



Alabama State University
Office of Research & Sponsored
Programs (ORSP)

o **Institutional Biosafety Committee Registration
Document for Synthetic and Analogues of
Naturally-occurring Chemicals and Non-
Infectious Agents and Biologicals**

ASU requires that all projects involving the use of synthetics and analogues of naturally-occurring chemicals and non-infectious agents and biologicals at or supported by this university be registered with an approved by the Institutional Biosafety Committee (IBC) prior to initiation of the project.

If you are using or synthetics and analogues of naturally-occurring chemicals and non-infectious agents and biological, please contact Dr. B. K. Robertson Biosafety Committee chair (334-229-4423) for further instructions. The use of synthetics and analogues of naturally-occurring chemicals and non-infectious agents and biologicals requiring use of BSL-4 containment is prohibited on the ASU campus. If using BSL-2 or BSL-3 containing, approval is required by the Biosafety Committee.

Instructions:

1. Provide complete information for every item. Blank or incomplete items may delay the processing of your application.
2. Consult the following reference materials prior to filling out the form.
 - a. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. J. Y. Richmond and R. McKinney, Editors (reserved at the ASU campus library)
 - b. Material Safety Data Sheets (MSDS) for Infectious Agents
 - c. Risk Group Classification for Infectious Agents
 - d. ASU Institutional Biosafety Manual
3. Attach a copy of the principal Investigator's CV if one is not already on file with the IBC.
4. Completed forms may be submitted by:
 - E-mail to brobertson@alasu.edu and follow with mailed hard copies of signature pages bearing original signatures.

- Mail to Dr. B. K. Robertson Institutional Biosafety Committee chair Department of Biological Sciences.
- BSL-2 or BSL-3 laboratories must pass inspection before initial approval for research activities can be granted for this proposed study. The Principal Investigator is responsible for scheduling an inspection by contacting the Biosafety Committee Chair at brobertson@alasu.edu or (334-229-4423).

Part A – Basic Information

A.1 Principal Investigator: _____
 Department: _____ Campus Mail: _____
 Building: _____ Office Room# _____
 E-mail: _____ Fax: _____
 Office Phone: _____ Lab Phone: _____
 PI's Study Coordinator: [Name] _____
 Coordinator Phone: _____
 Coordinator E-mail: _____

A.2 Type of Registration (see Appendix A for definitions):
 _____ Single Project _____ Multi Project

A.3 _____ New Registration _____ Renewal Registration: Previous IBC Study #

A.4 Project Title(s) (if multi-project, list titles of each project and assign a number to each):

A.5 Sponsor(s): _____

Part B – Project Information

1. List the synthetics and analogues of naturally-occurring chemicals and non-infectious agents and biological to be utilized

1.1 Provide all requested information for each agent/toxin that will be used in this project:

| Item # | Type | Name of Material | MSDS | Source | Risk Group | Biosafety Level BSL | Location of Use | Location of Storage (if different) |
|--------|------|------------------|------|--------|------------|---------------------|-----------------|------------------------------------|
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
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| 14 | | | | | | | | |
| 15 | | | | | | | | |

1. Please specify the type and name of source (e.g., vendor- or collaborator)
2. Refer to definitions in Appendix A of this form, use the NIH Guidelines, and the BMBL for RG and BSL designation.

1.2 Indicate the Biosafety Containment Level (BSL) if different than the (BSL) specified in Table 1.1:

____ BSL-1

____ BSL-2

____ BSL-3

Provide justification for the difference:

*Note: Research activities involving BSL-4 containment are prohibited on the ASU Campus.

2. Regulated Agents

2.1 Are any of the infectious agents / biological toxins (virulent or a virulent) on this application listed in Appendix B- Regulated Agents?

____ No Go to Section 3.

____ Yes Notify the Institutional Biosafety Officer immediately at (334-229-4423) to insure compliance with all federal mandates.

