LIMR INSTITUTIONAL BIOSAFETY COMMITTEE (LIMR IBC)
NEW PROTOCOL FORM

SECTION 3: Microorganism Usage

Principal Investigator(s) Name:

Project Title:

Investigator Classification:

- ☐ BSL-1
- ☐ BSL-2
- ☐ BSL-2+
- ☐ ABSL-1
- ☐ ABSL-2

3.1 What microorganism(s) will be used in this project (indicate strain where appropriate, such as for adenovirus, lentivirus)?

3.2 Is the organism known to be pathogenic for:

Humans?	☐ Yes	☐ No
Other Animals?	☐ Yes	☐ No
Plants?	☐ Yes	☐ No

Explain as necessary:

3.3 Is the microorganism on the CDC Select Agent List? (*See Appendix A*) ☐ Yes ☐ No

If yes, complete the APHIS/CDC Form 1 Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins and attach a copy with this form. https://www.selectagents.gov/forms/form1.htm

3.4 Is the microorganism on the USDA/APHIS Restricted Animal/Plant Pathogen List *(see Appendix A)?* ☐ Yes ☐ No

3.5 Where will the microorganism(s) be stored? (Building, Room No. and Freezer, if applicable)

Building	**Room/Lab Number**	**Freezer No.**

Submit completed document to SAFETY@LIMR.ORG.

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3.6 Identify all locations where the experiments will be conducted:

Building	**Room/Lab Number**

If the answers to 3.5 and 3.6 are different, outline the means of transportation:

3.7 What is the appropriate biosafety level for the microorganism(s)? ☐ BSL-I ☐ BSL-2

3.8 Does the experiment involve or does the microorganism synthesize a toxic molecule lethal for vertebrates at an LD_{50} < 100,000 ng/kg or is the toxin on the CDC Select Agent List *(see **Appendix A**)?* ☐ Yes ☐ No ☐ Unknown
*If yes, indicate the toxin and complete **Section 4, Biological Toxin***

3.9 Does the experiment involve the infection of vertebrate animals? ☐ Yes ☐ No

3.10 Is there a vaccine available and recommended for person(s) handling this microorganism? Refer to recommendations of the Advisory Committee on Immunization Practices (ACIP). https://www.cdc.gov/vaccines/acip/index.html ☐ Yes ☐ No
If yes, provide the name and method of vaccine:

3.11 Does the work involve the importation, production, manufacturing, or processing of new (intergeneric) microorganisms or significant new use of microorganisms for the purpose of obtaining an immediate or eventual commercial advantage for the researcher or the funding entity? ☐ Yes ☐ No

3.11.1 *If yes, has a Microbial Commercial Activity Notice (MCAN) been submitted to the United States Environmental Protection Agency?* https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/microbial-commercial-activity ☐ Yes ☐ No

3.12 Have all personnel involved with this project received training on the procedures for the safe handling of the specific microorganism? ☐ Yes ☐ No

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Appendix A: HHS AND USDA SELECT AGENTS AND TOXINS
7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS	OVERLAP SELECT AGENTS AND TOXINS
Abrin [6] *Bacillus cereus* Biovar *anthracis* [1] Botulinum neurotoxins [1] [6] Botulinum neurotoxin producing species of *Clostridium* [1] Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$) [6] *Coxiella burnetii* Crimean-Congo haemorrhagic fever virus Diacetoxyscirpenol [6] Eastern Equine Encephalitis virus [4] [5] Ebola virus [1] *Francisella tularensis* [1] Lassa fever virus Lujo virus Marburg virus [1] Monkeypox virus [4] Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus) Ricin [6] *Rickettsia prowazekii* SARS-associated coronavirus (SARS-CoV) Saxitoxin [6] South American Haemorrhagic Fever viruses: Chapare Guanarito Junin Machupo Sabia Staphylococcal enterotoxins (subtypes A,B,C,D,E) T-2 toxin [6] Tetrodotoxin [6] Tick-borne encephalitis complex (flavi) viruses: Far Eastern subtype [5] Siberian subtype [5] Kyasanur Forest disease virus [5] Omsk hemorrhagic fever virus [5] Variola major virus (Smallpox virus) [1] Variola minor virus (Alastrim) [1] *Yersinia pestis* [1]	*Bacillus anthracis* [1] *Bacillus anthracis* Pasteur strain *Brucella abortus* *Brucella melitensis* *Brucella suis* *Burkholderia mallei* [1] *Burkholderia pseudomallei* [1] Hendra virus Nipah virus Rift Valley fever virus Venezuelan equine encephalitis virus [4] [5]
	USDA SELECT AGENTS AND TOXINS
	African horse sickness virus African swine fever virus Avian influenza virus [4] Classical swine fever virus [5] Foot-and-mouth disease virus [1] [5] Goat pox virus Lumpy skin disease virus *Mycoplasma capricolum* [4] *Mycoplasma mycoides* [4] Newcastle disease virus [3] [4] Peste des petits ruminants virus Rinderpest virus [1] Sheep pox virus Swine vesicular disease virus[5]
	USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS
	Coniothyrium glycines (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*) *Peronosclerospora philippinensis* *(Peronosclerospora sacchari)* *Ralstonia solanacearum* *Rathayibacter toxicus* *Sclerophthora rayssiae* *Synchytrium endobioticum* *Xanthomonas oryzae*

[1] Denotes Tier 1 Agent

[2] C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins a-MI and a-GI (shown above) as well as a-GIA, Ac1.1a, a-CnIA, a-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

[3] A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

[4] Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus, west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumoniae (contagious caprine pleuropneumonia), all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category.

[5] For determining the regulatory status of nucleic acids that are capable of producing infectious forms of select agent viruses, please reference guidance here.

[6] For determining the regulatory status of Recombinant and/or Synthetic nucleic acids that encode for the toxic form(s) of any select toxins if the nucleic acids (i) can be expressed in vivo or in vitro, or (ii) are in a vector or recombinant host genome and can be expressed in vivo or in vitro; please reference guidance here.