

**Prescribed Application Form for Clearance of Research Project by IEC**  
**(St. Anthony's College, Shillong)**

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:
4. Protocol of the proposed research involving animal models and/or human samples/participants:  
Brief summary of the work to be carried out:  
  
Animals required – (i) Species  
(ii) Age/Weight/Size:  
(iii) Gender:  
(iv) Numbers to be used:  
(v) Number of days each animal will be housed:  
Rationale for animal usage:  
Why animal usage is necessary for these studies:  
Why are the particular species selected required:  
Why is the estimated number of animals essential:
5. Have similar experiments been conducted in the past? If so, the number of animals used and results obtained in brief:  
If yes, why is a new experiment required?  
Have similar experiment(s) been made by any other organization/agency?  
If so, their results in your knowledge:
6. Description of procedures to be used:  
Does the protocol prohibit use of anaesthetic or analgesic for the conduct of painful procedures (any which cause more pain than that associated with routine injection or blood withdrawal):  
If yes, explanation and justification  
Will survival surgery be done:  
If Yes, the following to be described  
(i) List and description of all such surgical procedures (including methods of asepsis):  
(ii) Names, qualifications and experience levels of operators:  
(iii) Description of post-operative care:  
(iv) Justification if major survival surgery is to be performed more than once on a single individual animal:
7. Care of Animals post-experimentation:  
Rehabilitation/Euthanasia (In case of euthanasia, justification for not undertaking rehabilitation and drug dosage and route for anaesthesia, where appropriate, as well as methods of carcass disposal post experimentation):  
Animal transportation methods if extra-institutional transport is envisaged:
8. Use of hazardous agents if any:
9. Ethical issues in the study and plans to address these issues:
10. Copies of Proforma/Case report forms/Questionnaires/Follow-up cards, etc.:
11. 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).

12. For any drug/device trial, all relevant publications/pre-clinical data and clinical trial data from other centers within the country and/or other countries, if available:

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

14. Regulatory clearances (other than IEC of St. Anthony's College) required, if any:

If 'Yes', enclose the Clearance Certificate:

15. Source of funding and financial requirements for the project:

16. An agreement to report only Serious Adverse Events (SAE) to IEC:

17. Statement of conflict of interest, if any:

18. 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:

19. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants:

20. Any other information relevant to the study:

I/we \_\_\_\_\_ 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:

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

Date:

Place:

Signature of the Head of the Institution.

Date:

Place:

**List of Enclosures:**