UNIVERSITY OF TOLEDO
SELECT AGENT REGISTRATION FORM (SARF)

INSTRUCTIONS

Principal investigators (PI's) must register the possession and transfer of ALL Select Agents with the UT Safety & Health Department, even if they are excluded or exempt from FEDERAL REGULATION (http://www.cdc.gov/od/sap/).

SELECT AGENTS (http://www.cdc.gov/od/sap/docs/salist.pdf) include certain microorganisms and biological toxins listed as such by the DHHS (CDC) and/or USDA (APHIS).

Exemptions/Exclusions from Federal Regulation:

1. The medical use of toxins for patient treatment is exempt.

2. The following select agent toxins are exempt if the aggregate amount under the control of one principal investigator does not, at any time, exceed:
   - 0.5 mg of Botulinum neurotoxins
   - 5 mg of Staphylococcal enterotoxins
   - 100 mg of abrin, Clostridium perfringens epsilon toxin, conotoxin, ricin, saxitoxin, shigatoxin, shiga-like ribosome inactivating protein, and tetrodotoxin
   - 1,000 mg of diacetoxyscirpenol and T-2 toxin

3. The following select agent organisms or toxins are also exempt:
   - Any agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
   - Non-viable select agent organisms or nonfunctional toxins.
   - The vaccine strains of Junin virus (Candid #1), Rift Valley fever virus (MP-12), Venezuelan Equine encephalitis virus vaccine strain TC-83.

4. Additional exclusions to these regulations are available at the websites for the CDC (www.cdc.gov) and APHIS (www.aphis.usda.gov).

A copy of this completed Form and a copy of Complying with the USA Patriot Act of 2001 (http://www.ehrs.upenn.edu/resources/docs/patriotact.pdf) must be given to all laboratory personnel to read. Each lab member must read the summary and the completed Form, and must sign Section 8 confirming that they are aware of the hazards present in the work area and that they are aware of and in compliance with the requirements of the Public Health Security and Bioterrorism Preparedness Response Act of 2002 (http://www.fda.gov/oc/bioterrorism/bioact.html).

Email an electronic copy of the completed form to: michael.valigosky@utoledo.edu. Forward the original SIGNED form to Mike Valigosky at Safety & Health, MLB Rm. 011, MS #1078. Keep a copy of the SIGNED form for your records.

If you have any questions regarding the completion of this form or the regulations mentioned above please contact Mike Valigosky at Michael.Valigosky@utoledo.edu, or at 419.383.4521.

CONTINUE TO THE FOLLOWING PAGE TO COMPLETE THE 3-PAGE SARF FORM.
SELECT AGENT REGISTRATION FORM (SARF)

DATE: (mm/dd/yyyy) ____

PRINCIPAL INVESTIGATOR:

Last Name: _____  First Name: _____  Middle Initial: ______
School: _______  Department: _____  Section/Division: ______
Position Title: _______  e-mail: _______
Lab Locations (Give buildings and room #s): ______

LAB MANAGER:

Last Name: _______  First Name: ______
Phone: 111-111-1111  e-mail: _______

1. Do you use or store any Select Agent organisms or toxins in your laboratory?  □ No  □ Yes If Yes, specify below.

A. Microorganisms/Infectious Agents

<table>
<thead>
<tr>
<th>Agent (Genus &amp; Species)</th>
<th>Strain</th>
<th>Recombinant</th>
<th>Exempt</th>
<th>Excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

1) If you possess exempt or excluded select biological agents indicate by checking below if you are complying with the requirements listed:
   a. Develop a written SOP specific for the biological agent work that occurs in your laboratory, including compliance with the appropriate biosafety level requirements for the agent(s) you possess. Complete descriptions of all of the biosafety levels are available at http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm
      □ No □ Yes
   b. Secure a BIOHAZARD ROOM SIGN. Request through Michael.Valigosky@utoledo.edu.
      □ No □ Yes
   c. Email Michael.Valigosky@utoledo.edu to request BIOHAZARD STICKERS for use on equipment where biological agents are used or stored.
      □ No □ Yes

2) Do you possess or use a biofermenter?  □ No  □ Yes, indicate capacity in liters:

