# ETHICAL REVIEW COMMITTEE
## Application Form
## Jinnah Medical & Dental College (JMDC) - Medicare Cardiac & General Hospital (MCGH), Karachi

Office: 021-111123789 Ext 2011, erc.jmdc@jmc.edu.pk

| | | | | | |
|---|---|---|---|---|---|
| **Title of the Project** | | | | | |
| **Name of Researcher** | | | | | |
| **Discipline/Specify Specialty** | MBBS ☐ | BDS ☐ | DPT ☐ | FCPS ☐ | Other research ☐ |
| **Supervisor** | | | | | |
| **Department** | | | | | |
| **Affiliation** | Sohail University | | Jinnah Medical & Dental College | | |
| **Sample type & number** | Patient Data | Blood | Biopsy | Data collection by questionnaire | Any other |
| **Study Population** | | | | | |

| | **Please answer each question by ticking the appropriate box** | **YES** | **NO** | **N/A** |
|---|---|---|---|---|
| 1. | Have you, before filling in this form, read a relevant research ethics guideline of animal, human or biological material research? Guidelines available online at https://www.who.int/publications/i/item/9789241502948 https://olaw.nih.gov/sites/default/files/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf | | | |
| 2. | Is the project multidisciplinary with involvement of different departments / institutes? | | | |
| 3. | Does the PI/Co-PIs of the project (early stage/experienced) have appropriate scientific skills and experience for execution of the project under consideration? | | | |
| 4. | Does the study involve participants who are particularly vulnerable? (e.g. refugees, prisoners, victims of violence, patients with sensitive medical conditions e.g. HIV/AIDS, drug addiction) or are unable to give informed consent (e.g. children, people with learning disabilities)? | | | |
| 5. | Does the study involve archival material collected during research/routine laboratory testing and the material cannot be traced to its origin or cannot be accessed? | | | |
| 6. | If the answer to the items 2,4,5 is yes, then have you taken formal approval from the collaborating institutes/organizations/centers? | | | |
| 7. | Will the study involve discussion of sensitive topics (e.g. sexual activity, drug use) or induce embarrassment, psychological stress or anxiety or cause harm or negative consequences? | | | |
| 8. | Is there any potential conflict of interest relating to the study? If yes then have you declared the nature of conflict in the proforma? | | | |
| 9. | Will financial inducements be offered to participants? | | | |

| | | | | |
|---|---|---|---|---|
| 10. | Will drugs, placebos, or other substances (e.g. food or drink constituents, dietary supplements) be administered to the study participants? | | | |
| 11. | If answer to 10 is yes, then is the proposed research registered with Drug Regulatory Authority of Pakistan according to DRAP Act 2012? (Guidelines available online at http://www.dra.gov.pk/userfiles1/file/ProcedureforClinicalTrialApplications.pdf) | | | |
| 12. | Does this study involve handling, transportation and storage of Infectious agents, toxins, or chemicals (pathogenic to humans, animals or plants)? | | | |
| 13. | If answer to 12 is yes, then are the standard biosafety measures (contamination control, spill response, waste management, use of protective apparel, and inventory control) ensured for the execution of this project? | | | |
| 14. | If the study involves distribution of questionnaires to the participants, has the right to Response Omission and Anonymity been provided to them? | | | |
| 15. | In case of animal studies, have you considered alternatives (*in vitro* systems, computer simulations and/or mathematical models) to reduce or replace the use of animals as far as possible? | | | |
| 16. | Will you make sure that the health of humans/animals be given prior consideration and avoid or minimize discomfort, distress, and all procedures will be kept aseptic, painless and minimally intrusive? | | | |
| 17. | Will you provide adequate care to all humans/animals and ailing study subjects shall be properly treated by the qualified care providers and will be removed from further study? | | | |
| 18. | Will you ensure confidentiality and data protection related to study participants? | | | |
| 19. | Will you share study findings with the participants and ERC when asked? | | | |
| 20. | Will you make sure that the results are only used for research purpose and information disseminated only through research publication / conference papers/presentations? | | | |
| 21. | Have you attached the consent form with explicit right of the participants to withdraw from study at their will? | | | |
| 22. | What is the sample size of your study i.e. how many samples/participants you required? | | | |
| 23. | What is the duration of your study? | | | |
| | Start Date: | End Date: | | |
| 24. | Describe the study setting (e.g. location, experimental set-up, community clinic, affiliated hospital). | | | |

**NOTE:** Duly filled and signed application should be submitted with following documents:

- ☐ Title Page of Research Synopsis / project
- ☐ Project Summary
- ☐ Methodology/Research Proformas, if any
- ☐ Statistical Analysis
- ☐ Informed consent (if applicable)
- ☐ Consent/NOC/ERC from the internal or external collaborating institution, if applicable
- ☐ A Copy of the filled application along with required documents should be emailed at erc.jmdc@jmc.edu.pk

**Declaration:** I/We declare that all the information given in this form and written in the proposal is correct and I/We will abide by the ethical guidelines relevant to this research. I/We will reapply for ethical approval if there is a significant change or revision in the design or protocol of the proposed study.

| | | |
|---|---|---|
| Researcher<br>Name:<br><br>Contact: | Institute:<br><br>Department:<br><br>Email: | Signature: |
| Supervisor<br>Name:<br><br>Contact: | Institute:<br><br>Department:<br><br>Email: | Signature: |
| Co - Supervisor (s)<br>Name:<br><br>Contact: | Institute:<br><br>Department:<br><br>Email | Signature: |
| Head of Department<br>Name:<br><br>Contact: | Institute:<br><br>Department:<br><br>Email: | Signature: |