# Institutional Biosafety Committee (IBC) Procedures and Principal Investigator Responsibilities

*(Companion document to Institutional Biosafety Committee (IBC) Policy*

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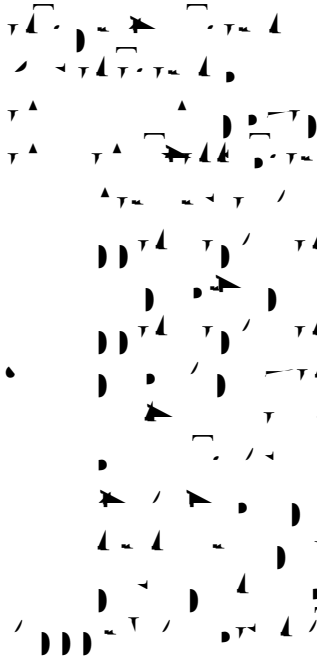


**1.0 INTRODUCTION**

**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.**

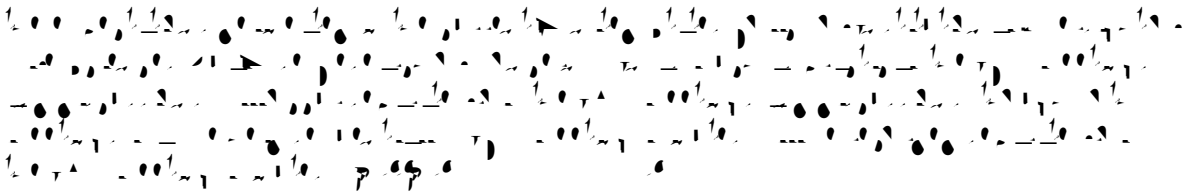
**D.**

**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***

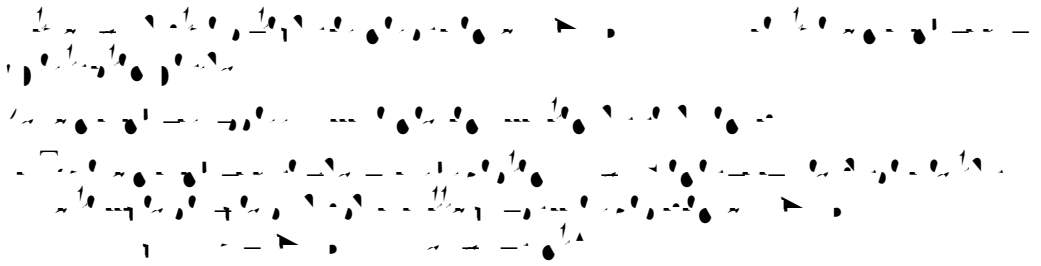
***Experiments Involving Transgenic Rodents at BSL-1 Containment:***

**B.**

## 10.0 SELECT AGENTS AND TOXINS USE IN RESEARCH

**10.1 Select Agent Registration & Access:**

**A.**



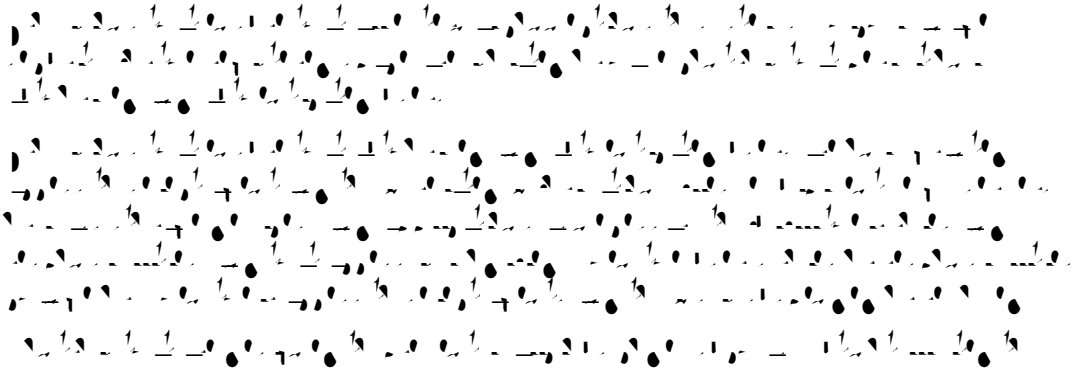
**A. Key Required Elements of the Select Agent and Toxins Security Plan:**

**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 |
|---|---|---|
| | | |
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