Institutional Biosafety Committee (IBC) Procedures and Principal Investigator Responsibilities

(Companion document to Institutional Biosafety Committee (IBC) Policy

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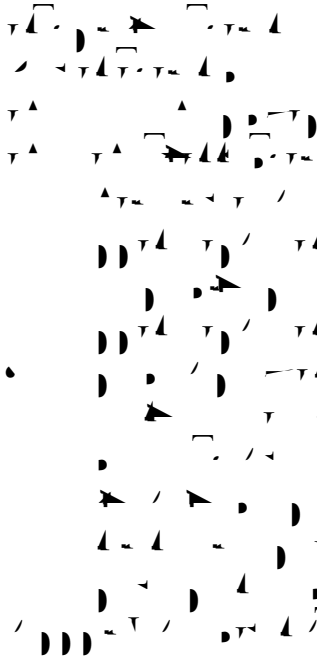


1.0 INTRODUCTION

2.9 BMBL:

2.10 CDC:

xRisk Group 3 (RG3)

xRisk Group 4 (RG4)

2.30 Security Risk Assessment:

2.31 Select Agents and Toxins:

2.32 Select Agent Regulations:

These rules are codified at

IMPORTANT! See the following WEB link for important details that may be applicable to your research:

2.33 Tier 1 Select Agents and Toxins:

3.0 IBC MEMBERSHIP

3.1 IBC Membership:

A.

B.

C.

H.

I.

J.

K.

L.

3.2 Chairperson and Vice Chairperson:

4.0 IBC MEETINGS

4.1 IBC Meeting Frequency:

A. Regular Meetings

B. Ad hoc Meetings

C. Cancellation of Regular Meetings

4.2 IBC Meeting Quorum:

A.

B.

C.

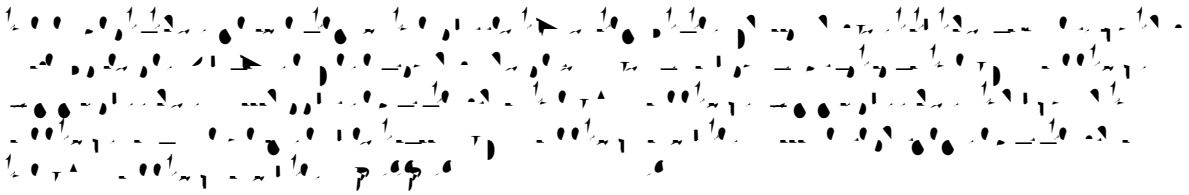
D.

E.

F.

G.

H.



6.0 BIOLOGICAL SAFETY OFFICER FUNCTIONS

6.1 Biological Safety Officer:

A. Inspections:

B. Reporting:

C. Emergency Plans:

7.0 PRINCIPAL INVESTIGATOR RESPONSIBILITIES & RESOURCES

7.1 Principal Investigator Responsibilities – IBC Research Protocol Application:

7.2 PI Responsibilities –Limitations on Acquiring New Biological Agents:

7.3 PI Responsibilities – Commitment to Safe Practices:

A. Laboratory Signage:

B. Work Surfaces Decontamination:

C. Personal Protective Equipment (PPE):

Wearing of PPE:

Laundering of Reusable PPE:

L. Training:

D. Environmental Health and Safety (EHS) Staff:

IBC Manager:

Biological Safety Officer (BSO):

Assistant

8.0 PRINCIPAL INVESTIGATOR PROCEDURES – IBC APPLICATION

8.1 Grant Applications or Contracts Requiring Prior IBC Notification or Approval Before Submitting to Granting Agency:

A. Select Agents and Toxins – Prior Notification of the BSO/RO Required:

B. Dual Use Research of Concern (DURC) – Prior Approval of IBC (IRE) Required:

8.2 Electronic IBC (eIBC) Research Protocol Application:

8.3 Types of IBC Research Protocol Application Submissions:

A. New IBC Research Protocol Application:

Timeline for Submission:

Full IBC Approval:

B. Amendment to Approved IBC Research Protocol Application:

Full IBC Approval – All Other IBC Research Protocol Amendments:

C. Renewal IBC Research Protocol Application:

Timeline for Submission:

8.5 Principal Investigator Review Guidance:

A. Determining Risk Group Assignment of Biological Agents:

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8.6 Risk Groups:

8.7 Containment Levels:

A. BSL-1 or BSL-2 Containment

B. BSL-3 Containment:

C. BSL-4 Containment:

B. PIs Using or Contemplating Use of Select Agents and/or Toxins:

Saint Louis University Select Agent & Toxins Security Plan:

BMBL:

B.

