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

Entity Name:
Inspection Date:
Street Address:
City, State, Zip:
RO:
ARO(s):

Lead Inspector:
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.

Entity Name:		**Inspection Date:**			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
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 (biocontainment) plan that is commensurate with the risk of the select agent or toxin, given its intended use.	☐	☐	☐	
CFR: Section 12(a)	The biosafety (biocontainment) plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent.	☐	☐	☐	
CFR: Section 12(a)	The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	☐	☐	☐	
CFR: Section 12(a)(1)	The biosafety plan must include the hazardous characteristics of each agent or toxin listed on the entity's registration and the biosafety risk associated with laboratory procedures related to the select agent or toxin.	☐	☐	☐	

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Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
CFR: Section 12(a)(2)	The biosafety plan must include safeguards in place with associated work practices to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: personal protective equipment and other safety equipment; containment equipment including, but not limited to, biological safety cabinets, animal caging systems, and centrifuge safety containers; and engineering controls and other facility safeguards.	☐	☐	☐	
CFR: Section 12(a)(3)	The biosafety plan must include written procedures for each validated method used for disinfection, decontamination or destruction, as appropriate, of all contaminated or presumptively contaminated materials including, but not limited to: cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding (if applicable), animal carcasses or extracted tissues and fluids (if applicable), laboratory surfaces and equipment, and effluent material.	☐	☐	☐	
CFR: Section 12(a)(4)	The biosafety plan must include procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.	☐	☐	☐	
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)(1)	In developing a biosafety plan, an individual or entity should consider: The CDC/NIH publication, “Biosafety in Microbiological and Biomedical Laboratories.” This document is available on the National Select Agent Registry website at http://www.selectagents.gov/. In developing a biocontainment plan, an individual or entity should consider the following: (1) Containment Facilities and Safeguards for “Exotic Plant Pathogens and Pests” (Robert P. Kahn and S.B.Mathur eds., 1999); and (2) “A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes” (Patricia L. Traynor ed., 2001).	☐	☐	☐	
CFR: Section 12 (c)(3)	In developing a biosafety plan, an individual or entity should consider: The “NIH Guidelines for Research Involving Recombinant or Synthetic Molecules,” (NIH Guidelines). This document is available on the National Select Agent Registry Web site at http://www.selectagents.gov.	☐	☐	☐	

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CFR: Section 12(d)	The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program.	☐	☐	☐	
CFR: Section 12(e)	The plan must be reviewed annually and revised as necessary.	☐	☐	☐	
CFR: Section 12(e)	Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan.	☐	☐	☐	
CFR: Section 12(e)	The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.	☐	☐	☐	
CFR: Section 12(e)	Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.	☐	☐	☐	
42 CFR 73: Section 13 (a) *HHS select agent*	An individual or entity may not conduct or possess products (i.e., select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, or recombinant and/or synthetic nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from, 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.	☐	☐	☐	
42 CFR 73: Section 13 (a) *overlap select agent*	In addition, an individual or entity may not conduct or possess products (i.e., select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, or recombinant and/or synthetic nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from, 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.	☐	☐	☐	

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9 CFR 121: Section13(a) *USDA only agent*	An individual or entity may not conduct or possess products (i.e., select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, or recombinant and/or synthetic nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the Administrator:	☐	☐	☐	
NIH: G-II-B-1-a	Access to the laboratory is limited or restricted by the Principal Investigator when work with organisms containing recombinant or synthetic nucleic acid 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 recombinant or synthetic nucleic acid 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 aerosols.	☐	☐	☐	
NIH: G-II-B-1-h	Experiments of lesser biohazard potential can be conducted concurrently in carefully demarcated areas of the same laboratory.	☐	☐	☐	

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Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
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.	☐	☐	☐	
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 recombinant or synthetic nucleic acid 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 or synthetic nucleic acid molecules;	☐	☐	☐	

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NIH: G-II-B-2-h	Gloves should be worn when handling experimental animals and when skin contact with the agent is unavoidable.	☐	☐	☐	
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 recombinant or synthetic nucleic acid 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 recombinant or synthetic nucleic acid 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.	☐	☐	☐	

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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.	☐	☐	☐	
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:**				
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 recombinant or synthetic nucleic acid 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.	☐	☐	☐	
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.	☐	☐	☐	

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NIH: G-II-B-4-f	An autoclave for decontaminating laboratory wastes is available.	☐	☐	☐	

Comments continued:

Inspector summary and comments:

Lead inspector: Date:

Other inspectors present: Date:

Lead inspector signature: _____ Date: _____

Print Form