs are getting resistant to it. A new drug known as [A] is supposed to be effective in treatment of disease (malaria) but there is not enough evidence that it is as good as other drugs used for treatment of disease (malaria)."

It should then state the following:

1. **PURPOSE OF THIS RESEARCH STUDY**
   - Include 3-5 sentences written in nontechnical language. "You are being asked to participate in a research study designed to..."
2. **PROCEDURES**
   - Describe procedures: "You will be asked to do..."
   - Identify any procedures that are experimental/investigational/non-therapeutic.
   - Define expected duration of subject's participation.

- Indicate type and frequency of monitoring during and after the study.

3. POSSIBLE RISKS OR DISCOMFORT

Note that these include not only physical injury, but also possible psychological, social or economic harm, discomfort, or inconvenience.

- Describe known or possible risks. If unknown, state so.
- Indicate if there are special risks to women of child bearing age; if relevant, state that study may involve risks that are currently unforeseeable, e.g., to developing fetus
- If subject's participation will continue over time, state: "any new information developed during the study that may affect your willingness to continue participation will be communicated to you."
- If applicable, state that a particular treatment or procedure may involve risks that are currently unforeseeable (to the subject, embryo or fetus, for example.)

4. POSSIBLE BENEFITS

- Describe any benefits to the subject that may be reasonably expected. If the research is not of direct benefit to the participant, explain possible benefits to others.

5. FINANCIAL CONSIDERATIONS

- Explain any financial compensation involved or state: "There is no financial compensation for your participation in this research."
- Describe any additional costs to the subject that might result from participation in this study.
- Please indicate any financial benefits to the subjects including therapeutic or diagnostic costs being covered by the study.

6. AVAILABLE TREATMENT ALTERNATIVES

- If the procedure involves an experimental treatment, indicate whether other non-experimental (conventional) treatments are available and compare the relative risks (if known) of each.

7. AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES

- "This study involves (minimal risk) (greater than minimal risk)." In the event that greater than minimal risk is involved, provide the subject with the following information.
- If you are injured as a direct result of taking part in this research study, emergency medical care will be provided by [name] medical staff or by transporting you to your personal doctor or medical center. Indicate who will pay for this treatment.

8. CONFIDENTIALITY

- Describe the extent to which confidentiality of records identifying the subject will be maintained.

  "Your identity in this study will be treated as confidential. The results of the study, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you."

  "However, any records or data obtained as a result of your participation in this study may be inspected by the sponsor or by AKU ERC members".

  In addition, list steps to protect confidentiality such as codes for identifying data.

9. TERMINATION OF RESEARCH STUDY

You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to

participate. You will be provided with any significant new findings developed during the course of this study that may relate to or influence your willingness to continue participation. In the event you decide to discontinue your participation in the study,

- These are the potential consequences that may result: (list)
- Please notify (name, telephone no., etc.) of your decision or follow this procedure (describe), so that your participation can be orderly terminated.

In addition, your participation in the study may be terminated by the investigator without your consent under the following circumstances. (Describe) It may be necessary for the sponsor of the study to terminate the study without prior notice to, or consent of, the participants in the event that (Describe circumstances, such as loss of funding.)

10. AVAILABLE SOURCES OF INFORMATION

- Any further questions you have about this study will be answered by the Principal Investigator:
  Name:
  Phone Number:
- Any questions you may have about your rights as a research subject will be answered by:
  Name:
  Phone Number:
- In case of a research-related emergency, call:
  Day Emergency Number:
  Night Emergency Number:

11. AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study.

Name of participant/Parents/Guardian (Printed or Typed):_____

Signature/Thumb Impression of participant/Parents/Guardian: _____

Date: _____

Name of person obtaining consent: _____

Signature of person obtaining consent:

Date: _____

Signature of Principal Investigator: _____

Date: _____

Guidelines for Researcher

All research projects involving human subjects, whether as individuals or communities, including the use of fetal material, embryos and tissues from the recently dead, supported and undertaken by UVAS faculty, staff or students, wherever conducted, shall be reviewed by the Ethical Review Committee (IRC) before the study begins.

Some research that involves human subjects may be exempted from the regulations requiring IRC approval. Examples include educational research, testing and survey procedures where no identifying information will be recorded that can link subjects to the data, and disclosure of the data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects financial standing, employability, or reputation. Such exemption would be conditional to:

- The informed consent is taken from the research subject.
- The information gathered being relevant/beneficial to the research subject and his/her community.
- Proposal includes planning for sharing study findings with the research subject/s and the relevant communities planned, as well as mechanisms for informing the research subject.
- Also exempted are the uses of existing data, documents or specimens, where no identifying information will be recorded that can link subjects to the data. Examples:
- Literature review; and theoretical analysis. In such cases the only ethical Concern would be acknowledgement of sources.
- Analysis of data, documents, specimen, not linked to individual subjects.
- Evaluation studies of intervention programmes/projects, especially by those who were partners in planning the intervention.
- All researchers must give the subject participants the option of sharing the results and specify how this will be done.

1. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others.
2. The human subjects in your project must participate willingly, having been informed about the research. Please provide all information that is likely to affect the person irrespective of age, sex, or literacy level of the subjects. If the human subjects in your project are part of a vulnerable population, such as prisoners, children or mentally handicapped then the researcher should clearly state why is it necessary to have such groups as their research subjects and how do they plan to administer the informed consent.

