COVERING LETTER

Date:

From,

To,

The Member Secretary
Institutional Animal Ethical Committee,
JSS College of Pharmacy, JSS University,
Sri Shivarathreeshwara Nagar, Mysore-15

Through*: Guide/Supervisor of the research proposal or Principal, JSS College of Pharmacy, Mysuru

Sir,

Sub: *Requisition to obtain permission in order to carry out animal experiments as a part of my PhD/M. Pharm/MSc/MD dissertation work-reg.*

With reference to the above cited subject, I, ……,pursuing ……..at ……hereby would like to submit a research proposal for your kind approval. Attached is the filled Form B (Part B) for your kind consideration. Kindly give me the permission to carry out the animal experimentation and oblige.

Thanking you,
Yours Sincerely,

		Investigator	Guide/Supervisor	Co-investigator
Name	**:**			
Designation	**:**			
Dept.	**:**			
College	**:**			
Signature with date	**:**			

*Researcher from JSS CPM process the application through respective guide(s) and Outsiders process through Principal JSS CPM.

Form B per rule 8(a)*

APPLICATION FOR PERMISSION FOR ANIMAL EXPERIMENTS

Application to be submitted to the CPCSEA, New Delhi after approval of Institutional Animal Ethics Committee (IAEC)

PART "A"

1	Name and address of establishment	:	JSS College of Pharmacy JSS University, SS Nagar, Mysuru - 570015, KA
2	Registration number and date of registration	:	155/PO/Re/S/1999/CPCSEA, Date: 25.11.14-24.11.17
3	Name, address and registration number of breeder from which animals acquired (or to be acquired) for experiments mentioned in parts B & C.	:	From CPCSEA Registered breeder.
4	Place where the animals are presently kept (or proposed to be kept).	:	Animal Facility, JSS College of Pharmacy, JSS AHER, Mysuru - 570015
5	Place where the experiment is to be performed (Please provide CPCSEA Reg.Number)	:	JSS College of Pharmacy JSS AHER, Mysuru - 570015 (155/PO/Re/S/1999/CPCSEA)
6	Date on which the experiment is to commence and duration of experiment.	:	Write the date (week/month/year) of commencing the experiment and duration of the project.
7	Type of research involved (Basic Research / Educational/ Regulatory/ Contract Research)	:	Basic Research

Date:.....

Place: Mysuru

Signature

Name of the investigator:

Signature

Name of the Guide:

Signature

Name of the co-investigator:

PART B

Protocol from for research proposals to be submitted to the committee/Institutional Animal Ethics Committee, for new experiments or extensions of ongoing experiments using animals other than non-human primates.

1. **Project / Dissertation / Thesis Title;"**Topic should be brief, specific and precise. Broad topics are not entertained. Topic should not contain any work related to *in-vitro*, standardization and non pharmacological activities. Topic should reflect the objective of the study.**"**

2. **Research Scholar** :

A	**Name**	:
B	**Designation**	:
C	**Dept / Div / Lab**	:
D	**Telephone No.**	:
E	**Experience**	:

3. **List of names of all individuals authorized to conduct procedures under this proposal**

			Co-Investigators
A	Name	:	
B	Address	:	Designation & Affiliation.
C	Experience	:	Mention the experience in preclinical studies employing laboratory animals.
A	Name	:	
B	Address	:	Designation & Affiliation.
C	Experience	:	Mention the experience in preclinical studies employing Laboratory animals.

4. **Funding source with complete address (Please attach the proof):** Mention the source of finding and attach a copy of project sanctioned letter as annexure. If no sanctioned project, write the name of the parent institution, University where the investigator works/studies.
5. **Duration of the project**

A	Number of months	:	Number of months
B	Date of initiation (Proposed)	:	Week/Month/Year
C	Date of completion (Proposed)	:	Week/Month/Year

(Do not write the duration of whole research project and it should be duration of the research proposed in the Form B)

6. **If date by which approval is needed is less than six weeks from date of submission, justification for the same.**

   Not applicable

7. **Detailed study plan may be given (not more than one page).**

   This section should include
   - Introduction
   - Review of literature
   - Objective of the study
   - Research envisaged (Need of the study)

Content should be explained in lay man language, so that nominees of CPCSEA will be able to understand easily. Quote proper reference and cite the reference in the text as ***numerical superscript.*** The above content should not exceed two printed pages (A4).

STUDY PROTOCOL

Name of the activity: Briefly write the name of the activity

Table1. Grouping, treatment and evaluation

GROUPS	**NO. OF ANIMALS**	**TREATMENT DOSE, DURATION & ROUTE**	**EVALUATION**
Total number of animals =			

Expected outcome: Explain the expected outcome of the research proposal, this section will justifies the need for animals study.

8. Animals required

A. Name of the activity- Give the animal details activity wise

A	Species/Strain/Common name	:	
B	Age/Weight	:	
C	Gender	:	
D	Number to be used (Activity/Models wise breakups and total figures needed to be given)	:	

Name of the activity/Model	No of animals
Total number of animals-	

E	Number of days each animal will be housed	:	Mention the number of days animals will be housed.
F	Proposed source of animals	:	From CPCSEA approved breeder

9. Rationale for animal usage

A	Why is animal usage necessary for these studies?	:	Explain why animal study is required for the proposed project. Weather it is not possible to do the research without use of the animals? If not, justify the need for the animals with suitable reference(s).
B	Why are the particular species selected required?	:	Justify the need for the particular species/strain with suitable reference(s).
C	Why is the estimated number of animals essential?	:	Justify the requested number of animals in each group and total numbers. Explain with reference why higher numbers of animals are required.
D	Are similar experiments conducted in the past? If so, the number of animals used and results obtained in brief.	:	Explain any kind of such experiments was performed and number of animals used. Explain the result obtained in such experiments in brief with reference.
E	If yes, why new experiment is required?	:	If such experiments are already performed as explained above explain why there is a need for new experiment? Justify with proper references.

