# JINNAH MEDICAL AND DENTAL COLLEGE
## Research Cell
## Ethical Review Committee (ERC)
## Application Form

## Instructions

- Please read the form carefully before filling.
- The principal investigator should fill in the form completely after reading through National Bioethics Committee guidelines https://nbcpakistan.org.pk/assets/nbc-erc-guidance-sheet-(2022).pdf
- For the studies involving animals separate Animal Study Protocol form will also be filled in addition to this ERC form.
- All communications will be through email ID: erc.jjmdc@jmc.edu.pk
- Please provide all required documents mentioned in checklist as well as any relevant additional document.
- ERC will take four to six weeks for evaluation; students' proposals will be expedited and be evaluated within two to three weeks.
- Reviewer`s comments should be incorporated in the proposal and re-submitted to ERC in one week time.
- ERC will issue the Approval Letter in name of Principal investigator after agreement from 60% of quorum.
- ERC reserves the right to reject any application if 60% quorum agrees upon.
- PI should intimate ERC upon completion of the project.
- PI should submit a copy of published article to ERC.

## Attachments Checklist

☐ Duly filled, signed and stamped ERC application form
☐ Study protocol, Technical Committee and UGRC (undergraduate students) approval letters
☐ Written Informed consent form (English & Urdu both)
☐ Data collection tools (questionnaire/Performa)
☐ Any other relevant supporting document / forms
☐ Budget (if applicable)

## Declaration Statement

- I accept the responsibility that the information provided in this form is accurate.
- I undertake to abide by the ethical principles underlying the declaration of Helsinki and good practice guidelines on the proper conduct of research.
- I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by Ethical Review Committee (ERC) in giving approval.
- I undertake to notify ERC of substantial amendments to the protocol or the terms of the approved application, and to seek a favorable opinion from the ERC before implementing the amendment.
- I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patients or other personal data. I understand that I am not permitted to disclose identifiable data to third party unless the disclosure has the consent of the subjects' data.
- I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
- I understand that after getting ERC approval letter, I must duly fill the "Data Access Form of JMDC" and take approval from competent authority before starting data collection.

**Principal Investigator Signature:** _____ **Date:** _____

**Supervisor / HOD Signature:** _____ **Date:** _____

## 1. Study Identification

| | | | |
|---|---|---|---|
| **Research Project Title** | | | |
| **Study Site** | | | |
| **Start Date** | | **End Date** | |

## 2. Principal Investigator

| | |
|---|---|
| **Principal Investigator** | ☐ **Faculty** ☐ **Student** |
| **Discipline** | ☐ **Medical** ☐ **Dental** |
| **Department** | |
| **Name & Academic Position** | |
| **Email Address & Phone** | |
| **Name of Supervisor / HOD** | |
| **Email Address & Phone** | |

| | |
|---|---|
| **Co-Investigator** | ☐ **Faculty** ☐ **Student** |
| **Discipline** | ☐ **Medical** ☐ **Dental** |
| **Department** | |
| **Name & Academic Position** | |
| **Email Address & Phone** | |

Add more tables if needed.

| | |
|---|---|
| **Co-Investigator** | ☐ **Faculty** ☐ **Student** |
| **Discipline** | ☐ **Medical** ☐ **Dental** |
| **Department** | |
| **Name & Academic Position** | |
| **Email Address & Phone** | |

## 3. Project involves the use of

Check all pertinent ones

- ☐ Experimental drug(s)
- ☐ Radioactive agents
- ☐ Non-therapeutic research
- ☐ Non-FDA approved use (drug repurposing) or non-approved dose for approved drugs
- ☐ Experimental surgical procedures
- ☐ Fetal research
- ☐ Behavioral research
- ☐ Gene molecular cloning
- ☐ Other (please specify):

## 4. Scientific Background and Rationale

### 4.1. Brief background of the problem:

### 4.2. Justification and relevance:

### 4.3. Study objectives:

## 5. Study Design and Methods

**5.1. Study design:**

**5.2. Study population:**

**5.3. Inclusion criteria:**

**5.4. Exclusion criteria:**

**5.5. Sample size and justification:**

**5.6. Study procedure(s):**

**5.7. Data collection methods:**

## 6. Risks and Benefits

**6.1. Length of time of involvement of participants**

**6.2. Potential risks to participants:**

**6.3. Risk minimization strategies:**

**6.4. Expected benefits to participants and/or Society**

## 7. Ethical Considerations

**7.1. Written informed consent process:**

**7.2. Confidentiality and data protection:**

**7.3. Vulnerable populations (if applicable):**

**7.4. Compensation or reimbursement:**

**7.5. Right of the participant for refusal**

## 8. Data and Specimen Handling

**8.1. Type of data/specimens collected:**

**8.2. Storage location and duration:**

**8.3. Future use of data/specimens:**

**8.4. Data sharing plan:**

## 9. Regulatory and Administrative Information

**9.1. ERC approval status at other sites (if any):**

**9.2. Funding source(s):**

**9.3. Conflict of interest declaration:**