Essentials of informed consent are:

4.1 Comprehension

Investigator must ensure that the informed consent is clearly comprehended by the subject / guardian

4.2 Purpose of research must be clearly explained.
4.3 Procedure
In simple word describe the procedure that the subjects would be expected to undergo. Identify any procedures that are experimental/ investigational/ non-therapeutic. Indicate type and frequency of monitoring during and after the study.
4.4 Length of time subject is expected to participate. If subject's participation is expected to continue over a long period of time, please indicate that any new information that develops during the study and may affect the subjects' willingness to continue participation will be communicated to them. This would apply even when the intervention/investigation phase of the study has ended but monitoring continues.
4.5 Benefits of the research must be shared with/communicated to:
a. Subjects
b. Other study participants
c. Society
In studies evaluating drugs or other products the subjects should be advised as to the availability of the product after discontinuation of the study. Please indicate whether drug would be available to the patients free of cost. If not, kindly specify expected local cost.
4.6 Please specify financial burden to be incurred by the research subject while participating in the study.
4.7 Explain all foreseeable risks or discomforts to the subjects. Note this not only includes physical injury, but also possible psychological, social, or economic harm, discomfort, or inconvenience. If risk is unknown, state so.|
4.8 Treatment for adverse experiences Explain what therapeutic measures would be available to the subjects in case of adverse reactions or injury as a result of being a participant in the study. All research related adverse reactions are the financial responsibility of the researchers.
4.9 Confidentiality
Describe the extent to which confidentiality of records identifying the subject will be maintained.
4.10 Person to contact for answers to questions, or in event of research related injury or emergency.
4.11 Statement that participation is voluntary and that refusal to participate will not result in any penalty or any loss of benefits that the person is otherwise entitled to receive.
4.12 Subjects right to withdraw from the study at any time.
4.13 How sharing of results with subjects will occur.
4.14 No abbreviations will be used.

Consent document must be clearly written and/or verbally explained so as to be understandable to subjects (local language wherever applicable). The language must be non- technical (comparable to the language in a newspaper or general circulation magazine), and scientific, technical or medical terms must be plainly defined. It is PI's responsibility to ensure quality of consent procedure.

3. The researcher should submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, potential conflicts of interest and incentives for subjects.

4. Specify the cost of management directly related to the study and indicate what portion of the cost would be incurred by the study participants.

5. The researcher should also declare any personal and institutional benefits (monitory or otherwise including travel) accrued through study participation.
6. Please also specify benefits of the study to the funding agency or sponsors if any.
7. The research protocol should indicate that there is compliance with the principles of Helsinki Declaration. In case of conflict kindly specify the particular clause, which is being contravened.
8. a) Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person.
   b) Non-medical research should be conducted by suitably qualified persons
9. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy and confidentiality of the patient's information. Minimize the impact of the study on the subject's physical, mental and social integrity.
10. In the conduct of research, the investigator must at all times respect the personality, rights, wishes, beliefs, consent and freedom of the individual subject.
11. Volunteers and patients should be reimbursed for travel and any out of pocket expenses e.g. any wage loss if applicable.

Application

12. The researcher responsible for the ethical and scientific conduct of the research should submit a typed application for review of the ethics of proposed biomedical research. The procedure is as follows:

    All information and application forms are available at IRC website Institutional Review Committee General Principles.
13. IRC meets every second Friday of the month.
14. The deadline for submission of the application is 2 weeks prior to the next meeting.
15. Applications will be acknowledged and researchers shall be informed of the review date. The researchers shall also be communicated regarding the incompleteness of an application. This will obviously delay the review process.
16. The outcome of review shall be communicated to the researchers within a week after the IRC meeting.
17. In cases where the IRC requests supplementary information or changes to documents from the applicant, such information should be provided at least a week before the next meeting.
18. In cases where clarification is sought and researchers fail to respond within 3 months, IRC will send a reminder and allow a further 3 months period for response. Beyond these 6 months, the file will be closed.
19. Researcher may be asked to present the case in the meeting if required.
    a) Follow-up (of the researcher).
    b) At the end-report

    Documents for submission

20. Applications which are not submitted by e-mail will not be reviewed and discussed in the meeting.
21. "Two hard copies of the IRC application form (see annexure) should be submitted in addition to electronic submission".
22. Two copies of research protocol (clearly identified and dated), together with supporting documents and annexes. This should always include description of the ethical considerations involved in the research.
23. Questionnaire (if applicable) intended for research participants should be included.
24. When the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g. recent investigator's brochure, published data, a summary of the product's characteristics).
25. A description of the process to be used to obtain and document consent.
26. Informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and, when required in other languages.
27. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants.
28. CIOMS guideline "Research subjects who suffer physical injury as a result of their participation are entitled to such financial or other assistance as would compensate them equitably for any temporary or permanent impairment or disability. In the case of death, their dependents are entitled to material compensation. The right to compensation may not be waived".
29. A description of the arrangements for insurance coverage for research participants, if applicable.
30. A statement of agreement to comply with ethical principles set out in relevant guidelines.
31. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other IRCs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions should be provided.

Approval Conditions

32. Approval is given for a specified period. If the project takes longer than the specified period to complete, a request for an extension of the ethics clearance should be sought.
33. Approval is given on condition that any alterations proposed to the approved protocol are submitted to the Committee for approval prior to the alterations being affected.
34. Approval is given on condition that a copy of the research project final report is lodged with the Ethics Committee for its information.

35. Approval is given subject to researchers notifying the Ethics Committee if and when a project is curtailed, terminated or completed.
36. Approval is given for therapeutic trials subject to the principal investigator notifying the Ethics Committee within seven (7) days of any adverse event or occurrence that takes place during that trial.

Research could be audited by IRC during the research period to ensure compliance with guidelines.

References:

Ethics Review Committee Guidelines for Biomedical Research Prepared by The Aga Khan University, Karachi, Pakistan

International Ethical Guidelines for Biomedical Research Involving Human Subjects Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), Geneva 1993.

Institutional Review Board Guidebook, National Institutes of Health, USA Year 2000.

Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization, Geneva 2000.