Inspection Checklist for NIH BL2 Laboratories (7 CFR 331; 9 CFR 121; 42 CFR 73; NIH Guidelines)

Entity Name:	0	**Insp. Date:**	January 0, 1900
Street Address:	, ,		
City, State, Zip:	, ,	**RO:**	0
Lead Inspector:	0	**ARO(s):**	
Other Inspectors:			
Building/Room(s):			
PI(s):			
HHS Agents:			
Overlap Agents:			
USDA Agents:			

When information is entered in this form, the form is to be considered "*Sensitive Select Agent Information*."

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Reference	Statement	Response			Comments
		Yes	No	N/A	
NIH BL2 (rDNA) Requirements					
CFR: Section 12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use.				
CFR: Section 12(a)	The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.				
CFR: Section 12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).				
CFR: Section 12 (c)(3)	In developing a biosafety plan, an individual or entity should consider: The "NIH Guidelines for Research Involving Recombinant DNA Molecules," (NIH Guidelines). Copies may be obtained from the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia, 30333 or from the CDC web site at http://www.cdc.gov/. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia.				
CFR: Section 12(d)	The plan must be reviewed annually and revised as necessary.				
CFR: Section 12(d)	Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan.				
CFR: Section 12(d)	The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.				

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CFR: Section 13 (a)	An individual or entity may not conduct a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary.				
CFR: Section 13 (a)	In addition, an individual or entity may not conduct a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary, after consultation with Administrator.				
CFR: Section 13 (b)(1)	*Restricted experiments:* Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.				
CFR: Section 13 (b)(2)	*Restricted experiments:* Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight.				
A					
NIH: G-II-B-1-a	Access to the laboratory is limited or restricted by the Principal Investigator when work with organisms containing recombinant DNA molecules is in progress.				
NIH: G-II-B-1-b	Work surfaces are decontaminated at least once a day and after any spill of viable material.				
NIH: G-II-B-1-c	All contaminated liquid or solid wastes are decontaminated before disposal.				
NIH: G-II-B-1-d	Mechanical pipetting devices are used; mouth pipetting is prohibited.				
NIH: G-II-B-1-e	Eating, drinking, smoking, and applying cosmetics are not permitted in the work area.				
NIH: G-II-B-1-e	Food may be stored in cabinets or refrigerators designated and used for this purpose only.				
NIH: G-II-B-1-f	Persons wash their hands: (i) after handling materials involving organisms containing rDNA molecules and animals, and (ii) when exiting the laboratory.				
NIH: G-II-B-1-g	All procedures are performed carefully to minimize the creation of splashes or aerosols.				
NIH: G-II-B-1-h	Experiments of lesser biohazard potential can be conducted concurrently in carefully demarcated areas of the same laboratory.				
B					
NIH: G-II-B-2-a	Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory.				

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NIH: G-II-B-2-b	The Principal Investigator limits access to the laboratory. The Principal Investigator has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.				
NIH: G-II-B-2-c	The Principal Investigator establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific entry requirements (e.g., immunization) may enter the laboratory or animal rooms.				
NIH: G-II-B-2-d	When the organisms containing rDNA molecules in use in the laboratory require special provisions for entry (e.g., vaccination), a hazard warning sign incorporating the universal biosafety symbol is posted on the access door to the laboratory work area.				
NIH: G-II-B-2-d	The hazard warning sign identifies the agent, lists the name and telephone number of the Principal Investigator or other responsible person(s), and indicates the special requirement(s) for entering the laboratory.				
NIH: G-II-B-2-e	An insect and rodent control program is in effect.				
NIH: G-II-B-2-f	Laboratory coats, gowns, smocks, or uniforms are worn while in the laboratory.				
NIH: G-II-B-2-f	Before exiting the laboratory for non-laboratory areas (e.g., cafeteria, library, administrative offices), this protective clothing is removed and left in the laboratory or covered with a clean coat not used in the laboratory.				
NIH: G-II-B-2-g	Animals not involved in the work being performed are not permitted in the laboratory.				
NIH: G-II-B-2-h	Special care is taken to avoid skin contamination with organisms containing recombinant DNA molecules;				
NIH: G-II-B-2-h	Gloves should be worn when handling experimental animals and when skin contact with the agent is unavoidable.				

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NIH: G-II-B-2-i	All wastes from laboratories and animal rooms are appropriately decontaminated before disposal.				
NIH: G-II-B-2-j	Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles.				
NIH: G-II-B-2-j	Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for the injection or aspiration of fluids containing organisms that contain rDNA molecules.				
NIH: G-II-B-2-j	Extreme caution should be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal.				
NIH: G-II-B-2-j	Needles should not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use.				
NIH: G-II-B-2-j	The needle and syringe should be promptly placed in a puncture-resistant container and decontaminated, preferably autoclaved, before discard or reuse.				
NIH: G-II-B-2-k	Spills and accidents which result in overt exposures to organisms containing rDNA molecules are immediately reported to the Institutional Biosafety Committee and NIH / OBA. Reports to NIH / OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).				
NIH: G-II-B-2-k	Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.				
NIH: G-II-B-2-l	When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored.				
NIH: G-II-B-2-l	Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.				
NIH: G-II-B-2-m	A biosafety manual is prepared or adopted.				
NIH: G-II-B-2-m	Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.				
C					
NIH: G-II-B-3-a	Biological safety cabinets (Class I or II) or other appropriate personal protective or physical containment devices are used whenever:				

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NIH: G-II-B-3-a-(1)	Procedures with a high potential for creating aerosols are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of materials whose internal pressures may be different from ambient pressures, intranasal inoculation of animals, and harvesting infected tissues from animals or eggs.				
NIH: G-II-B-3-a-(2)	High concentrations or large volumes of organisms containing rDNA molecules are used. Such materials may be centrifuged in the open laboratory if sealed beads or centrifuge safety cups are used and if they are opened only in a biological safety cabinet.				
D					
NIH: G-II-B-4-a	The laboratory is designed so that it can be easily cleaned.				
NIH: G-II-B-4-b	Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.				
NIH: G-II-B-4-c	Laboratory furniture is sturdy and spaces between benches, cabinets, and equipment are accessible for cleaning.				
NIH: G-II-B-4-d	Each laboratory contains a sink for handwashing.				
NIH: G-II-B-4-e	If the laboratory has windows that open, they are fitted with fly screens.				
NIH: G-II-B-4-f	An autoclave for decontaminating laboratory wastes is available.				

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		Yes	No	N/A	
Inspector summary and comments:					
Recommendations:					
Inspector completing checklist:					**Date:**
Other inspectors present:					**Date:**