APPLICATION FORM

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Institutional Review B o a r d (I R B)

Mehran University of Engineering & Technology, Jamhsoro

Submission address: IRB Chairmen, USPCAS-W Mehran University of Engineering & Technology, Jamshoro
Ph: +92-22-2109145 E-mail: uspcasw@admin.muet.edu.pk URL: http://water.muet.edu.pk/about-us/

Note: All research projects must be submitted to IRB Chairmen, USPCAS-W Mehran University of Engineering & Technology, Jamshoro. Ph: +92-22-2109145 E-mail: uspcasw@admin.muet.edu.pk

Checklist

This checklist is prepared in order to facilitate an investigator in preparing a complete application and to help MUET, Institutional Review Board for expedited review.Your cooperation in completing it will be highly appreciated.

- ☐ One copy of IRB Application form with checklist
- ☐ One copy of Research Protocol
- ☐ A copy of Drug Brochure or any supplementary information enclosed (if applicable).
- ☐ One copy of informed consent in English and Urdu or Sindhi relevant to the population study.
- ☐ One copy of Questionnaire in English and Urdu or Sindhi administered during the study (if applicable).
- ☐ Please make a copy of this entire application for your files.
- ☐ I have submitted the application form, research protocol and informed consent with Urdu translation by e-mail.

_____ _____
Signature: Principal Investigator Date

_____ _____
Signature of supervisor (if applicable) Date

_____ _____
Signature of Chairman of the Department Date

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Instructions / guidelines for researchers

1. Form to be filled out and submitted with the research protocol when requesting IRB review.

2. Please use the IRB Framework– Guidance document to help answer the questions below. If appropriate, you may directly copy-paste text from the research protocol sections in the protocol.

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

4. The review process takes take 6 weeks in granting approval.

5. Application must be signed by Principal Investigator. In case of student's/ resident's application, it should also be signed by the supervisor.

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Introductory Questionnaire

Research Proposal
Title:
Date created:
Duration of proposed study (one year, two years, more than two years):
Name of Principal Investigator (PI):
PI Institute/Organization:
Address of PI Institute/Organization:
Country of PI Institute/Organization:
Collaborating Institutions: (Please provide information about all Institutions/Organizations collaborating in this research)

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1. Research Question and Methodology

(1.1) What is the research question? Why is it important?

(1.2) How is the methodology and proposed analysis appropriate given the research question(s)?

(1.3) What is the context in which the research will be conducted? How has this influenced the research design? The protocol must include details (if applicable) about existing and planned community engagement and collaborative partnerships and how they have influenced or shaped the proposed research.

(1.4) Are there any other parties involved in the research? What potential interests of these parties might be in conflict?

(1.5) Are all relevant resources and protections for the research secured?

(1.6) ***Have the research staff the relevant training and protections?***

2. Respecting and Protecting Research Participants and Communities

(2.1) What are the anticipated harms and benefits?

(2.2) What are your plans for obtaining consent?

(2.3) How do you plan to protect confidentiality?

(2.4) How do you plan to access, store and distribute any collected biological material? Guidelines for Collection, Usage, Storage and Export of Human Biological Materials are available on National Bioethics Committee website: http://nbcpakistan.org.pk/guidelines.html

3. Implications and Implementation of the Research Findings

(3.1) What will happen when the research is either stopped or is complete?

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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 close relative
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 and Urdu with translation into 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.

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Important Notes

1. Studies should not 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.

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Sample Informed Consent

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

Project Information	
Project Title:	Project Number:
ERC Ref No:	Sponsor:
Principal Investigator:	Organization:
Location:	Phone:
Other Investigators:	Organization:
Location	Phone:

Consent document must be clearly written and understandable to subjects. The language must be nontechnical (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.

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."

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- 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."

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 :

  Name:

  Phone Number:

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- Any questions you may have 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 understood the 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. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Participant Name (Printed or Typed):
Date:

Participant Signature:
Date:

Principal Investigator Signature:
Date:

Signature of Person Obtaining Consent:
Date:

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