2.2 Have you registered the synthetics or analogues with the CDC/USDA (refer to Appendix B for exemptions)?

____ No Explain the exemption/exclusion criteria.

____ Yes Explain the status of the CDC/USDA select agent registration/certificate for this project: Submit a copy of CDC/USDA registration:

A. Describe the specific security procedures that you will use to ensure secure (a) access, (b) use, (c) storage, and (d) disposal:

B. Describe the inventory control system for the agents/toxins you plan to use (e.g., procedures used to account for the agents and to detect missing material):

3. Human Use

3.1 Will human subjects and /or human clinical specimens be used in any aspect of the experiment?

No **Go to Section 4.**

Yes

3.2 Has this research protocol been approved by the IRB? ORB?

No Date of Intended Submission to IRB: _____

Yes IRB study #: _____ Date approved: _____

Approval Pending: Date Submitted to IRB: _____

3.3 Will you administer infectious agents/biological toxins to humans?

No

Yes Submit copies of the following documents:

- a. Informed Consent form
- b. ASU Institutional Research Board (IRB) application or IRB approval of exemption
- c. Sponsor's investigational brochure
- d. Protocol

4. Animal Use

4.1 Will you administer infectious agents/biological toxins to animals or animal tissue?

No **Go to Section 5.**

Yes Specify the animal species or in vitro cell types used to analyze materials: _____.

4.2 Indicate the Animal Biosafety Containment Level (ABSL) at which the project will be conducted:

ABSL-1

ABSL-2

4.3 Has this research protocol received ASU Institutional Animal Care & Use Committee (IACUC) approval?

Yes No Date of Intended Submission to

IACUC _____

Yes IACUC study#: _____ Date approved: _____

____ Approval Pending: Date Submitted to IACUC: _____

4.4 List the animal facility (e.g., Life Sciences Building, Allied Health, Science Building, etc) and the area/room number(s) where the animals will be housed or used:

4.5 Will the animals exposed to the infectious agents/biological toxins be transported within the animal facility or to other areas within ASU:

____ No

____ Yes Describe how and where the animals will be transported.

4.6 Route of agent administration:

____ Intravenous ____ **Intraperitoneal** ____ **Subcutaneous** ____

Intramuscular

____ Other [Please specify]

4.7 Will the infectious agents/toxins present any risk of exposure to animal care staff

____ No **Go to Section 5.**

____ Yes **Answer parts A, B, and C**

A. What animal sources/routes (e.g., urine, feces, blood, bite/scratch), present a potential risk of exposure to the animal care staff?

B. What Personnel Protective Equipment is required to be worn by the animal care staff to protect them from potential risk of exposure from the animal sources(s) mentioned in part A?

Face masks: ____ N 95 (HEPA)

____ Face Shield

____ N 100 (HEPA)

____ Safety Glasses

____ Head Covers

____ Lab Gown

____ Double Gloves

____ Tyvek/Disposable Suits

____ Gloves

Lab Coats
 Surgical Mask

Shoe Covers
 Other: [Please specify]

C. What safety practices are in place to protect the animal care staff from potential risk of exposure from the animal sources(s) mentioned in part A?

D. What disinfectants will be used (check all that apply):

NOTE: The IBC requires a minimum concentration of 10% bleach solution as the primary disinfectant. Unless noted on this application with an explanation and approved by the IBC, all other disinfectants (e.g., 70% alcohol) are secondary disinfectants to be used after the 10% bleach.

5. Medical Information

5.1 Are there any risks of adverse effects* to humans, animals and /or plants that might result from exposure to these organisms/toxins?

No

Yes Describe the potential adverse effects to humans, animal, plants, and/or environment for each infectious agent/biological toxin*, including:

5.2 Describe the process to inform the personnel working with infectious agents/toxins of the potential hazards, including that an immunocompromised / immunosuppressed condition can increase the risk of infection (e.g., signage on door, specific training, read and initial this application).

5.3 Is antibiotic resistance expressed naturally by any of the infectious agents?

No

____ Yes indicate each agent and the specific antibiotic resistance expressed:

6 Experimental Procedures

- 6.1 Describe your research objectives in lay terms:
- 6.2 Provide below or attach a one-page (maximum) description of the specific laboratory procedures (e.g., culturing, vortexing, incubating, etc.) and specific safety precautions regarding these procedures for handling the infectious agent(s) and /or toxins. Specifically address the procedures by detailing the physical manipulations (not why the manipulations are being done). Include the animal and animal tissue handling procedures during the experiment, if applicable. **All necessary safety precautions will be taken**
- 6.3 Will any of the procedures described in the protocol result in acquisition of a new characteristic, such as enhanced virulence, infectivity, drug resistance, or change in host range?
- 6.4 A. For each agent/toxin, list the greatest volume/weight (e.g., ml, g) of the agent/ toxin that you expect to have on hand at any one time.

