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:
2. Name and department/address of the investigator/student with course pursuing:
3. Name of Faculty (Guide/Co-guides/co-investigators) with designation & department:
4. Date of approval by SRM Scientific Committee:
5. Sources of funding
6. Primary & secondary objectives of the study:
7. Background & Justification for the conduct of the study
8. Study hypothesis/research question
9. Methodology:
    a. Study design
    b. Sample size with justification
    c. No of groups
    d. Inclusion criteria
    e. Exclusion criteria
    f. Intervention:
    g. Control:
    h. Dosages of drug & frequency with duration
    i. Investigations /procedures to be done etc.
    j. Type of randomization & method used
    k. Method of allocation concealment
    l. Blinding/masking if any
    m. Brief procedure
10. Setting in which subjects will be recruited from:
11. Period of recruitment:
12. Potential risks involved to the participants of the study:
13. Describe what benefits might be reasonably expected by the participant as a result of study participation.
14. Do you need exemption from obtaining Informed Consent from study subjects ?– if yes, give justifications
15. Whether Consent forms part 1 and 2 in English and in tamil are enclosed?
16. If appropriate, is there a children's assent? If yes, please submit a copy of this form

17. 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)*