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1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to provide general information and guidelines for the Institutional Biosafety Committee process at USC.

2.0 DEFINITIONS/ACRONYMS/ABBREVIATIONS

BSO	Biosafety Officer
BSP	Biosafety Specialist
BUA	Biological Use Authorization
CDC	Centers for Disease Control and Prevention
DNA	Deoxyribonucleic acid
EH&S	Environmental Health and Safety
IBC	Institutional Biosafety Committee
IRB	Institutional Review Board
iStar	IRB Submission Tracking and Review
NHP	Non-human primate
NIH	National Institute of Health
OPIM	Other potentially infectious materials
PI	Principal Investigator
SOP	Standard Operating Procedure
USC	University of Southern California

3.0 RESPONSIBILITY

Research studies involving biohazards must be reviewed and approved by the Institutional Biosafety Committee (IBC) prior to inception. The Principal Investigator (PI) shall submit a Biological Use Authorization (BUA) in iStar for any projects that involve biohazards.

PIs are responsible for understanding that they are required to seek an IBC approval for their BUAs and for updating any modifications to the BUA including changes in procedures, agents, personnel, location, and use of laboratory animals.

The Biosafety Program resides in the Office of Environmental Health & Safety, under the leadership of the Biosafety Officer (BSO). The BSO and the Biosafety Specialists (BSPs) serve as the liaison between the laboratories and the IBC. Biosafety personnel will initially assess biological materials in the BUA application and create a preliminary risk assessment to determine the hazards and risk mitigation.

The Institutional Biosafety Committee is responsible for reviewing submitted BUAs to ensure that all appropriate safeguards are in place to conduct the proposed research or teaching activities.

4.0 PROCEDURES

Principal Investigators (PIs) must have an approved Biohazard Use Authorization (BUA) for research studies involving:

- Recombinant or synthetic nucleic acids
- Potentially infectious microorganisms
- Human, animal, and plant pathogens
- Human and non-human primate (NHP) blood
- Human and non-human primate cell lines
- Other potentially infectious human or non-human primate materials (OPIM)
- Specific hazardous chemicals used in biomedical research e.g., chemotherapy, carcinogens, and toxins of biological origin

4.1 Three items are ultimately required to conduct research with biohazards:

- Complete and submit a BUA application to the IBC for review through iStar. https://ehs.usc.edu/research/bio/bua/
- Ensure that staff members on the project have undergone the appropriate training. https://ehs.usc.edu/research/bio/training/
- Undergo the annual laboratory biosafety inspection. https://ehs.usc.edu/research/bio/inspections/

4.2 BUA Review Process

- Deadline. A BUA submitted on or before the first Monday of the month will be reviewed by the IBC that month if the BUA is complete and accurate.
- Pre-review. Each BUA is reviewed by a member of the Biosafety Program.
- Expedited review. Projects that do not require full committee review are approved by the BSO.
- Full committee review. Projects that require an IBC review are sent to 3 IBC members for evaluation and determination of approvability.
- IBC either approves the project or asks for changes to be submitted by the PI.
- Once the required changes are addressed, the project is fully approved.
- Rarely, a project is tabled until further information is obtained.
- BUAs are approved for 3 years unless they are clinical trials which are approved for one year

4.3 Amendments and Renewals

- Changes to the BUA require amendments to be completed and submitted in iStar.
- Every 3 years, the PI is asked to submit a renewal prior to the expiration date of the BUA.

5.0 REFERENCES

- Biosafety Manual
- Biosafety in Microbiological and Biomedical Research Laboratories (BMBL)
- NIH Guidelines for Recombinant DNA Research
- NIH PI Brochure
- Pathogen Data Sheets (PDS) from Public Health Agency of Canada

6.0 SOP REVIEW/REVISION

This SOP will be reviewed and updated annually.

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