B. Biological Toxins

<table>
<thead>
<tr>
<th>Toxin Name</th>
<th>Amount (mg)</th>
<th>Supplier</th>
<th>Exempt</th>
<th>Excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

1) If you possess exempt quantities of select agent toxins, indicate by checking below if you are complying with the requirements listed:
      □ No □ Yes
   b. Establish a log book to track toxin use.
      □ No □ Yes
   c. Secure a ROOM SIGN REQUEST through Michael.Valigosky@utoledo.edu.
      □ No □ Yes
   d. Use TAPE to demarcate areas where you use toxins (acutely toxic materials).
      □ No □ Yes (Email Mike.Valigosky@utoledo.edu to request a roll of “Designated Area” tape.)

2. If the Select Agents you have specified are excluded or exempt from registration with the CDC and/or APHIS, explain why:
3. If the Select Agents you have specified are NOT excluded or exempt from registration, provide the CDC and/or APHIS registration # or contact Mike Valigosky at Michael.Valigosky@utoledo.edu to initiate the registration process.

   A. Do you have a reasonable justification for the type and quantity of Biological Agents, Toxins and Delivery Systems you possess?  □ No  □ Yes
      If you answered “No”, please specify the type and quantity of Biological Agents, Toxins and Delivery Systems:
   B. It is your responsibility to ensure that Restricted Persons (http://www.ehrs.upenn.edu/protocols/patriot/restricted.html) and/or unauthorized persons do not possess, ship, transport, receive or otherwise have access to any Select Agents in your laboratory.
      Do you ensure this to be true for you and your laboratory members?  □ No  □ Yes

      The responsibilities stated above may not be shifted to unauthorized personnel.

5. Describe how and where you secure your non-exempt, non-excluded Select Agents.
   At a minimum indicate:
   A. How access to Select Agents is controlled so that restricted persons and/or unauthorized persons do not have access to them.
   B. How stored Select Agents are secured (locked). Stock vials must be stored in locked containers. The containers must be kept locked at all times. Locked boxes must be secured to the refrigerator/freezer/cabinet.
   C. How Select Agents not in storage are controlled and maintained under constant surveillance.
   D. The specific locations where Select Agents are stored and used.
   E. Any other pertinent information.

6. Disinfection/Destruction
   A NOTIFICATION OF THE PROPOSED DESTRUCTION OF SELECT AGENTS FORM may be found at Destruction of Select Agents Form. Federal law requires that the CDC must be notified five (5) working days in advance of the destruction of select agent organisms or toxins. Do not destroy any Select Agent without prior approval from Mike Valigosky (Michael.Valigosky@utoledo.edu).
   A. Location of autoclave used by laboratory personnel:
      Building:_____  Room:______
   B. Type of disinfectant used in your laboratory room(s): _____
   C. Disposal method if material cannot be rendered non-hazardous by autoclaving or disinfecting: _____

7. Security Risk Assessment
   As part of the CDC/APHIS Select Agent registration process, it is your responsibility to ensure that a Security Risk Assessment has been completed for individuals who have access to Select Agents. Security Risk Assessments are NOT required for individuals who have access to exempt or excluded materials. To initiate the assessment process, contact Michael.Valigosky@utoledo.edu.

8. Laboratory Personnel
   Provide the requested information for all laboratory personnel who have the potential to come in contact with any of the above materials.
All Lab Personnel: By signing here, you warrant that:

1) you have read and understood this SELECT AGENT Registration Form and the summary, Complying With The USA PATRIOT Act (http://www.ehrs.upenn.edu/resources/docs/patriotact.pdf),

2) you are aware of the hazards present in the work area, and

3) you are aware of and are in compliance with the requirements of the Public Health Security and Bioterrorism Preparedness Response Act of 2002 (http://thomas.loc.gov/cgi-bin/query/z?c107:H.R.3448.ENR).

<table>
<thead>
<tr>
<th>Last Name (PRINT)</th>
<th>First Name (PRINT)</th>
<th>8 digit PENN ID #</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I acknowledge that the above information is complete.

I understand that I accept responsibility for the safe conduct of work with these agents under appropriate containment. I have informed all personnel who have potential exposure to the agents of the safety practices that must be followed.

Name (typed or printed) ______________________________ Date __________________________

Signature

