**ANNEXURE 4: Form IA**

**Proforma to be submitted to the Institutional Ethics Committee (Human studies)**

**(**for projects other than those mentioned in form IB**)**

*Kindly submit 10 Hard copies of proforma and consent forms in English & Hindi to the Member Secretary, Institutional Ethics Committee (Human Studies), IGMC Shimla*

*A soft copy is to be sent to email id of institutional Ethics committee*[*iec.igmc.sml@gmail.com*](mailto:iec.igmc.sml@gmail.com)*.*

1. Title of the project:
2. Name of the Principle investigators/co-investigators:

Designation:

Department:

Email ID:

Contact no:

1. Number of projects already with the investigators/co-investigators:
2. Date of approval by scientific committee IGMC Shimla
3. Sources of funding
4. Objectives of the study:
5. Justification for the conduct of the study:
6. Methodology: It should provide details of the number of patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations to be done etc.:
7. Permission from Drug Controller General of India (DCGI) if applicable
8. Costs involved (Appx. In Rs)
9. Investigations c. Disposables
10. Exempted d. Drugs/Contrast Media
11. Ethical issues involved in the study:

*less than minimal risk / more than minimal risk to the study subjects (for guidance please consult ICMR guidelines.*

1. Do you need exemption from obtaining Informed Consent from study subjects- if so, give justifications?
2. Whether Consent forms part1 and 2 in English and in local language are enclosed?
3. Documents attached
   1. Brief CV of investigators (including no. of projects with him/her)-Needed only for investigator/s from outside IGMC Shimla Brochure
   2. Investigator’s Brochure
   3. Others
4. Conflict of interest for any other investigator(s) (if yes, please explain in brief)
5. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirement of the ICMR guidelines (2017)

Signature of the Investigators:

Email ID:

Contact No:

Signature of the Head of the Department

(Note: The proforma must be accompanied by consent forms I & II in English and Hindi Consent form I is equivalent to Patient Information Sheet. The investigators must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format)