PRINCIPAL INVESTIGATOR REGISTRATION FOR SELECT AGENTS

In order to gain approval by the CDC for use of select biological agents the CDC requires, as part of their application procedure (Sections 3B through 3G) that the PI provide the following information. They will not approve use of these select agents without this information.

Please answer the following questions:

1. Briefly state (paragraph in length) the objectives of the work that will be done with the select agent(s), including a description of the types of methodologies or laboratory procedures that will be used. State if you will be working with any host-vector systems. If you will be working with live agent as well as recombinant DNA and/or nonviable DNA, then include these procedures in your description.

2. Include a diagram of the floor plan (preferably not blueprints) showing the layout and rough dimensions of the laboratory(s) where select agents will be handled or stored. Clearly indicate on your diagram the following: entry and exit ways; air supply and exhaust vents; incubators; freezers; autoclaves; sinks; eyewash and emergency shower stations; biosafety cabinets (BSCs), fume hoods, centrifuges, and any other major laboratory equipment present in the laboratory.

3. Describe the operation of the air-handling system in the laboratory where the work will be performed; specifically state if the air is single pass (dedicated exhaust or connected to building exhaust system) or recirculated within the laboratory. Indicate methods of maintaining air balance in the laboratory (i.e., variable air volume versus constant air volume, redundant exhaust fans, and emergency backup power systems). If applicable, include the type of supply and/or exhaust filtration utilized, and how airflow is visually monitored by laboratorians (e.g., pressure differential gauges, or other monitoring systems).

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4. State whether a Biosafety Cabinet (BSC) will be used. If yes, then describe the procedures to be done in the BSC. State what type of BSC will be used (e.g., Class II, Type B2). Describe if the BSCs are recirculating, or directly exhausted. If the BSC exhaust is connected to the building exhaust system, provide details of exhaust ductwork (hard-ducted or thimble connection). State how often the BSCs are inspected and certified.

5. State whether a chemical fume hood will be used. If yes, then describe the procedures to be performed in the chemical fume hood. State what type of filters, if any, are utilized with the chemical fume hood. Is there a visual method to verify inward airflow? State how often the fume hood is certified and the filters, if present, are changed.

6. Describe how your facility limits access to the laboratories where select agents are being manipulated and stored to only authorized and qualified persons (e.g., is there a guard at the entrance? card key access? door keys or combination-locked?)
   (A) Describe the policy in place to limit further access to this laboratory and/or storage area when a temporary employee (e.g ., students, post-doctoral fellows, etc.) leaves the facility.
   (B) Are only personnel working with the select agents allowed in the specified laboratory? If not, who else is allowed? Are guests escorted in the laboratory at all times? Are maintenance personnel allowed in the laboratory? How many people have access to the laboratory where select agents are handled or stored?
   (C) Is the laboratory secured when no one is present during regular working hours?

7. Please indicate if all your protocols had been reviewed and approved by the Institutional Biosafety Committee (IBC) prior to working with select agents at this facility? If yes, then has the IBC approved the work proposed in this application?

8. Please indicate if your laboratory had been inspected by USDA, FDA, CLIA, or others? If yes, then give date of last inspection(s).

To be completed by applicants working with infectious select agents

9. Please provide a brief summary regarding the strains of organisms that will be used. Provide an estimate of the maximum quantities (e.g., number of petri dishes or flasks) and concentration of organisms grown at a given time.

To be completed by applicants working with select agent genomic DNA or nonviable organisms

10. Please provide a written verification that material has been rendered nonviable for which you receive select agent DNA or nonviable organisms. In the interest of the health and safety of the laboratorians that will be working with the select agent material, it is particularly critical due to the severe illnesses that many of these agents cause. Provide a concise assurance on the following points regarding inactivation of live agent:

    (A) A procedure is in place for inactivating live agent.

(B) The procedures employed for inactivating live agent have been verified. It is particularly critical that select agents be rendered nonviable because of the severe illnesses that many of these agents may cause.

To be completed by applicants working with recombinant DNA

11. Give an estimate of the range in length (in bp's) of the recombinant select agent DNA material and what it encodes for. What type of host-vector system(s) will be used?

To be completed by applicants working with small animals (ABSL2 – ABSL4)

12. What route of infection will be used with the select agent(s)?

13. Facilities for laboratory animal studies should be physically separate from areas with other activities, such as clinical laboratories and those that provide patient care. Include with your sketch of the floor plan (question number 3 above), another sketch that shows the animal rooms to be used and rooms adjacent to them. Indicate what type(s) of activities are conducted in areas adjacent to the animal rooms.

14. Has the protocol that involves animal been reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) prior to work with animals at this facility? If yes, has the proposed work with select agents in small animals been approved by the IACUC?

15. Is the laboratory space described in this application AAALAC accredited?

To be completed by applicants working with select agent toxins

16. Clearly state the form(s) of the toxin that will be used (e.g., are the toxins received in liquid or dry form?). If the toxin is received in dry form, describe decontamination procedures prior to removing material from the chemical fume hood.

17. What concentration of toxins will be handled? What volume of toxins are you working with or storing?

18. Are dilution procedures and other manipulations of the concentrated toxins conducted in a fume hood or biosafety cabinet with two knowledgeable people present? Is there a hazard sign on the door when toxins are present?

19. If toxins are to be produced from live agent, then briefly describe procedures used for doing so. Include in your summary an estimate of the maximum quantities (e.g., number of plates) grown at a given time.

All applicants must complete this table;

TYPE OF WORK TO BE PERFORMED AT FACILITY

Principal Investigator's Name:_____ Date:_____

INDICATE WITH AN "X" FOR EACH AGENT AS APPROPRIATE

Select Agent Name	Viable	Nonviable	Purified Genomic material	Recombinant DNA	Small Animal	Large Animal	Large Scale	Toxin	Laboratory Area		Storage Area		1. Safety Level	2. Culture	3. Isolate Toxins	4. Transport
									Bldg	Room	Bldg	Room				

1.Legend for Safety Levels
Biosafety Level2 =BSL2 Animal Biosafety Level2 =ABSL2 rDNA BSL2=NIHBL2 rDNA Large Animal BSL2=NIH BL2N rDNA Large Scale BSL2=NIH BL2-LS

2. Please indicate if you culture the agent for production

3. Please indicate if you culture to isolate the toxin

4. Transport includes internal and external transport of agents to others