SECTION - 2

(For Institute Ethics Committee (IEC)-Human Studies)

Proforma to be submitted to the JKKNInstitutional Ethics Committee for MDS Students (for Thesis or Dissertation)

l. Title of the project:

2. Name and department/address of the Student Researcher:

3. Name of Faculty (Guide/Co-guide) with designation & department:

4. Date of approval by Departmental PG monitoring committee:

5. Ethical issues involved in the study [Along with level of risk, the risks should be written in detail. If you feel there will be no risk, give justification]:

   less than minimal risk / minimal risk / minor increase over minimal risk/more than minimal risk to the study subjects (for guidance please consult "National Ethical Guidelines for Biomedical and Health Research involving Human Patticipants, 2017")

6. Do you intend to co-enroll participants from other studies where the guide or co-guide are the principal investigator or co-investigator? Yes / No

7. If co-enrollment will be done, details of the other projects should be given as following:

8. Benefit of the study:

9. Details of Informed Consent Process:

a) Who will take the informed consent?

b) When will the informed consent be taken?

c) How will the informed consent be taken?

d) Where will the informed consent be taken?

10. Do you need exemption from obtaining Informed Consent from study subjects - if so give justifications.

1 1. Whether Consent forms in English and in local language are enclosed? (if the consent form in local language is not applicable, appropriate explanations must be provided)

12. Documents attached

   a. Waiver Application Form (Annexure-I)-if applicable
   b. Review Exemption Application Form (Annexure-2)-if applicable
   c. Brief CV of Guides and Co-Guides (including no. of projects with him/her) - Needed for all Investigators for each project separately
   d. For student projects, the guide should give a signed statement on a separate sheet with details of the project proposal that "I take full responsibility and accountability for planning, execution and adverse events occurring during the study. The data collected and records will be retained by me for a period of three years".
   e. Investigator's brochure
   f. Others

13. Conflict of interest for any other investigator(s) (if yes, please explain in brief)

14. 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 requirements of the ICMR guidelines (2017)

A. Signature of the Student Researcher
(Name & Designation)

Signature of the guide
(Name & Designation, Department,
Seal and Date)

Signature (s) of the co-guide
(Name & Designation, Department,
Seal and Date)

Signature of Head of the Department of the candidate
(Name & Designation, Department,
Seal and Date)

B. Signature(s) of the Co-guide from collaborating department (s)
(Name & Designation, Department,
Seal and Date)

Signature(s) of Head(s) of the Collaborating department (s)
(Name & Designation, Department,
Seal and Date)

Note: The proforma must be accompanied by Informed Consent Document (ICD) in English and Tamil. Informed Consent Document should comprise Patient Information Sheet and the consent form. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format. Studies involving children below 7 years should include parent / LAR consent form, while studies involving children above 7 years and below 18 years of age should also include written assent form for children 12-18 years of age and verbal assent for children 7-12 years to be mentioned in parent/LAR consent form, in addition to parent / LAR consent form

ECLARATION

Title of the Study:

I take full responsibility and accountability for planning, execution and adverse events occurring during the study. The data collected and records will be retained by me for a period of three years.

(Name & designation of guide)

Signature of Guide