**Form B (per rule 8(a))**

# APPLICATION FOR PERMISSION FOR EXPERIMENTS INVOLVING ANIMALS

Application to be submitted to (tick or delete, as appropriate):

* Institutional Animal Ethics Committee (IAEC), Christian Medical College, Vellore
* CPCSEA, New Delhi (for experiments involving large animals) after approval of Institutional Animal Ethics Committee (IAEC)

**Part A**

1. Name and address of establishment:
Christian Medical College, Bagayam, Vellore - 632002, Tamil Nadu.

2. Registration number and date of registration:
88/PO/RcBi-S/Rc-L/1999/CPCSEA. Reg Date-28.04.1999, Date of renewal-16.06.2022.

3. Name, address and registration number of the breeder from which animals are to be acquired for experiments mentioned in part B of this form:
Christian Medical College, Bagayam, Vellore - 632002, Tamil Nadu (Reg. no. 88/PO/RcBi-S/Rc-L/1999/CPCSEA)

4. The place where the animals are presently kept (or proposed to be kept) (tick or delete, as appropriate):

* Central Animal Facility (CMC, Hospital Campus)
* College Animal Facility (CMC, Bagayam [College Campus])
* CSCR Animal Facility (CSCR, CMC, Bagayam)

5. Place where the experiments are to be performed (tick or delete, as appropriate)

* Central Animal Facility (CMC, Hospital Campus)
* Animal Facility (CMC, Bagayam [College Campus])
* CSCR Animal Facility (CSCR, CMC, Bagayam)

6. Proposed date on which the study will commence and duration of the study:

7. Type of research involved (tick or delete, as appropriate)

* Basic Research
* Educational
* Regulatory
* Contract Research

Signature

Name and Designation of Principal Investigator:

Date and place:

**PART B**

**Protocol form for research proposals to be submitted to the Institutional Animal Ethics Committee for new experiments or extension of ongoing experiments using animals other than non-human primates**

1. Title of project / dissertation / thesis :

2. Principal Investigator:

1. Name :
2. Qualification :
3. Designation :
4. Dept / Div/ Lab :
5. Telephone No. :
6. E-mail: :
7. Experience in the field (years) :

3. List of Co-investigators (provide all details for all such individuals)

1. Name :
2. Qualification :
3. Designation :
4. Dept / Div/ Lab :
5. Telephone No. :
6. E-mail: :
7. Experience in the field (years) :

List of individuals authorized to conduct procedures on animals under this proposal (provide all details for all such individuals)

1. Name :
2. Qualification :
3. Designation :
4. Dept / Div/ Lab :
5. Telephone No. :
6. E-mail: :
7. Experience in the field (years) :

4. Source of funding (please enclose proof – IRB approval letter (mandatory) and sanction letter of funding agency (if applicable)

5. Duration of the project

1. Number of months :
2. Date of initiation (proposed) :
3. Date of completion (proposed) :

6. **Plan of study including brief introduction and background; methodology and expected outcomes (include all relevant details; word limit: 1000 words)**

Note: Please ensure that the rationale of the study and methodology to be used are clearly presented without using technical terms and scientific jargon as far as possible. Avoid using abbreviations without defining them at first mention.

7. Animals required

1. Species and strain :
2. Age and weight :
3. Gender :
4. Number to be used (*Provide full details of sample size calculation)*
5. Please provide a table with year-wise break-up and number of animals per experimental group)

8. Rationale for animal usage (provide details as appropriate under the following headings).

1. Why is use of animals necessary for this study?
2. Whether similar study has been conducted on *in vitro* models? If yes, describe the leading points to justify the requirement of animal experiment.
3. Why is the particular species selected appropriate for your study?
4. Why is the estimated number of animals essential (*justification of sample size calculated*)?
5. Have similar experiments been conducted in the past in your establishment? If yes, justify why new experiment is required.
6. Have similar experiments been conducted by any other organization in same or other *in vivo* models? If yes, enclose the reference and justify why new experiment is required.

9. Description of the procedures to be used.

1. List and describe all invasive and potentially stressful non-invasive procedures that animals will be subjected to in this study
2. Furnish details of injections / schedule / substances:
	* Doses:
	* Sites:
	* Volumes:
3. Blood withdrawal details:
* Volumes:
* Sites:
* Frequency:
1. Radiation (dosage and schedules):
2. Nature of compound / broad classification of drug / new chemical entitiy (NCE)

10. Does the protocol prohibit the use of anesthetics or analgesics for the conduct of painful procedures (procedures which cause more pain than that associated with routine injection or blood withdrawal)? If yes, please provide an explanation and justification for this.

11. Will survival surgery (surgical procedures performed on animals in which the animals are expected to recover from anesthesia) be done?

