

IBC FAQs: TIPS FOR PREPARING A SUCCESSFUL IBC PROTOCOL

Quick Start Tips

1. **Review** the University of Hawaii Institutional Biosafety Committee Operating Policies and Procedures and the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
2. **Gather** all information ready before you begin!
 - a. Ensure personnel already completed required training for their job tasks and you have those training dates ready to enter
3. **Read** instructions carefully – any question(s) not answered correctly or with insufficient detail will result in your protocol being returned for modification and will delay approval of your protocol and consequently, your ability to start/ continue your research.
4. **Ask** for clarification BEFORE you submit your protocol.
5. If appropriate, **obtain** DURC approval before submitting full protocol for IBC approval.
6. Respond to all reviewer comments during the review period and update content in the protocol fields as you go.

Information Required by Section of the IBC Protocol

Check the required fields of the IBC protocol below to ensure you have all the information needed before you begin your submission.

1. Administrative Data
 - 1.1. IBC Registration Requirements
 - 1.2. Submission Type
 - 1.3. Reference Number
 - 1.4. Protocol Number
 - 1.5. Principal Investigator
 - 1.6. Author
 - 1.7. Co-Author
 - 1.8. Title
 - 1.9. Department
 - 1.10. Granting Agency Proposal Title
 - 1.11. Anticipated Start Date
 - 1.12. Project End Date
 - 1.13. Accounts
 - 1.14. Grant Information (External Awards)
 - 1.15. Internal Grants Information
 - 1.16. No Awards
 - 1.17. Protocol Associates
 - List all individuals who will be involved in the research and their duties; names only will result in return for modification
 - 1.18. Personnel Biosafety Training (Required for All Staff)
 - List training dates for General Biosafety training (or refresher) and Bloodborne Pathogens for **all** individuals listed in section 1.17

- 1.19. Supplemental Training (Protocol Specific)
 - List additional training and dates as appropriate (e.g., DURC)
- 1.20. Confidential, Proprietary or Sensitive Information
- 1.21. Summary of Biological Materials
- 1.22. Preserved, Inactivated or Attenuated Biological Material
- 1.23. Laboratory Inventory Declaration
2. Project Classification
 - 2.1. Brief Project Description
 - 2.2. Exempt Experiments Under NIH Recombinant Guidelines
 - 2.3. Regulated (Non-Exempt) Experiments Under NIH Recombinant Guidelines
 - 2.4. NIH Guidelines
3. Description of Biological Material Activity
 - 3.1. Nature of the Modified DNA (if applicable)
 - 3.2. Vectors (if applicable)
 - 3.3. Recipient Organism (if applicable)
 - 3.4. Toxin or Oncogene Expression
 - 3.5. Alteration of Vector Host Range
 - 3.6. Adventitious or Inherent Viral Particle
 - 3.7. Genetically Modified, Transgenic, KO, KI or Mutant Animals
 - 3.8. Biological Dosing
 - 3.9. Plants and Plant Derived Biological Materials
 - 3.10. Select Agents and Toxins
4. Experimental Design
 - 4.1. Description of Project Procedures
5. Dual Use Research of Concern (DURC)
 - 5.1. Dual Use Research of Concern or Gain of Function Research
 - 5.2. Criteria 1: Vaccine
 - 5.3. Criteria 2: Drug Resistance Trait
 - 5.4. Criteria 3: Enhance Virulence
 - 5.5. Criteria 4: Increase Transmissibility
 - 5.6. Criteria 5: Alteration of Host Range
 - 5.7. Criteria 6: Diagnosis Prevention
 - 5.8. Criteria 7: Weaponization
 - 5.9. Criteria 8: Use of Synthetic Biology Techniques
 - 5.10. Criteria 9: Transfer of Antibiotic Resistance
 - 5.11. Misuse
6. Risk Assessment
 - 6.1. Infectious, Pathogenic or Disease-Causing Materials
 - 6.2. Use of Large Scale Bioreactors
 - 6.3. Large Scale Quantities of Biological Material
 - 6.4. Risk Group Classification
 - 6.5. Support for Risk Classification (Environmental Assessment/Environmental Impact)
 - 6.6. Hazardous Procedures
 - 6.7. Exposure Routes

7. Risk Management
 - 7.1. Research Locations
 - 7.2. Designated Work Areas
 - 7.3. Biosafety Level(s)
 - 7.4. Movement and Storage
 - 7.5. Personal Protective Equipment
 - 7.6. Equipment Engineering Control
 - 7.7. Equipment Certification
 - 7.8. Autoclave Quality Control Testing
 - 7.9. Biological Indicators
 - 7.10. Decontamination and Waste Disposal
8. Incident Response Plan
 - 8.1. Lab Specific Incident Response Plan
 - 8.2. Occupational Health or Medical Surveillance Program
 - 8.3. Respiratory Protection
 - 8.4. Tuberculosis Monitoring
 - 8.5. Other Surveillance Programs
 - 8.6. Bloodborne Pathogens
 - 8.7. Hepatitis B Vaccine
 - 8.8. Other Occupational Programs/Medical Surveillance
9. Federal/State Permits and Other Approvals
 - 9.1. Permits
 - 9.2. Other UH Review Committee Approval
 - 9.3. Other Review Committee (if not listed above)
10. Miscellaneous
 - 10.1. Miscellaneous Section Instructions
 - 10.2. Human Gene Transfer (Recombinant)
 - 10.3. Human Gene Transfer (Native)
 - 10.4. Material Transfer, Non-Disclosure, MOU, LOI, IOA or Unfunded Research Agreement