B. For each agent/toxin, list the greatest concentration (e.g., cfu/unit of volume) of the agent/toxin that you expect to have on hand at any one time.

6.5 A. Will you culture an organism?

a **Yes Go to item 6.6**

B. Does the study involve the generation or use of more than 10 liters of culture?

No

Yes explain the culture procedures, including identification of:

- (a) The culture room
- (b) The types of equipment used for culture growth/handling
- (c) Any special precautions to handle such large volumes.

6.6 A. Indicate the types of experimental manipulations which you will use that have the potential to generate aerosols/splashes (check all that apply):

Homogenization Centrifugation
 Sonication Dissection
 Pipetting Other: [Please specify]

None **Go to Question 6.7**

B. What special practices/procedures will you use for containment of aerosols/splashes for the above-mentioned experimental manipulations checked in item 6.6 A?

6.7 Have all personnel working with infectious agent(s) been instructed and trained in lab-specific clean up procedures for biohazardous spills (i.e., ASU Biosafety Training Course and PI provided training)?

___ No
___ Yes

*NOTE: For general biohazard spill procedures see Appendix C.

6.8 Will the organism/toxin be inactivated / lysed?

___ No
___ Yes Answer part A, B, and C:

A. Method of inactivation (heat, chemical other)

B. At what stage of the experiment will the agent/toxin be inactivated/lysed:

C. How will you verify inactivation / lysing?

Exposure Control Procedures

6.9 Indicate the Personnel Protective Equipment that will be used (check all that apply);

| | | |
|----------------------------|-----------------|----------------------------|
| ___ Face mask | ___ N 95 (HEPA) | ___ N100 (HEPA) |
| ___ Face Shield | | ___ Head covers |
| ___ Safety Glasses/Goggles | | ___ Double Gloves |
| ___ Lab Gown | | ___ Gloves |
| ___ Tyvek/Disposable Suits | | ___ Shoe Covers |
| ___ Lab Coats | | ___ Other [Please specify] |

*Note: The use of particulate masks such as N-95 requires medical evaluation, fit testing and training prior to its use per OSHA regulations.

6.10 Indicate the Safety Equipment you will use (check all that apply).

- Automatic pipettors Safety blender
 Low aerosolization pipette tips Chemical fume hood (for
 chemical use)
 Centrifuge with safety cups or sealed rotors heads
 Other: [Please specify]

6.11 Do you intend to use a Biological Safety Cabinet (BSC)?
 No Explain what safety procedures you will use instead of the BSC to eliminate the risk of aerosols exposures.

Yes Answer A and B below:

A. What type of BSC do you intend to use?

- Class II A2 (30% exhausted) Class II B2 (100% exhausted)
 Class II B1 (70% exhausted) Other: [Please specify]

B. BSC should be certified annually. Provide the date of the last certification:

Administrative Control Procedures

- 6.12 Indicate the administrative controls you will use (check all that apply):
- Controlled/restricted access Appropriate training of research staff
 Reporting spills and exposures Biohazard signage
 "Sharps" precautions and disposal* Prohibition of eating/drinking in lab
 Storage of food for human consumption not permitted in lab
 Hand washing Mouth pipetting prohibited
 Other :[Please specify]

*ASU Environmental Health and Safety's Web Page (In progress)

Facility Controls

- 6.13 Indicate the facility controls you will use (check all that apply):
- Hand-washing sink Eyewash Station
 Carpets/rugs in labs not permitted
 Bench top impervious to chemicals/water and resistant to heat
 Lab chairs covered with non-porous material
 One pass room ventilation (air is not recirculated)

- Negative room pressure (relative to hallway)
- NEPA filtered exhaust to outside
- Lab located away from public access areas
- Other: [please specify]

Decontamination and Disposal

- 6.14 What disinfectants will be used (check all that apply):
- 10 % Bleach Solution (1:10 dilution bleach to water)
 - Iodophor (Concentration :____)
 - Phenolic agents (Concentration :____)
 - Other: [Please specify]
- 6.15 Indicate how biohazardous solid waste will be decontaminated and disposed.
- Autoclaved Time: _____ minutes Temp: _____ Celsius
 - Chemically inactivated: [Please specify]
 - Packaged as biohazardous waste per ASU policy
 - Other: [Please specify]
- 6.17 If using a toxin(s), please describe how the toxin(s) will be inactivated and disposed.

