NATIONAL INSTITUTE OF TECHNOLOGY

(Established by Ministry of Human Resources Development, Govt. Of India)
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RESEARCH & DEVELOPMENT CELL

INSTITUTIONAL ETHICS COMMITTEE (IEC)

INITIAL REVIEW SUBMISSION FORM FOR ETHICAL CLEARENCE

(Form to be filled by the Principal Investigator (PI)/Supervisor for submission to IEC)

Code No. of IEC (To be filled by IEC Member Secretary):

1. Title of the research proposal.

2. Name of the Principal Investigator(s)/Supervisor with qualification and designation.

3. Name of the Co-Investigator(s)/Co- Supervisor with qualification and designation.

4. Name of the Institute/Hospital/Field area where research will be conducted.

5. Cover letter forwarded from the Head of the Department/Institution/PI/Supervisor.

6. Consent from the HODs of all the departments where the study is going to be conducted is mandatory for submission of the research proposal to the Ethics Committee.

7. Protocol of the proposed research.

8. Ethical issues in the study and plans to address these issues.

9. Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow-up cards etc.

10. Informed consent process, including patient information sheet and informed consent form in English and local language(s).

11. For any drug / device trial, all relevant pre-clinical animal data and clinical Trial data from other centers within the country/other countries, if available.

12. Usefulness of the project/trial

13. Expected 'benefits' to volunteers/community

14. 'Benefits' to other categories if any

15. Explain all anticipated 'risks' (adverse events, injury, and discomfort) of the Project.

16. Efforts taken to minimize the 'risks'

17. Research proposal approval by Scientific Advisory Committee, Drug Controller General of India, Health Ministry screening committee (if needed).

18. Any regulatory clearance required.

19. Source of funding and financial requirements for the project.

20. Other financial issues including those related to insurance.

21. Agreement to report all Serious Adverse Events (SAE) to SCIC-IEC.

22. Statement of conflicts of interest, if any.

23. Agreement to comply with the relevant national and applicable international guidelines.

24. Statement describing any compensation given to study participation (including expenses and access to medical care).

25. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.

26. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification (s) to the protocol made on that account. The reasons for negative decisions should be provided.

27. Specific ethical issues, as identified by the investigating team.

28. Curriculum vitae of all the investigators with relevant publications in last five years.

29. Plans for publication of results/positive or negative/while maintaining the privacy and confidentiality of the study participants.

30. Register the proposal with Clinical Trials Registry India (CTRI) www.ctri.in and submit the CTRI number along with the proposal, if required.

31. Any other information relevant to the study.

Signature of the Principal Investigator/Supervisor with date