

## **Prescribed Application Form for Clearance of Research Project by IEC**

1. (a) Name of the Principal Investigator with designation:  
(b) Name(s) of the Co-Investigators:
2. Name of the Department/Centre where research will be conducted:
3. Approval of the Department/Centre obtained: Yes / No
4. Protocol of the proposed research involving animal models and/or human samples/participants:
5. Ethical issues in the study and plans to address these issues:
6. Copies of Proforma/Case report forms/Questionnaires/Follow-up cards, etc.:
7. A brief statement explaining the process of obtaining Informed consent:  
(Please enclose a copy/format of informed consent form in local language and its translation in English).
8. For any drug/device trial, all relevant publications/pre-clinical data and clinical trial data from other centres within the country and/or other countries, if available:
9. Curriculum vitae of all the investigators with relevant publications in last five years:
10. Regulatory clearances (other than IEC of St. Anthony's College) required, if any:  
If 'Yes', enclose the Clearance Certificate:
11. Source of funding and financial requirements for the project:
12. An agreement to report only Serious Adverse Events (SAE) to IEC: Yes / No
13. Statement of conflict of interest, if any:
14. A statement specifying pecuniary risks involved and the measure(s) taken to provide compensation to the research participants such as the human subjects involved as participants in research (as defined in the guidelines of various national agencies), the researchers themselves, and such other persons who may be directly or indirectly at risk in the conduct of the research:
15. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants:
16. Any other information relevant to the study:

I/we \_\_\_\_\_ Department(s) \_\_\_\_\_ of hereby declare that the statements given in this application are true to the best of my/our knowledge and belief, and agree to comply with the guidelines/decisions of IEC, St. Anthony's College, Shillong as well as the ethical guidelines of relevant national agencies for conducting research on animal models and/or human samples/participants.

Signature of Principal Investigator (PI)

Date:

Place:

Signature of Head(s) of the Department(s)

Date:

Place:

Signature of the Co-Investigator.

Date:

Place:

*List of Enclosures:*