

# Instructions for Registration of Facility - LR/SAT

## Section 1: Forms required to be completed by all applicants

Please Obtain and *Read* a copy of 42 CFR Parts 72, 73 *before* completing this form

(1) “**Background Information/Certification and Signature**” form (Section 2). This form must be signed by the **responsible facility official\*** for your institution. Indicate the select agents your facility works with and intends to receive or transfer under this regulation. Facilities registering for nonviable material or genetic elements only should indicate this to the side the applicable select agent listed on the form. [ \* **MSSM Biosafety Officer, 241 – 1451** ]

(2) Information about Select Agents facility intends to work with or transfer. **All facilities** are required to complete Section 3A (Table on page 3-2), and Section 3B. Complete Sections 3C through 3G as appropriate for your facility.

### Facility Risk Assessments and Safety Levels; Requirements for Handling Select Agents

All Select Agent facilities must base their facility risk assessments on the applicable sections of most recent edition of the *BMBL(CDC)*, *NIH Guidelines, 29 CFR 1910.1450 (OSHA)* or other required assessment materials. [ go to: [www.mssm.edu/biosafety](http://www.mssm.edu/biosafety) to access these documents under “Links” ]

- Laboratories working with live select agent viruses, bacteria, fungi or rickettsiae will base the facility risk assessments on the most current edition of the CDC /NIH BMBL. Use the BMBL supplement (Attachment 5) to determine the appropriate Biosafety Level (BSL) for various types of work you will do with each of the select agents you have listed in Section 3A.
- Laboratories working with recombinant DNA, genetic elements, or inactivated agents may refer to either the appropriate BMBL-based requirements, and/or those of the *NIH Guidelines for Research Involving Recombinant DNA* to determine the recommended Biosafety Level (BSL) the various types of work you will do with each of the select agents you have listed in Section 3A. The responsible facility official may determine this based on which document is used for that institution’s policies and procedures for work with those select agents. Institutions using recombinant DNA for large animal studies or in large scale production should base their facility risk assessments on the *NIH Guidelines*, as there are no corresponding sections in the BMBL.
- Laboratories working with select agent toxins must meet the requirements of 29 CFR 1910.1450 and the toxin guidelines contained in the appendix of the current edition of the BMBL. If the facility is also working with intact toxin-producing organisms or recombinant DNA encoding for select agent toxins, the laboratory should base its facility risk assessments on BMBL and/or *NIH Guidelines* in addition to 29 CFR 1910.1450. Certain uses of the select agent toxins are exempt from the requirements of this regulation (see 42 CFR 72.6 subsection (h)).

### Send the completed application package to:

Centers for Disease Control and Prevention  
Office of Health and Safety  
Laboratory Registration/Select Agent Transfer Program  
1600 Clifton Road, NE., Mail Stop A13  
Atlanta, GA 30333

### Additional materials you may need

(1) *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). The BMBL is available the internet at <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm> , or you may obtain single copy of this document by faxing a request to CDC, Office of Health and Safety. The fax number is 404- 639-0880. An errata sheet for the most current edition of the BMBL is available at the internet website: <http://www.cdc.gov/od/ohs/biosfty/bmbl4/toc.htm> . Please note that some corrections are applicable to Select Agent transfers.

(2) *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*, March 1996 or more recent edition. The *NIH Guidelines* are available on the internet at <http://www4.od.nih.gov/oba/guidelines.html> , or contact NIH (phone 301-496 -9838).

(3) 29 CFR 19 10.1450 - *Occupational Exposure to Hazardous Chemicals in the Laboratory*. Available on the Internet at <http://www.osha.gov/> or from the U.S. Government Printing

Office (phone 202-512-1800).

(4) Additional information and clarification is available through the CDC Laboratory Registration/Select Agent Transfer Program website: <http://www.cdc.gov/od/ohs/lrsat.htm>.

### **How to amend your registration**

To add, delete or change information on your registration, complete Section 3A (Table on page 3-2), Section 3B, and Sections 3C through 3G as appropriate, to include any new information not currently on file with CDC. In addition, the RFO must complete and sign the Certification and Signature form for each new amendment request (Section 2). These forms are available on the internet at <http://www.cdc.gov/od/ohs/lrsat.htm>, or may be requested from our office (404-639-4418).

To designate a different or an alternate RFO, the current RFO must send or fax to our office a signed statement on official facility letterhead requesting such changes. We remind you that when you designate an alternate RFO that your designated alternate must also meet the requirements set forth in section "(j) Definitions" for Responsible facility official. That definition is reprinted below for your convenience.

"Responsible facility official means an official authorized to transfer and receive select agents covered by this part on behalf of the transferor's and/or requestor's facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility."