 If yes, please provide the following details.

1. List and describe all such surgical procedures (including methods of asepsis)
2. Names, qualifications and experience of persons performing such procedures
3. Description of post-operative care
4. In case major survival surgery is to be performed more than once on a single individual animal, please provide justification for the same

12. Describe post-experimentation procedures

1. Scope for reuse:
2. Rehabilitation (name and address of facility where the animals are proposed to be rehabilitated):
3. Describe method of euthanasia (*specific method to be mentioned as per Annexure 6 of the Compendium of CPCSEA 2018 available at https://www.cmch-vellore.edu/sites/research/Index.html#):*
4. Method of carcass disposal after euthanasia:

The carcass will be handed over for appropriate disposal by Ken Biolinks Pvt. Ltd.

13. Animal transportation methods
(*Provide details if animal will be transported from the vendor. If animals are being imported from overseas for this project, please provide details of import license issued by DGFT*)

14. Use of hazardous agents (use of recombinant DNA-based agents or potential human pathogens requires documented approval of the Institutional Biosafety Committee (IBSC). For each category, the agents and the biosafety level required, appropriate therapeutic measures and the mode of disposal of contaminated food, animal wastes and carcasses must be identified).

If, your project involved use of any of the below mentioned agent, attach copy of

the approval certificates of the respective agencies:

1. Radionucleotides (AERB)
2. Microorganisms / Biological infectious Agents (IBSC)
3. Recombinant DNA (RCGM)
4. Any other Hazardous Chemical / Drugs

If your project involves use hazardous agents, attach a copy of the minutes of IBC granting approval.

**Investigators’ declaration**

* 1. I certify that I have determined that the research proposal described here is not unnecessarily duplicative of previously reported research.
	2. I certify that I am qualified and have adequate experience in the experimentation on animals.
	3. For procedures listed under item 10, I certify that I have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described herein which may cause less pain or distress.
	4. I will obtain approval from the IAEC/ CPCSEA before initiating any changes in this study.
	5. I certify that performance of experiment will be initiated only upon review and approval of scientific intent by appropriate expert body (Institutional Review Board / funding agency / other body).
	6. I certify that I will submit appropriate certification of review and concurrence for studies mentioned in point 15
	7. I shall maintain all the records as per format (Form D) and submit to Institutional Animal Ethics Committee (IAEC).
	8. I certify that, I will not initiate the study before approval from IAEC/ CPCSEA received in writing. Further, I certify that I will follow the recommendations of IAEC/ CPCSEA.
	9. I certify that I will ensure the rehabilitation policies are adopted (wherever required).

Signature of Principal Investigator

Name:

Date:

Co-investigators (signature, name, date):

1.

2.

3.

Note: The Principal Investigator must sign at the bottom of all the pages of this proposal.

## Office Use Only

## CERTIFICATE

This is to certify that the project proposal number \_\_\_\_\_\_\_\_\_\_\_\_titled \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_submitted by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_has been approved by the IAEC of Christian Medical College, Vellore in its meeting dated \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and has been sanctioned \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_under the proposal for a duration of **\_\_\_\_\_\_\_\_\_** months.

**Authorized by: Name Signature Date**

Chairperson of IAEC Dr. Solomon Sathishkumar

Member Secretary Dr. Joe Varghese

Main nominee of CPCSEA Dr. P. Kumarasamy

Date:

**Checklist to be submitted along with Form B**

1. Are the following submitted?
	1. Covering letter Yes/No
	2. Form B (version 6 July 2021) Yes/No
	3. IRB approval Yes/No
	4. Approval of external funding agency (if applicable) Yes/No/NA
2. **Form B**
	1. **Part A –**
		1. Animal facility to be used specified Yes/No
		2. Signature Yes/No
	2. **Part B:**
		1. PI, co-PI and co-I detail filled in correctly Yes/No

Note: PI or co-PI must be affiliated to CMC, Vellore

* + 1. Section 7:
			- 1. Species, age and gender of animal required given Yes/No
				2. Sample size calculation given Yes/No
				3. Year-wise break-up given in table format Yes/No
				4. Number of experimental groups clearly indicated Yes/No
		2. Section 8: Justification given for each sub-section, especially for sample size? Yes/No
		3. Section 9: List of procedures and details given clearly Yes/No

Details for each procedure in the list given (dose, site etc.) Yes/No

* + 1. Section 12: Method of euthanasia given as per Annexure 6 of CPCSEA Compendium Yes/No
		2. Section 13: Transportation details given if applicable Yes/No/NA
		3. Section 14: Use of biohazardous material mentioned Yes/No
		Note: If yes, then approval of IBC is required
		4. Investigator’s declaration signed by PI and all co-Is Yes/No