Storage and Transport

- 6.18 Will any of these agents/toxins be transported or transferred outside of the room in which they are stored?
- No
 - Yes Answer A and B below
- A. To what location(s) outside of your laboratory will you transport/transfer these agents/toxins?
- B. How will these agents/toxins be packaged (i.e., double containment) during transportation? (Refer to Appendix A)

- 6.19 Will any of these agents/toxins be shipped via commercial carrier (e.g., Federal Express)?
_____No
_____Yes Identify the person(s) that will be preparing the agents/toxins for shipping and provide their Transportation of Dangerous Good training dates.

7. **Diagram of Laboratory Areas**

- 7.1 Attach a clearly labeled diagram of the laboratory that shows the following:
- 1) Where the agent(s)/toxin(s) will be manipulated and stored;
 - 2) Location of biological safety cabinets, eye-wash, sink, and other safety equipment;
 - 3) Room entry/exit;
 - 4) Location of the nearest available autoclave (if autoclave is not available in laboratory, list the location using text)

8. **Personnel**

The Institutional Bio safety committee (IBC) must be notified of any new personnel who will be directly involved in the conduct of the experiment and/or for whom a potential risk exists by virtue of their presence within the research environment.

- 8.1 List the names of all personnel involved and have each person initial the following assurance:
- I have read and understand the nature of these experiments.
 - I have the knowledge and training required to safely handle the materials described.
 - I agree to conduct these experiments in accordance with all ASU IBC policies and the ASU Biosafety Manual:
 - I have attended/will attend the annual ASU biosafety training indicated.

| Name | Initial here | Date | Bio safety Training | Training Date | E-mail |
|------|--------------|------|----------------------|---------------|--------|
| | | | ___ Yes or ___ NO | | |
| | | | ___ Yes or ___ NO | | |
| | | | ___ Yes or ___ NO | | |
| | | | ___ Yes or ___ NO | | |
| | | | ___ Yes or ___ NO | | |
| | | | ___ Yes or ___ NO | | |
| | | | ___ Yes or ___ NO | | |
| | | | ___ Yes or ___ NO | | |
| | | | ___ Yes or ___ NO | | |
| | | | ___ Yes or ___ NO | | |

*The following types of training classes are required:

- Core – Must be completed by those who have not done so previously.
- Continuing Education – Must be completed annually.
- Special Topics – Required for a person involved in certain types of work

9. Laboratory Inspection

BSL-2 or BSL -3 laboratories must pass inspection before initial approval for research activities can be granted for the proposed study. The Principal Investigator is responsible for scheduling an inspection by contacting the Biosafety Committee chair at brobertson@alasu.edu or (334)229-4423.

Information on biosafety containment levels and other guidance is available in the [NIH Guidelines for Research Involving Recombinant DNA Molecules](#), the [Biosafety in Microbiological and Biomedical Laboratories, 5th Edition](#), and the [ASU Institutional Biosafety Manual](#). Investigators are encouraged to consult these sources to ensure that their laboratories meet the required standards for sound biosafety practices.

A [Sample BSL-2 Checklist](#) is provided to help you prepare for a laboratory inspection.

9.1 Has your laboratory been scheduled for inspection?

Yes Please provide the date: _____

No Inspection is pending due to: _____

Does not apply because the laboratory involved is BSL-1.

10. Investigator Assurance

- I agree to use lab practices that meet the highest biosafety level (BSL) specified in Table 1.1 with all work with infectious agents/biological toxins in this project.
- I have read the Biosafety in Microbiological and Biomedical Laboratories, 5th Edition and I acknowledge my responsibility for the conduct of this research in accordance with the procedures described in it.
- I have the Knowledge and training required to safely handle the materials described.
- I acknowledge my responsibility for the conduct of this research in accordance with University Policy, Section IV B-7 of the NIH Guidelines and/or the recommendations of the CDC/NIH published in Biosafety in Microbiological and Biomedical Laboratories, 5th Edition and the ASU Institutional Biosafety Manual.
- I acknowledge my responsibility to secure and control the biological agents used in this project.
- Entry doors to the laboratory will be closed and locked when the laboratory is unattended.

X

Signature of Principal Investigator