



**Ethical Review Committee**

**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).

Permission letter/evidence from concerned authorities if study setting is other than FUSH

Soft copy to be send on erc.fush@fui.edu.pk

**------------------------------------------- ----------------------------** Signature: Principal Investigator Date

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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:

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 one hard copy of the study project with references and any other supporting documents have to be deposited. The research protocol must have following important information:
	1. A brief background of the study indicating the need for the study.
	2. Materials and methods used in the study
	3. 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)
5. 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)
6. 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.
7. **Title of the Study:**
8. **Investigators details**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| S.# | Name of Investigator | Designation | Department | Signature |
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1. **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 |  | Intervention/experimental procedures |
| 6 |  | Fetal research or Pregnant women |
| 7 |  | Vulnerable population (prisoners, mental retardation, children) |
| 8 |  | Behavioural research |
| 9 |  | Gene molecular cloning |
| 10 |  | Diagnostic investigations |
| 11 |  | Any other (please specify): |

1. **Please indicate source of funding and has funding been approved?**

1. **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 fetal research, give brief explanation of need to use these particular individuals.

1. **Compensation:**
	1. To research subject:

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

* 1. Investigators: Yes No

If yes, then:

Monetary: Travel: Gifts: Amount:

Other Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Adverse effects:**
	1. Describe adverse effects/risks (if any) expected to the subjects involved in the investigation during the study?

* 1. What is the provision for managing these effects and if required who is going to pay for them?

* 1. 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?

* 1. 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?

1. **Location of study:**

OPD: Inpatients Wards FFH/FUMC/

 FUCD/FUCP/

FUCN

Other than FFH/FUMC/FUCD/FUCP/FUCN (please specify the location):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **What are the actual potential benefits if any, to be obtained?**
	1. By participants?

* 1. By society as a result of this study?

* 1. Any benefit of the study to the funding agency or sponsors?

* 1. Any benefit of the study to institution where study is being conducted?

1. **How will confidentiality of the subjects be ensured?**

1. **How will the study findings be shared with study subjects, department and at institution as a whole?**