**Ethical Considerations & Declaration Format for PG Students (Investigators) of MGMMCH**

**Title of Synopsis/Research Proposal: ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………**

1. **Statement of Ethical Considerations: -**

This Synopsis/Research proposal has been approved by Departmental Research Advisory Committee/Head of Department and Guide, MGM Medical College and MGM Medical College Hospital Jamshedpur.

All procedures performed in presented study involving human participants will be in accordance with the ethical standards of the institutional Ethics committee.

1. The proposed work will be assessed by the MGMMC Ethics Committee on Human Research.
2. Participant Information Sheet (PIS) will be shared with each participant and informed consent (ICF) will be taken from the participants
3. The study will also be reviewed, approved and monitored by the ethics committee.
4. Privacy and confidentiality of study participants will be assured.
5. Participants will be informed that this is a research study.
6. Participants will be informed that participation is entirely voluntary and they are free to decline or withdraw from participation
7. Potential risk: Risks associated with blood sample and any other testing samples collection. However, trained nurses/technicians will collect biological specimens. Any adverse event during the study procedure will be immediately brought to the notice of treating physician and site PI to ensure timely intervention at the participating hospital.
8. The Proposal work has not been started. The work will be started after permission of the IEC of MGMMC, Jamshedpur.
9. The IEC expects that, the researchers keep the committee informed for the following:
   1. All procedures performed in presented study involving human participants will be in accordance with the ethical standards of the institutional Ethics committee and its later amendments or comparable ethical standards.
   2. All cases of protocol, Informed consent and patient information sheet amendments will be submitted to IEC review and approval before implementation.
   3. Serious and unexpected adverse events, Protocol deviation related to the conduct of the study will be informed with adequate justification to IEC.
   4. Any new information that may affect the risk/benefit ratio of the study will be informed to IEC.
   5. Quarterly & Annual progress report of Research will be informed to IEC in quarterly manner Final Research report will be submitted at the end of the study.
10. **Undertaking, Declaration & Attestation**
11. I/We have read the all terms and conditions of DRAC & IEC. All necessary Institutional facilities will be provided if the research project is approved.
12. All research procedure will be done as per ICMR/Good Clinical Practice guidelines and SOP of IEC, MGMMC, Jamshedpur. All Principal Investigator and Co-Investigator declare that they will no conflict of interests. The Research projects passed by the Departmental Research Advisory committee will have to be researched under IEC, MGM Medical College, Jamshedpur.
13. I/We agree to submit Project report within one month from the date of completion of the project.
14. The Co-Investigator will be selected by the Principal Investigator. The Co- Investigator has to follow the instructions of the Principal Investigator. In the absence of the Principal Investigator, the Co- Investigator of the project has to carry forward the work of the project. In case of non-compliance of these rules, the Principal Investigator can remove the Co- Investigator from his project and select a new Co- Investigator. All Principal Investigator and Co-Investigator and staffs declare that they will no conflict of interests. All these incidents will have to be given to IEC administration.
15. I also declare that there is no conflict of interest in any manner or with anyone. This work will be done without any financial support by any sponsor or by other means.

**Signature of Principal Investigator**

**Name:**

**Date:**