Institutional Biosafety Committee (IBC)

S. S. Institute of Medical Sciences & Research Centre
Davangere, Karnataka, India

Protocol for Research Involving Bio-hazardous Materials

SUBMISSION INSTRUCTIONS

SUBMISSION DOCUMENTS:

You may electronically send the completed application or mail a hard copy to Member Secretary, IBC. The signature page should include the PI, departmental and Head of the institutional signatures. Following final review and approval, the PI will receive a letter approving the protocol and authorizing the studies to begin.
IBC approval is required for experiments utilizing bio-hazardous or regulated materials in whole animals.

LABORATORY INSPECTION:

Laboratories will be inspected by the Biosafety Committee designates. This inspection will determine compliance with standards for BSL1, BSL-2 and BSL-3 containment as outlined in the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) manual (https://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf). During the pre- application process, the IBC, Member Secretary will contact the PI to arrange for the inspection.

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IBC#:

Section I

1. APPLICATION DATA

PI (Principal Investigator) Name:

The individual must have a formal affiliation with SSIMS & RC.

PROJECT TITLE:

CO-PI NAME:

LABORATORY PERSONNEL:

Include only those individuals who will be handling the biohazardous materials and thus will require Biosafety Training.

DEPARTMENT:

LAB:

(Where the research will beconducted)

BIOSAFETY LEVEL OF CONTAMINATION:
List the BSL level.
Refer *NIH Guidelines for Research Involving Recombinant DNA* to determine the level of biological containment required i.e., BSL-1, BSL-2, or BSL-3.

FUNDING SOURCE:

PI of Grant: Grant Proposal Number:

Section II

General Biosafety Information

INSTRUCTIONS: To review your proposal, the IBC requests the following information. Each subpart must be addressed independently in the listed sequence without reliance on information covered under other subparts. Please include sufficient information to facilitate an effective review by all members of the IBC. All abbreviations and terms not part of common usage should be defined and simplified language should be used as much as possible. **Only complete Section III if the project involves the transfer of recombinant DNA molecules into human research participants and Section IV if the protocol involves animals**.

1. Experiment Overview.

Give a brief overview of the proposed work. Discuss the use any hazardous or potentially hazardous agents (i.e. bacteria, virus, cells, etc.) that will be utilized.

2. List All Biohazardous Material to be Utilized and Their Risk Group (RG) Classification.

Name the infectious agent(s) (describing risk group [RG] classification, toxin, cell line(s), or recombinant DNA. Identify the source of the biohazardous material and any information available to describe the material in detail including genus, species, and strain type. If applicable, describe the nature of the vector DNA (for example, plasmid, phage, cosmid, or virus), the nature of inserted DNA sequences (include the species of origin), gene product, gene product function (if known), and the host cells used for propagation or expression. Also describe whether an attempt will be made to express the foreign gene or not. For clinical specimens known to contain a pathogenic agent, name the agent present which may require special precautions in handling.

3. Safety Practices Summary.

Summarize the biosafety practices used in your laboratory for the physical containment at the Biosafety Level.

4. Risk for Occupational Exposure.

Describe precautions necessary to prevent occupational exposure to employees. Include requirements for specific training, vaccination, and/or baseline serum testing when appropriate. Identify the primary antimicrobial agent(s) used to treat human infection caused by the infectious agent proposed.

5. Storage of Biohazardous Materials.

For Risk Group -2 and Risk Group-3 agents, list the method of storage and the location(s) where the biohazardous materials are stored. For Risk Group-3 agents only, also record the quantity in storage and describe the security measures utilized for the storage of these materials.

6. Special Instructions for Biosafety Level 3 Containment

If applicable, describe in detail how access to the laboratory will be controlled, the personal protective equipment to be used, the decontamination procedures that will be utilized (include the location of the autoclave for waste sterilization), how major/minor spills will be handled, and any other unique details needed to conduct the experiments.

7. Relevant Training or Experience that Qualifies You to Conduct this Proposed Research

Document relevant training and/or experiences that demonstrates your competence in the work you are proposing to conduct.

Note. All investigators and participating personnel must have documentation of completion of biosafety training program.

Section III
Human Gene Transfer Supplement

INSTRUCTIONS: This section is submitted along with Section I and Section II only if the protocol involves the **transfer of recombinant DNA molecules into human research participants** (human gene transfer experiments). The initial review process by IBC will determine whether the experiment presents characteristics that warrant expert review and discussion. The IBA will notify the PI or sponsor about the results of this initial review process.

Section IV
Animal Use Supplement

INSTRUCTIONS:
After the approval by IBC, if the protocol involves the transfer of infectious agents, regulated biological toxins and/or non-exempt r DNA molecules into animal research subjects than the complete protocol should be submitted to Institutional Animal Ethical Committee to get the approval.
IAEC approval number must be submitted to the IBC prior to beginning studies with the animals.

Section V
Declaration by PI with signature of the Head of Department and Head of the institution

ANNUAL UPDATE:
All IBC approved protocols will be re-evaluated on an annual basis. The PI will receive a letter requiring a response prior to the annual initiation date to determine if the protocol is still active and if any changes to the protocol are needed. Additionally, laboratories using BSL-2 containment will be re-inspected every three years and those using BSL-3 containment labs will be re-inspected every year to determine compliance with approved protocols.
The PI is responsible for ensuring that all laboratory personnel working with biohazardous materials have documentation of biosafety training. Failure to ensure that all personnel have received this training may result in suspension of IBC approval.