### **Obtaining extra copies of the forms in this package**

One copy of each form is included in this packet. Photo copy the originals contained in this application package if additional copies are needed. This application package is also available on the internet at the CDC Laboratory Registration/Select Agent Transfer program website (<http://www.cdc.gov/od/ohs/lrsat.htm>).

### **How the information in this application package will be used**

Each section of the application package is designed to obtain certain information required under 42 CFR 72.6: (1) The "Background Information/Certification and Signature" form will provide us with the information required under 42 CFR 72.6(c)(2)(i); (2) The "Information on Select Agents" forms will: (A) Help determine whether your laboratory is equipped to work safely with the select agent(s) in question, so that you may take appropriate action if necessary before applying for registration under this regulation, and; (B) Assist CDC in determining whether your laboratory meets the requirements of 42 CFR 72.6(a)(2)(ii). [ [Read and answer all questions, carefully!!](#) ]

### **Public reporting burden**

Public reporting burden of this collection of information is estimated to average 120 minutes for completion of the **Background Information/Certification and Signature, Information about Select Agents facility intends to work with or transfer** forms, including the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

CDC/ATSDR Reports  
Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0199)  
OMB Control Number 0920-0199  
Forms approved  
Expiration date 6/30/03

## LR/SAT Application for Laboratory Registration- Section 2

### Background Information/Certification and Signature

Name of facility Mt. Sinai School of Medicine  
Address One Gustave L. Levy Place  
Address Box 1155  
City New York State New York Zip 10029

Name of designated Responsible Facility Official (RFO): **Philip G. Hauck, MS, MSHS, CIH, SM(NRM)**  
Title of Responsible Facility Official (e.g., biosafety officer): Institutional Biosafety Officer  
Address: Same  
Address  
City State Zip  
Telephone: 212 241-1451  
FAX 212 241-5550  
E-mail [philip.hauck@mssm.edu](mailto:philip.hauck@mssm.edu) Website: [www.mssm.edu/biosafety](http://www.mssm.edu/biosafety)

Name of alternate Responsible Facility Official: Jane Tsambis  
Address : 1425 Madison Avenue (East Bldg.) New York, New York 10029 (or Box 1079, address above)  
Telephone: 212 659-8970  
FAX 212 876-6789  
E-mail [jane.tsambis@mssm.edu](mailto:jane.tsambis@mssm.edu)

**Mark an "x" in the ( ) to the left of each select agent for which your facility wishes to register its laboratories** (If you are registering only for inactivated agents or genomic materials please indicate this next to the appropriate agent).

#### Viruses

- Crimean-Congo haemorrhagic fever virus
- Eastern Equine Encephalitis virus
- Ebola viruses
- Equine Morbillivirus (Hendra virus)
- Lassa fever virus
- Marburg virus
- Rift Valley fever virus
- South American haemorrhagic fever viruses
- Junin
- Machupo
- Sabia
- Flexal
- Guanarito
- Tick-borne encephalitis complex viruses
- Variola major virus (Smallpox virus)
- Venezuelan Equine Encephalitis virus
- Viruses causing hantavirus pulmonary syndrome
- Yellow fever virus

#### Bacteria

- Bacillus anthracis*
- Brucella abortus*, *B. melitensis*, *B. suis*
- Burkholderia (Pseudomonas) mallei*
- Burkholderia (Pseudomonas) pseudomallei*
- Clostridium botulinum*

- Francisella tularensis*
- Yersinia pestis*

#### Rickettsiae

- Coxiella burnetii*
- Rickettsia prowazekii*
- Rickettsia rickettsii*

#### Fungi

- Coccidioides immitis*

#### Toxins

- Abrin
- Aflatoxins
- Botulinum toxins
- Clostridium perfringens* epsilon toxin
- Conotoxins
- Diacetoxyscirpenol
- Ricin
- Saxitoxin
- Shigatoxin
- Staphylococcal enterotoxins
- Tetrodotoxin
- T-2 toxin

#### Recombinant organisms/molecules

- Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.

- Genetically modified microorganisms or genetic elements that contain nucleic acid sequences

## Certification and Signature

I hereby certify that I have been designated as the **Responsible Facility Official** for the institution/organization listed above, that I am authorized to bind the institution/organization, and that the information supplied in this registration package is to the best of my knowledge accurate and truthful. The institution/organization listed above meets the requirements specified in 42 CFR 72.6 (a)(5), is equipped and capable of safely handling the agent(s), and will use/transfer these agents solely for purposes authorized by 42 CFR 72.6. I understand that a false statement on any part of this agreement or failure to comply with the provisions of 42 CFR 72.6 will result in immediate revocation of this institution's/organization's registration as described in 42 C FR 72 .6(a)(4) and could result in a fine of up to \$500,000 or imprisonment for up to five years, or both for each violation (42 U.S.C. §§ 264, 271; 18 U.S.C. § 1001; 18 U.S.C. §§ 355 9, 3571).