9.0 RECOMBINANT OR SYTHETIC NUCLEIC ACID MOLECULE RESEARCH

9.1 Research Involving Recombinant or Synthetic Nucleic Acid Molecules Requiring IBC Review:

A. E

F. Experiments Involving the Use of Infectious DNA or RNA Viruses Or Defective DNA or RNA Viruses in the Presence Of Helper Virus in Tissue Culture Systems:

G. Experiments Involving Whole Animals:

transgenic animals

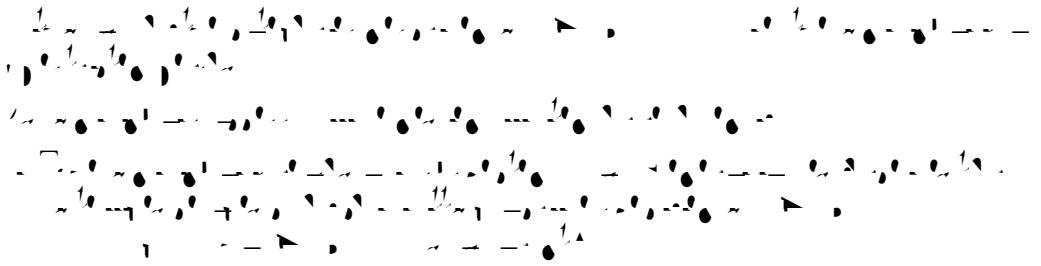
Experiments Involving Transgenic Rodents at BSL-1 Containment:

B.

10.0 SELECT AGENTS AND TOXINS USE IN RESEARCH

10.1 Select Agent Registration & Access:

A.



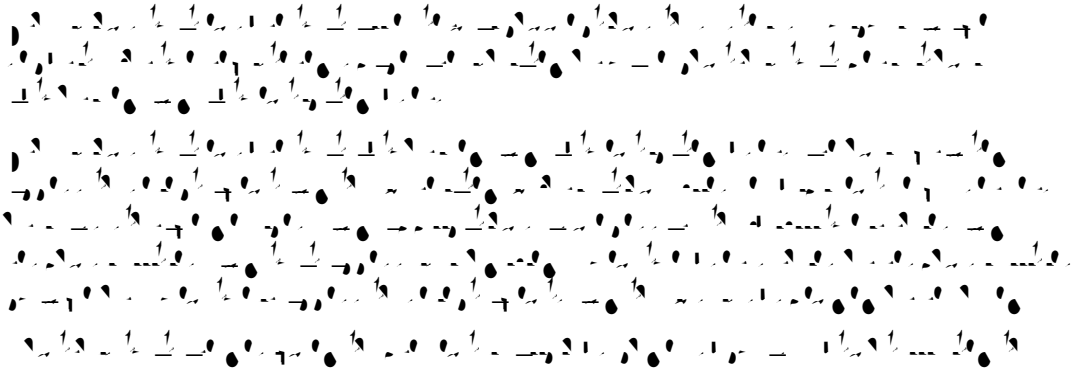
A. Key Required Elements of the Select Agent and Toxins Security Plan:

B. Saint Louis University Select Agent & Toxins Security Plan:

C. BMBL:

10.3 Information Security:

A. Key Elements of Information Security



11.0 DUAL USE RESEARCH OF CONCERN (DURC)

11.1 Dual Use Research of Concern – Scope of Research Requiring Oversight:

A. DURC Agents and Toxins:

11.2 Responsibilities of Principal Investigators Regarding DURC:

A. PIs Must Notify the IBC through the Biological Safety Officer:

or

B. IBC Notification Requires PI Assessment:

C. PI Required Commitments:

Work with the IBC:

Risk Mitigation Plan:

Know and Comply with All Policies and Procedures:

Training:

Communicate DURC in a Responsible Manner:

A. IBC (IRE) Membership:

Number of Members:

IBC (IRE) Breadth of Experience:

IBC (IRE) Expertise on Relevant U.S. Government Policies, Risk Assessment, Risk Management, Biosafety and Biosecurity:

F. Ensuring Compliance with the DURC Requirements and Approved Risk Mitigation Plans and Immediate Reporting of Non-Compliance:

Immediate Reporting of Non-Compliance to Biological Safety Officer:

30 Day Reporting to Funding Agency:

G. Assisting PIs:

12.0 NON-COMPLIANCE AND SANCTIONS

12.1 Impact of Violations:

12.2 Reporting of Violations:

12.3 Sanctions:

13.0 REFERENCES

13.1 **Saint Louis University** ***Institutional Biosafety Committee (IBC) Policy dated February 7, 2024. It can be downloaded at this link:***

13.2 ***Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)***

13.3 ***Saint Louis University Exposure Control Plan for Bloodborne Pathogens***

13.4 ***Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition, June 2020.***

13.5 ***Code of Federal Regulations (CFR), Title 42: Public Health, Part 73 – Select Agents and Toxins.***

13.6 ***Code of Federal Regulations (CFR), Title 9: Animals and Animal Products, Part 121 – Possession, Use, and Transfer of Select Agents and Toxins.***

13.7 ***Code of Federal Regulations (CFR), Title 7: Agriculture, Part 331 – Possession, Use, and Transfer of Select Agents and Toxins.***

13.8 ***United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern***

APPROVAL SIGNATURES

DOCUMENT HISTORY

EFFECTIVE DATE	VERSION NUMBER	MODIFICATION