Biological Agent Registration Form

Principal investigators (PI's) must complete this form to register the use of biological agents, biological toxins, and human source materials with the OSU-Center for Health Sciences Institutional Biosafety Committee.

The USA PATRIOT ACT of 2001 prohibits the possession of a "Biological Agent, Toxin or Delivery System" of a type or in a quantity that, under circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose.

The "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Public Law 107-188) requires that all persons possessing select biological agents or toxins deemed a threat to public health, animal or plant health, or animal or plant products register with the appropriate federal agency. Rules were published in the Federal Register by the Departments of Health and Human Services (HHS) and Agriculture (USDA) governing facilities that possess, use or transfer select biological agents or toxins became effective on February 7, 2003.

Possession, use, transfer or disposal of select biological agents and toxins may not occur without approval of the Institutional Official. Contact the Office of Research for more information.

Institutional Biosafety Committee
1111 W. 17th Street
Tulsa, OK 74107

For Office Use ONLY:

Date Received: _____

Protocol Number: _____

Date Approved: _____

Expiration Date: _____

Instructions: Complete electronically. Send fully signed application to the Office of Research.

Biological Agent(s) Registration Form

A. Investigator Information:

Principal Investigator (PI) Name:	
Professional Title:	
Department:	
Campus Address:	
Office Phone Number:	
Emergency Phone Number:	
E-mail Address:	

Co-Principal Investigator (Co-PI) Name:	
Professional Title:	
Department:	
Campus Address:	
Office Phone Number:	
Emergency Phone Number:	
E-mail Address:	

Investigator Assurances:

Pursuant to applicable State and Federal laws and regulations and Oklahoma State University policies and procedures:

- To the best of my knowledge, I affirm that all information contained herein is accurate and complete.
- I agree to accept responsibility for the training of all personnel involved in this research and that all personnel have been trained.
- I understand that any and all changes must be reported in writing to the IBC in the prescribed format, and that IBC approval shall be obtained prior to implementation of these changes.

Principal Investigator Name	Principal Investigator Signature	Date
Co-Responsible Faculty Name	Co-Responsible Faculty Signature	Date
Department Head Name	Department Head Signature	Date
Dean/Research Director Name	Dean/Research Director Signature	Date

B. Project Information:

Project Title:	

Funding Agency:	

Will work involve use of a CDC Select Agent? *	☐ no ☐ yes
Will work involve use of a USDA/APHIS Restricted Animal Pathogen? **	☐ no ☐ yes
Do you use or generate rDNA? ***	☐ no ☐ yes ↓ If YES, IBC protocol number:
Do you use Human Source Material? (blood, blood products, tissue, by-products, cell lines, etc.)	☐ no ☐ yes
Are any of the microorganisms/infectious agents, select biological agents or toxins, other biological toxins, recombinant DNA or human source materials stored without planned/contemplated use?	☐ no ☐ yes, specify ↓

Project Summary/Abstract: Please describe your project clearly and simply.

Project Personnel:	
Name:	**Initials acknowledging project participation:**
Relevant Training/Experience:	Project Responsibilities:
Name:	**Initials acknowledging project participation:**
Relevant Training/Experience:	Project Responsibilities:
Name:	**Initials acknowledging project participation:**
Relevant Training/Experience:	Project Responsibilities:
Name:	**Initials acknowledging project participation:**
Relevant Training/Experience:	Project Responsibilities:
Name:	**Initials acknowledging project participation:**
Relevant Training/Experience:	Project Responsibilities:

Will any foreign nationals (non-US citizens without a green card) be working on this project?	☐ no ☐ yes

* http://www.selectagents.gov/index.html
** http://www.cdc.gov/OD/ohs/biosfty/bmbl4/b4ad.htm
*** http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