F	Have similar experiments been made by any other organization agency? If so, their results in your knowledge.	:	Any such experiments are performed elsewhere explain with brief results with references.

10. Description of the procedures to be used.

Name of the activity-

Briefly explain the protocol of the proposal including-

- **Details about test materials.**
- **Method of preparation of test/standard drug solution for administration.**
- **Grouping of animals including any pre grouping training.**
- **Method of induction of disease/disorder**
- **Dose of test/standard drug to be administered.**
- **Route of administration of test/standard substances.**
- **Volume of test/standard solution to be administered.**
- **Blood withdrawal if any- Route, volume, time and frequency of blood collection.**
- **Radiation if any- Mention the dose and duration of radiation.**
- **Duration of treatment**
- **Evaluation parameters - Explain briefly method of evaluation of each parameter with proper references.**
- **Methods of organ collection and its processing**

The above content should be explained in a lay man language so that CPCSEA nominees will be able to understand easily. There should be clarity in each parameter said above. Form B will not be entertained if any ambiguity regarding dose, route, duration and evaluation involved in the proposal. Quote proper reference and cite the reference in the text as *numerical superscript.* The above content should not exceed two printed pages (A4).

11. Please provide brief descriptions of similar studies from *in-vitro* / *in-vivo* (from other animal models) on same / similar test component or line of research. If, enough information is available, justify the proposed reasons.

If any studies are already carried out using the test substances on animal models and explain the result obtained. Justify why new animal model(s) are required with the same test substances. Justify with proper references.

12. 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.

If experimental procedure prohibits the use of anaesthetics/analgesics the reasons are explained here. If experimental procedures involves pain full procedure, then use of analgesics/anaesthetics is not used, proper justification should be provided with reference(s).

13. Will survival surgery be done? -

If Yes, the following to be described

a	List and description of all such surgical procedures (including methods of asepsis)	:	Explain the method of surgical procedure with suitable references.
b	Names, qualifications and experience levels of operators	:	The details of person performing the surgical procedure are given here.
c	Description of post-operative care	:	Explain the post operative animal care.
d	Justification in major survival surgery is to be performed more than once on a single individual animal.	:	If experimental procedure requires multiple surgeries, then it should be justified here with proper references. However multiple surgeries are not encourages on single animal, but if the investigator justifies IAEC may take its decision.

14. Methods of disposal post-experimentation

a	Euthanasia (Specific method)	:	Carbon dioxide euthanasia followed by decapitation

b	Method of carcass disposal	:	As per the Guidelines of Animal Facility, JSS College of Pharmacy, Mysuru.
c	Rehabilitation	:	Not applicable for small Aminals.

15. Animal transportation methods if extra-institutional transport is envisaged.

If animal are transported from the breeding centre, method of transport (Road/Train/Air) should be mentioned here. Refer CPCSEA guideline before writing this section.

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

a	Radionuclides	:	If any radioactive compound is used, mention its dose, duration and use with references.
b	Microorganisms / Biological infectious Agents	:	If any microorganisms are used in the protocol, explain the nature of the organism, expertise involved in the experimental procedure.
c	Hazardous chemicals or drugs	:	Any hazardous chemicals are used in the experimental protocols, then handling and precautions are explained with proper references.
d	Recombinant DNA	:	If any rDNA products are used in the experimental procedures, details of rDNA products should be provided.
e	Any other (give name)	:	

If, your project involved use of any of the above, attach copy of the minutes of IBC granting approval.

REFERENCES:- Should be Vancouver style.

(In the running text- numerical Superscript)

Example-

1) Sahu BD, Kuncha M, Sindhura GJ, Sistla R. Hesperidin attenuates cisplatin-induced acute renal injury by decreasing oxidative stress, inflammation and DNA damage. *Phytomedicine* 2013; 20: 453-60.

INVESTIGATOR'S DECLARATION

1. I certify that I have determined that the research proposal herein is not
2. Unnecessarily duplicative of previously reported research.
3. I certify that, I am qualified and have experience in the experimentation on animals.
4. For procedures listed under item 11, 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.
5. I will obtain approval from the IAEC/ CPCSEA before initiating any significant changes in this study.
6. Certified that performance of experiment will be initiated only upon review and approval of scientific intent by appropriate expert body (Institutional Scientific Advisory Committee / funding agency / other body (to be named).
7. Institutional Biosafety Committee's (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agent's of human pathogens).
8. I shall maintain all the records as per format (Form D)
9. I certify that, I will not initiate the study unless approval from CPCSEA received in wiring. Further, I certify that I will follow their commendations of CPCSEA.
10. I certify that I will ensure the rehabilitation policies are adopted.

Signature	Signature	Signature
Name of Investigator	Name of the Guide	Name of the Co-Guide

Date:

CERTIFICATE

This is to certifythat the project title **"Write the title of research proposal submitted"** has been approved by the IAEC meeting.

Name of the Member Secretary: Dr. K. L. Krishna

Signature with date

Name of Chairman CPCSEA nominee: Dr. Palle Saibaba

Signature with date

Name of the Chairman: Dr. T. M. Pramodkumar

Signature with date

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)