

Ethical Review Committee
Foundation University Medical College
Islamabad, Pakistan



APPLICATION FORM

PRINCIPAL INVESTIGATOR'S NAME: _____

DESIGNATION: _____

DEPARTMENT: _____

Checklist

- ☐ A copy of ERC Application.
- ☐ A copy of Research Protocol.
- ☐ A copy of Drug Brochure or any supplementary information enclosed (if applicable).
- ☐ A copy of informed consent in English, Urdu or any other local language of the population study.
- ☐ A copy of Questionnaire being administered during the study (if applicable).
- ☐ A List of Researchers Involved.
- ☐ Soft copy to be send on. erc.fumc@fui.edu.pk

Signature: Principal Investigator

Date

Signature of supervisor (if applicable)

Date

Signature of Head of the Department

Date

GUIDELINES FOR APPLICANTS:

The study project should be submitted to president ERC for review by the committee. Following are the requirements for the submission to ERC at least two weeks prior to ERC meeting which takes place every third Tuesday of the month.

1. 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 for review and discussion in the committee and it 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 dead line 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 primary investigator and Head of Department. In case of student's/ resident's application, it should be signed by supervisor also.
4. One soft copy and three hard copies of the study project with references and any other supporting documents have to be deposited. The research protocol must have following important information:
 - a. A brief background of the study indicating the need for the study.
 - b. Materials and methods used in the study
 - c. Expected duration of the study period (to completion).
 - d. Expected duration of study on each individual subject.
 - e. Criteria for inclusion and exclusion of patients and controls
5. Along with research protocol following other documents are needed to be deposited.
 - a. Investigator's Curriculum vitae
 - b. Informed consent form given to patients or study subjects (If applicable) in English, Urdu or any other local language which research participants can easily understand. (A sample consent form is given within the application)
 - c. A filled copy of one of questionnaire (If applicable)
6. 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 should be submitted (e.g., recent investigator's brochure, published data, a summary of the product's characteristics)

7. All significant previous decisions (e.g. those leading to a negative decision or modified protocol whether in the same location or elsewhere) by other ERCs or any other regulatory authorities for the proposed study should be provided.

1) Title of Study Protocol -----

2) Investigators details

S.#	Name of Investigator	Designation	Department	Signature

3) This project/research involves the use of:

(Check all pertinent ones)

Serial No.	Check or cross	Type of research and subjects involved
1		Any new experimental drug(s) or Radioactive agent
2		Left over body samples (Blood, body fluids, tissues etc)
3		Non-therapeutic research (informational Surveys)
4		Non-approved use or non-approved dose for approved drugs
5		Experimental surgical procedures
6		Fetal research or Pregnant women
7		Vulnerable population (prisoners, mental retardation, children)
8		Behavioural research
9		Gene molecular cloning
10		Any other (please specify):

4) Please indicate source of funding and has funding been approved?

5) Subject information.

a) Group: ☐ Patients ☐ Students ☐ Others

b) Age range:

c) Gender: ☐ Male ☐ Female ☐ Both

d) 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.

6) Compensation:

a) To research subject:

Monetary:	Yes ☐	No ☐	Amount:
Other:	Yes ☐	No ☐	Specify:
Reimbursement of expenses:	Yes ☐	No ☐	Type & amount:

b) Investigators: Yes ☐ No ☐

If yes, then:

Monetary: ☐ Travel: ☐ Gifts: ☐ Amount:

Other Specify:

7) 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 and if required who is going to pay for them?

c) In cases where therapeutic need of the research subject is identified during the course of the study, what is the provision for managing these cases and who will pay for them?

d) Will any tests be performed which are not routinely included as part of the work-up for these types of patients and who or what agency will pay for these tests?

8) Location of study:

OPD:

Inpatients
Wards:

FUMC/FFH
Department:

Other than FFH/FUMC (please specify the location):

10) What are the actual potential benefits if any, to be obtained?

a) By participants?

b) By society as a result of this study?

c) Any benefit of the study to the funding agency or sponsors?

d) Any benefit of the study to institution where study is being conducted?

11) How will confidentiality of the subjects be ensured?

12) How will the study findings be shared with study subjects, department and at institution as a whole?

13) Any other information relevant to the study in context to Pakistan?

14) Is there any similar study conducted elsewhere earlier? If yes where? Please give positive and negative points in it.

Guidelines for drafting an informed 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 he/she 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, consent from guardian / parents is needed.
4. In case of a mentally or physically incapacitated subject or children, consent should be obtained from parents/guardian or immediate 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. 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.



FOUNDATION UNIVERSITY MEDICAL COLLEGE

CONSENT FORM

For MINIMAL RISK Medical Human Subject Research

(e.g., for blood draws, data collection, leftover specimens, interviews, surveys etc.)

- Instructional text appears in red **and should be removed prior to submission to the ERC.**
- Red text in parentheses () should be replaced by information for your study, e.g., (your name here)

CONTACT INFORMATION:

Name of Study protocol Director -----

Address and phone number -----

DESCRIPTION: ☐ You are invited to participate in a research study on

- (describe project in non-technical language; include types of questions that will be asked, if applicable;
- (Explain purpose of the research).
- (Describe procedures, questions, survey, mention video/audio recording (if applicable), and what will become of tapes after use, e.g., shown at scientific meetings; describe the final disposition of the material, data, recording).

RISKS AND BENEFITS:

- The risks associated with this study are (describe foreseeable risks or discomfort to subjects; if none, state as such).
- The benefits which may reasonably be expected to result from this study are (describe any benefits; if none, state as such).
- Your decision whether or not to participate in this study will not affect your employment/medical care.

TIME INVOLVEMENT: Your participation in this experiment will take approximately (amount of time).

PAYMENTS: You will receive (describe reimbursement; where there is none, state as such) as payment for your participation.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand that

- Your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.
- You have the right to refuse to answer particular questions.
- If you agree, your identity will be made known; otherwise ☐ your privacy will be maintained in all published and written data resulting from the study.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant kindly check that whether your following rights have been fulfilled:

- ✓ Be informed of the nature and purpose of the experiment;
- ✓ be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- ✓ Be given a description of any attendant discomforts and risks reasonably to be expected;
- ✓ Be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- ✓ Be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- ✓ Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- ✓ Be given an opportunity to ask questions concerning the experiment or the procedures involved;
- ✓ Be instructed that consent to participate in the medical experiment may be withdrawn at any time and you may discontinue participation without prejudice;
- ✓ Be given a copy of the signed and dated consent form; and
- ✓ Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

The extra copy of this consent form is for you to keep.

Signature of Adult Participant

Date

When consent is obtained from legally authorized representative LAR (e.g., parent(s), guardian), include these signature lines for representatives and a description of their authority to act for the participant:

Signature of Parent, Guardian

Date

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject’s Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

Signature of Person Obtaining Consent

Date

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a **short form** foreign language consent.

Signature of witness

Date

(e.g., staff, translator/interpreter, family member, or other person who speaks both English and the participant’s language)

- Translated short form must be signed and dated by both the participant (and their LAR) and the witness.
- The English consent form (summary form) must be signed by the witness and the POC. The non-English speaking participant does not sign the English consent.