\_\_\_\_\_  
(Signature) (Date)

### 42 CFR 72.7 - Penalties

Individuals in violation of this part are subject to a fine of no more than \$250,000 or one year in jail, or both. Violations by organizations are subject to a fine of no more than \$500,000 per event. **A false, fictitious or fraudulent statement or representation on the government forms required in the part for registration of facilities or for transfers of select agents is subject to a fine or imprisonment for not more than five years, or both for an individual; and a fine for an organization.**

**Send completed application package to:** Centers for Disease Control and Prevention, Office of Health and Safety, Laboratory Registration/Select Agent Transfer Program, 1600 Clifton Road, NE., Mail Stop A13, Atlanta, GA 30333

**Contact the Mount Sinai School of Medicine Institutional Biosafety Officer before forwarding these forms to the CDC for a formal inspection of the indicated laboratory (ies).**

## LR/SAT Program/Application for Laboratory Registration - Section 3 Information about Select Agents facility intends to work with or transfer

### Section 3A: To be completed by all applicants

All applicants must complete the Table on page 3-2\*\*. For each of the select agents you plan to use, list the following information on a separate line: the select agent(s); the characteristics of each select agent you plan to use (e.g., viable, nonviable, purified genomic, recombinant material, use in small or large animals, or large scale), the building and room number(s) where select agent(s) will be worked with and stored; and, the facility risk assessment based on the requirements for the type of activities done in each of the rooms.

**Example 1.** A facility needs to register one principal investigator: Dr. Jane Doe will be working with viable *Bacillus anthracis* in Bldg A, Room 2 at BSL-2; genetic elements from *Bacillus anthracis* in Bldg A, Room 5 at BSL2, and *Bacillus anthracis* in small mammals in Bldg B, Room 200 at ABSL2.

Storage of the agents will be in the same locations where the work will be done.

\*\***Review example and Complete the form available at:** <http://www.cdc.gov/od/ohs/lrsat.htm> and <http://www.cdc.gov/od/ohs/pdffiles/4thApplication.pdf>

## Descriptions of laboratories and procedures for work with select agents at your Facility

Provide the following information on a **separate sheet** for each principal investigator (PI). Lack of sufficient detail will result in a delay processing your application at the CDC.

## Section 3B: To be completed by all applicants

[Failure to provide any information *will delay your application!*]

1. State the name of the individual responsible for the laboratory (e.g., principal investigator or laboratory supervisor). Include a current resume or Curriculum Vitae from the principal investigators for our files. **[ include a list of all personnel that will work with Select Agents and / or Toxins ]**
2. 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.
3. 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. [ contact the BioSafety Officer for plans ]**
4. 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 system s). 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).
5. 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 B 2**). 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. **[Contact the MSSM Biosafety Officer for assistance]**
6. 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.
7. 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?) **[Required under 42 CFR Part 73 – must be answered]**
  - (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. **[Required under 42 CFR Part 73 – must be answered]**
  - (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? **[Required under 42 CFR Part 73 – must be answered]**
  - (C) Is the laboratory secured when no one is present during regular working hours? **[Required under 42 CFR Part 73 – must be answered]**

## Section 3C: To be completed by applicants working with infectious select agents

8. Does an Institutional Biosafety Committee (IBC) review and approve protocols prior to working with select agents at this facility? If yes, then has the IBC approved the work proposed in this application?

9. Is the facility inspected by USDA, FDA, CLIA, DoE, DoD or others? If yes, then give date of last inspection(s).

10. 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.

### **Section 3D: To be completed by applicants working with select agent genomic DNA or nonviable organisms**

11. We strongly recommend that your facility request written verification that material has been rendered nonviable from each of the facilities for which you receive select agent DNA or nonviable organisms. These recommendations are made in the interest of the health and safety of the laboratorians in your facility that will be working with the select agent material, and 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.

### **Section 3E: To be completed by applicants working with recombinant DNA**

12. Give an estimate of the range in length (in bp's) of the recombinant select agent DNA material and what it encodes for.

13. What type of host-vector system(s) will be used?

### **Section 3F: To be completed by applicants working with small animals (ABSL2 – ABSL4)**

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

15. 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.

16. Does the facility require that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols 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? **[Yes; ( give date of approval by MSSM IACUC]**

17. Is the laboratory space described in this application AAALAC accredited? If yes, when was the date of the last inspection for these rooms?

### **Section 3G: To be completed by applicants working with select agent toxins**

18. 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.

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

20. 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?

21. 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.

