**Form -A**

**Proforma to be submitted to the SRM MCH &RC Institute Ethics Sub-Committee (Human Studies) for MBBS/MD/MS/DM/M.Ch/MDS/MSc/B.Tech/M.Tech Students/Pharm.D/other courses**

**(for Thesis or Dissertation)/ projects**

*Kindly submit 10 copies of proforma and consent forms in 2 parts (in English and Tamil) to the Member Secretary, Ethics (Human) committee, Dept of Pharmacology, SRM MCH &RC*

**1.** Title of the project:

1. Name and department/address of the investigator/student with course pursuing:
2. Name of Faculty (Guide/Co-guides/co-investigators) with designation & department:
3. Date of approval by SRM Scientific Committee:
4. Sources of funding
5. Primary & secondary objectives of the study:
6. Background & Justification for the conduct of the study

**8.** Study hypothesis/research question

1. Methodology:
   1. Study design
   2. Sample size with justification
   3. No of groups
   4. Inclusion criteria
   5. Exclusion criteria
   6. Intervention:
   7. Control:
   8. Dosages of drug & frequency with duration
   9. Investigations /procedures to be done etc.
   10. Type of randomization & method used
   11. Method of allocation concealment
   12. Blinding/masking if any
   13. Brief procedure
2. Setting in which subjects will be recruited from:
3. Period of recruitment:
4. Potential risks involved to the participants of the study:
5. Describe what benefits might be reasonably expected by the participant as a result of study participation.
6. Do you need exemption from obtaining Informed Consent from study subjects ?– if yes, give justifications
7. Whether Consent forms part 1 and 2 in English and in tamil are enclosed?
8. If appropriate, is there a children’s assent? If yes, please submit a copy of this form
9. Has the Case report form (data collection form) been enclosed?

Signature of the Investigators: Date :

Signature of the Head of the Department Date:

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