10

Form B (per rule 8(a)* for Submission of Research Protocol (s)

Application for Permission for Animal Experiments

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

Section -I

1.	Name and address of establishment	Department of Veterinary Medicine, LUVAS, Hisar, 125004
2.	Registration number and date of registration	1669/GO/ReBiBt- S/Re- L/12/CPSCEA dated 06/12/2012
3.	Name, address and registration number of breeder from which animals acquired (or to be acquired) for experiments mentioned in parts B & C	Animals will not be acquired, study will be conducted at farmer's level and different animal husbandry setups.
4.	Place where the animals are presently kept (or proposed to be kept).	Animals will not be kept.
5.	Place where the experiment is to be performed (Please provide CPCSEA Reg. Number)	Samples will be collected from field and clinical cases at VCC and processed at Department of Clinical complex, VMD and ABT-LUVAS, Hisar
6.	Date and Duration of experiment.	2 year from date of approval
7.	Type of research involved (Basic Research / Educational/ Regulatory/ Contract Research)	Basic Research

Signature:

Name and Designation of Investigator

Dr. Tarun Kumar (Major Advisor) Asst. Prof.

Date: 04/02/2022

Place: Hisar, Haryana

Section -II

Protocol form for research proposals to be submitted to the Institutional Animal Ethics Committee/ CPCSEA, for new experiments or extensions of ongoing experiments using animals.

1. Project / Dissertation / Thesis Title: **Identification of Bovine Cystatin- C domain as synthetic renal biomarker and determination of antimicrobial resistance of *Escherichia coli* isolates from bovine urinary tract infections**

2. Principal Investigator / Research Guide / Advisor:

   a. Name: **Dr. Tarun Kumar**
   b. Designation: **Assistant Professor**
   c. Dept / Div/ Lab: **Veterinary Medicine, LUVAS, Hisar**
   d. Telephone No: **8901304347**
   e. E-mail Id: **tarunvet@gmail.com**
   f. Experience in Lab animal experimentation: **7 years**

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

   a. Name: Dr. Annu Yadav, Dr. Neelesh Sindhu, Dr. Babu Lal Jangir, Dr. Joshi Vinay Ganesh Rao, Dr. Devender Singh Bidhan
   b. Designation: PhD scholar, Assistant Professor, Assistant Professor, Scientist, Associate Professor
   c. Department: Veterinary Medicine, VPP, ABT, LPM, LUVAS, Hisar
   d. Telephone No: 9053497396, 9896395679, 8619975584, 8683867495, 9416363913.
   e. E-mail Id: yadavannu1726@gmail.com, drneeleshsindhu@gmail.com, drbabu.jangir@luvas.edu.in vinaygjoshi18@luvas.edu.in, dsbidhan@gmail.com
   f. Experience in Lab animal experimentation: Nil

4. Funding Source / Proposed Funding Source with complete address (Please attach the proof)

   Department of Veterinary Medicine, LUVAS, Hisar (Ph.D thesis work)

5. Duration of the animal experiment.
   a. Date of initiation (Proposed): After approval from IAEC
   b. Date of completion (Proposed): Two years from date of approval

6. Describe details of study plan to justify the use of animals (Enclose Annexure)

Livestock sector contributes about 26 per cent of the total GDP from agricultural sector in India. So their health and early disease diagnosis is of major importance. Urinary system is one of the most important systems in the animal's body. Any defect in this system functioning affects the functions of other systems because it contributes to the regulation and conservation of body fluid components, responsible for removal of toxic wastes from the body. Cystitis and pyelonephritis are the most common UTI in buffaloes along with indirect effects on reproductive performance. In this context not much work has been conducted in direction of diagnosis, treatment, antimicrobial resistance and biomarker standarisation of UTI in buffaloes. So keeping above facts under consideration, study was planned with the following objectives:

a) **Identification and synthesis of suitable epitopic region of Bovine Cystatin C domain (CST3)**
b) **To study the occurrence of bovine urinary tract infections in different animal husbandry setups**
c) **Phenotypic characterization and antimicrobial resistance determination of *E. coli* isolates**
d) **To compare different therapeutic regimens for bovine urinary tract infections**

7. Animals required

a. Species and Strain: Bovine (Cattle and Buffaloes)
b. Age and Weight: Any age and weight
c. Gender: Female
d. Number to be used (Year-wise breakups and total figures needed to be given in tabular form): 400 bovine (200 cattle + 200 buffaloes)
e. Number of days each animal will be housed: Not housed

8. Rationale for animal usage

a. Why is animal usage necessary for these studies?
India has largest bovine population in the world and ranks first among world milk producing nations. Urinary tract affections affecting bovine health is of major concern. So there is need of determining occurrence of UTIs in bovines.

b. Whether similar study has been conducted on in vitro models? If yes, describe the leading points to justify the requirement of animal experiment.
Not much work has been conducted in the bovines.

c. Why are the particular species selected?

Bovines have significant impact on India economy, so there is need of proper and early disease diagnosis and treatment. Urinary tract infections in bovines are least studied in India till date.

d. Why is the estimated number of animals essential?

To get significant results from problem studied.

e. Are similar experiments conducted in the past in your establishment?

Detailed work on this problem has not be been conducted

f. If yes, justify why new experiment is required? NA

g. Have similar experiments been conducted by any other organization in same or other in vivo models? If yes, enclose the reference.

No detailed studies are available on this problem.

9. Describe the procedures in detail:

a. Describe all invasive and potentially stressful non-invasive procedures that animals will be subjected to in the course of the experiments)

Urine samples will be collected aseptically. Ultrasonography will be conducted in selected cases through per rectal and transcutaneous approach using ultrasound machine.

b. Furnish details of injections schedule Substances:
Doses: NA
Sites: NA
Volumes: NA

c. Blood withdrawal Details:
Volumes: 10ml blood samples transferred into EDTA containing vial and without anticoagulant containing vial for the estimation of haemato-biochemical parameters
Sites: Jugular vein

d. Radiation (dosage and schedules): NA

e. Nature of compound/Broad Classification of drug/NCE: NA

10. Does the protocol prohibit use of anesthetic or analgesic for the conduct of painful procedures? If yes, justify. NA

11. Will survival surgery be done? No surgery is involved, therefore no anaesthetic or analgesic is required

No surgery will be done

If yes, the following to be described.

a. List and describe all surgical procedures (including methods of asepsis): NA
b. Names, qualifications and experience levels of personnels involved: NA
c. Describe post-operative care: NA
d. Justify if major survival surgery is to be performed more than once on a single animal: NA

12. Describe post-experimentation procedures.

a. Scope for Reuse: NA

b. Rehabilitation (Name and Address, where the animals are proposed to be rehabilitated): NA

c. Describe method of Euthanasia (If required in the protocol): NA

d. Method of carcass disposal after euthanasia: NA

13. Describe animal transportation methods if extra-institutional transport is envisaged. NA

14. 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 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:

No such work in our research plan

(a) Radionucleotides (AERB): NA
(b) Microorganisms / Biological infectious Agents (IBSC): NA
(c) Recombinant DNA (RCGM): NA
(d) Any other Hazardous Chemical / Drugs: NA

Investigator's declaration

1. I certify that the research proposal submitted is not unnecessarily duplicative of previously reported research.

2. I certify that, I am qualified and have 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 Scientific Advisory Committee / funding agency / other body).

6. I certify that I will submit appropriate certification of review and concurrence for studies mentioned in point 14.

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

Dr. Tanu Kumar

Name of Investigator

Date: 04/02/2022