### **Additional Information:**

Contact the **Mt. Sinai Institutional BioSafety Officer** at **241-1451** for assistance in filling out the forms and replying to the specific questions. Certain plans and documentation can be provided to you by the Institutional Biosafety Officer in order to complete the forms. For select agents that are being imported, you will have to obtain permits before bringing any material into the U.S. If exporting materials, a License issued by the Department of Commerce is required for several classes of biomedical material considered “dual use” by the Government.

In all of your submissions to the CDC **be accurate and concise**. Information that you include **will be used as the basis** of questions and items or points to inspect during the CDC LR/SAT site inspection **(the CDC conducts the follow-up inspections)**. If you say that you do a particular activity, have proof in the way of documentation or a **written agent- specific standard operating procedure** that can be produced on request of the inspectors to corroborate these statements. If a written log for agents / toxins, permit or license is required, have copies on hand to produce upon request. **[Required under 42 CFR Part 73 – there must be logs for toxins, and logs showing arrival, use and final disposal for Select Agents and toxins]**

## Attachment #5

# BSL RECOMMENDATIONS FOR SELECT AGENTS – Supplement to CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, 4th ed. (BMBL)

Summary of biosafety level (BSL) recommendations for Select Agent bacteria, viruses, rickettsiae and fungi listed in Appendix A to Part 72\*

Select Agent	Clinical Specimens (diagnostics)	Biosafety Level Propagation	Animal Work
<b>Viruses</b>			
Crimean-Congo hemorrhagic fever virus	4	4	4
Eastern Equine Encephalitis virus	2	2-3	3
Ebola viruses	4	4	4
Equine Morbillivirus (Hendra virus)	3-4	4	4
Lassa fever	4	4	4
Marburg virus	4	4	4
Rift Valley fever virus <sup>a</sup>	3 & HEPA <sup>b</sup>	3 & HEPA	3 & HEPA
South American hemorrhagic fever viruses			
Junin <sup>c</sup>	4	4	4
Machupo	4	4	4
Sabia	4	4	4
Flexal	3	3	3
Guanarito	4	4	4
Tick-borne encephalitis complex viruses			
Absettarov <sup>d</sup>	4	4	4
Hanzalova <sup>d</sup>	4	4	4
Hypr <sup>d</sup>	4	4	4
Kumlinge <sup>d</sup>	4	4	4
Kyasanur Forest disease	4	4	4
Omsk hemorrhagic fever	4	4	4
Russian Spring-Summer encephalitis	4	4	4
Venezuelan Equine Encephalitis virus	3 & HEPA	3 & HEPA	3 & HEPA
Variola major virus (Smallpox virus)	4	4	4
Viruses causing hantavirus pulmonary syndrome	3	3-4	3-4
Yellow fever virus	3 & HEPA	3 & HEPA	3 & HEPA
<b>Bacteria</b>			
<i>Bacillus anthracis</i>	2	2-3	2-3
<i>Brucella abortus</i> , <i>B. melitensis</i> , <i>B. suis</i>	2	3	3
<i>Burkholderia (Pseudomonas) mallei</i>	2	2-3	3
<i>Burkholderia (Pseudomonas) pseudomallei</i>	2	2-3	3
<i>Clostridium botulinum</i>	2	2-3	2-3
<i>Francisella tularensis</i>	2	3	3
<i>Yersinia pestis</i>	2	2-3	2-3
<b>Rickettsiae</b>			
<i>Coxiella burnetii</i>	2	3	3
<i>Rickettsia prowazekii</i>	2	3	2-3
<i>Rickettsia rickettsii</i>	2	3	2-3
<b>Fungi</b>			
<i>Coccidioides immitis</i>	2	3	2-3

suppl\_4ed\_Final0.wpd Rev: 18 Mar 2001

\*Note that BSLs listed are agent specific, and actual safety levels used should be based on individual laboratory risk assessments and procedures performed. If available, licensed vaccines, Investigational New Drugs (IND), or toxoids are recommended when working with certain select agents; <sup>a</sup>Vaccine strains of some viruses may be handled at lower BSLs; <sup>b</sup>HEPA = Hepa filtered exhaust; <sup>c</sup>The Subcommittee on Arbovirus Laboratory Safety (SALS) has lowered the biohazard classification of Junin virus to BSL-3, provided that all at-risk personnel are immunized and the laboratory is equipped with HEPA-filtered exhaust; <sup>d</sup>The Subcommittee on Arbovirus Laboratory Safety (SALS) has reclassified the group of Central European Tick-borne encephalitis (CETBE) viruses (presently consisting of Absettarov, Hanzalova, Hypr, and Kumlinge) to BSL-3 when personnel handling these or antigenically similar viruses are immunized with CETBE vaccine. Russian Spring-Summer encephalitis (RSSE) and antigenically related viruses should be handled at BSL-4.

**Pgh: 11/2002 (rev.1.2003)**