C. Biosafety Information

Determination of Biosafety Level (BSL)	
Check the Risk groups (or Class) of all material(s) used in this project in the boxes below	
☐ Risk Group 1	*Please reference Appendix B of the NIH Guidelines (see below) for assistance with classification.*
☐ Risk Group 2	
☐ Risk Group 3	
☐ Risk Group 4	
Describe the potential Biosafety risks of this research proposal below: (Risk Assessment)	
Pathogenicity Humans ☐ no ☐ yes Other Animals ☐ no ☐ yes Plants ☐ no ☐ yes	
Route of transmission	
Agent stability	
Infectious dose (indicate host)	
Concentration (identify as stock concentration or concentration employed in experiment such as dose, etc.)	
Origin	
Availability of effective prophylaxis	
Check the highest biological safety level required for this project	Please reference Appendix G of the NIH Guidelines for additional information on Biosafety Containment Level descriptions and the BMBL (see links below.)
☐ BSL-1, BL-1P, ABSL-1	Low risk agents, special containment equipment not required
☐ BSL-2 ,BL-2P, ABSL-2	Moderate risk agents, biosafety cabinets, restrictions to research areas
☐ BSL-3, BL-3P, ABSL-3	High risk agents, BSL-3 containment facilities, and practices

NIH Guidelines http://oba.od.nih.gov/rdna/nih_guidelines_oba.html
Biosafety in Microbiological and Biomedical Laboratories (BMBL) http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm

D. Microorganisms/Infectious Agents

List the organism(s)/infectious agent(s) used or stored in your laboratory in the table below. Indicate where each agent is stored and used. If you are working with an organism/infectious agent that are not on the list, you must still provide as much information as you have available regarding the agent.

Agent (Genus & Species) ↓	Strain ↓	Recombinant ↓	Antibiotic Resistance ↓ (Specify)	Risk Group ↓	Where Stored Room & Building ↓	Where Used Room & Building ↓
		☐ No ☐ Yes				
		☐ No ☐ Yes				
		☐ No ☐ Yes				
		☐ No ☐ Yes				
		☐ No ☐ Yes				
		☐ No ☐ Yes				

Will any of these items be sent out of the country?	☐ no ☐ yes, specify ↓

E. Biological Toxins

Toxin Name ↓	Select Agent ↓	Number of Vials ↓	Amount ↓ (mg)	Where Stored Room & Building ↓	Where Used Room & Building ↓	Supplier ↓
☐ Abrin	☐ YES					
☐ Botulinum neurotoxins	☐ YES					
☐ Conotoxins	☐ YES					
☐ Diacetoxyscirpenol	☐ YES					
☐ Ricin	☐ YES					
☐ Saxitoxin	☐ YES					
☐ Shigatoxin & Shiga-like ribosome	☐ YES					

inactivating proteins						
☐ Staphylococcal enterotoxins	☐ YES					
☐ Tetrodotoxin	☐ YES					
☐ T-2 toxin	☐ YES					
☐ Venoms	☐ YES					
☐ Other:	☐ YES					
☐ Other:	☐ YES					
☐ Other:	☐ YES					

Will any of these items be sent out of the country?	☐ no ☐ yes, specify ↓

F. Research Facilities

Room and Building for all locations of this project ↓	Procedures performed in each location ↓	BSL – Currently approved biosafety containment level for EACH procedure room ↓	Last inspection date for each location ↓

NOTE:

If work is to be conducted at biosafety level 2, the lab must be registered as such. Contact the Biological Safety Officer for more information. The Biosafety Standard Operating Procedures (SOPs) for <u>each location</u> must be available for review. Submitting them with the application is recommended to help avoid delays in approving the work.

Do you have any Biological Safety Cabinets? →	☐ yes ☐ no →	If NO, this section is complete. If YES, complete table below. ↓
Class/Type ↓	Certification Date ↓	Room & Building ↓

NOTE:

A Laminar Flow Clean Bench in not a biological safety cabinet. It does not provide personal protection and is not to be used for work with biohazardous materials.

G. Animal Use Information

Does the work involve use of vertebrate animal(s)? →	☐ yes ☐ no	If NO, this section is complete. If YES, complete Appendix B.