12.0 NOTIFICATION OF USE FOR BIOLOGICAL AGENTS AND RECOMBINANT DNA

12.1 INTRODUCTION

A Notification of Use for Biological Agents must be submitted to the UTMB Biological Safety Committee and Recombinant DNA (rNOU) form must be submitted to the UTMB Institutional BioSafety Committee for review and approval when the project meets the following criteria:

**Biological Agents:** An NOU must be completed and submitted for all risk group 2 and above pathogens and all human products, human tissues and human cell lines.

**Recombinant & Synthetic DNA:** An rNOU must be completed and submitted for all rDNA Class 1 and above. When genes are propagated in living cells, submission of an NOU for a biological agent and for the rDNA is required.

**Select Agents:** Select Agent use requires that an NOU be completed for the biological agent and rDNA. Select agent users must comply with regulations issued by the Health and Human Services, Centers for Disease Control and Prevention and the U. S. Department of Agriculture.

12.2 Select Agent Use

Specific steps for compliance are as follows:

- Before submitting the Form 961 and fingerprint cards for new staff to the FBI, the University must notify the CDC Select Agent Program of the change to the University’s registration. Security Risk Assessments
- (Form 961) cannot be submitted until the University receives a unique identification number for the employee being added. Once Form 961 is submitted it may take up to 45 days for approval to be granted.
- Access to a select agent laboratory cannot be granted until the Security Risk Assessment has been completed and approval is granted by the CDC/USDA Select Agent Program.
- Laboratories handling select biological agents must meet requirements outlined in the CDC/HHS publication *Biosafety in Microbiological and Biomedical Laboratories*, current edition.
- Laboratories are subject to inspection by CDC/USDA or their designee for compliance with the regulation.
- Select agents must be destroyed or deactivated in the laboratory and documented
• Storage of select agent material requires the creation of an inventory to be kept up to date and regularly inspected by EHS. Access to the inventory needs to be secured and limited.
• Laboratories will comply with documentation and notification requirements when ordering or transferring agents.
• Laboratories will develop a Chemical Hygiene Plan and meet requirements outlined in the OSHA Lab Standard (29 CFR 1910.1450 “Occupational Exposure to Hazardous Chemical in Laboratories”) when using toxins.
• Laboratories using select agents will maintain strict security in select agent storage as well as maintaining a locked laboratory at all time. Access to those laboratories will be restricted to authorized personnel and documented.
• Clearance from the Department of Justice will be required for all select agent users; contact EHS Biological and Chemical Safety at ext 21781 for more information.
• Permits are required for transfer or transportation of select agent material.

12.3 Changes to the Select Agent Registration

Contact Environmental Health and Safety when changes to staffing (adding or deleting), lab assessments and use of select agents occurs. EHS will coordinate the notifications with the CDC/USDA Select Agent Program

12.4 Select Agent List

Agents regulated by Federal Select Agent Program

HHS Select Agents and Toxins:
- Abrin
- Botulinum neurotoxins*
- Botulinum neurotoxin producing species of Clostridium*
- Conotoxins (short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5CX_7$)’
- Coxiella burnetii
- Crimean-Congo haemorrhagic fever virus
- Diacetoxyscirpenol
- Eastern Equine Encephalitis virus
- Ebola viruses*
- Francisella tularensis*
- Lassa fever virus
- Lujo virus
- Marburg virus*
- Monkeypox virus
- Reconstructed replication competent forms of the 1918 pandemic virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
- Ricin
- Rickettsia prowazekii
- SARS-associated coronavirus (SARS-CoV)
- Saxitoxin
- South American Haemorrhagic Fever viruses:
  - Chapare
  - Guanarito
- Junin,
- Machupo,
- Sabia,
- Staphylococcal enterotoxins A, B, C, D, E subtypes
- T–2 toxin
- Tetrodotoxin
- Tick-borne encephalitis complex (flavi) viruses:
  - Far Eastern subtype
  - Siberian subtype
- Kyasanur Forest disease virus
- Omsk hemorrhagic fever virus
  - Variola major virus (Smallpox virus)*
  - Variola minor virus (Alastrim)*
  - Yersinia pestis*

**Overlap select agents and toxins:**
- *Bacillus anthracis*
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*
- *Burkholderia mallei* *
- *Burkholderia pseudomallei* *
- Hendra virus
- Nipah virus
- Rift Valley fever virus
- Venezuelan Equine Encephalitis virus

**USDA only Agents and Toxins**
- African horse sickness virus
- African swine fever virus
- Avian influenza virus (highly pathogenic)
- Classical swine fever virus
- Foot-and-mouth disease virus*
- Goat pox virus
- Lumpy skin disease virus
- *Mycoplasma capricolum*
- *Mycoplasma mycoides*
- Newcastle disease virus
- Peste des petits ruminants virus
- Rinderpest virus*
- Sheep pox virus
- Swine vesicular disease virus

**USDA Plant Protection and quarantine Select Agents and Toxins**
- *Peronosclerospora philippinensis*
- *Phoma glycicincola*
- *Ralstonia solanacearum*
- *Rathayibacter toxicus*
- *Sclerophthora rayssiae*
- *Synchytrium endobioticum*
• *Xanthomonas oryzae*

*Denotes Tier 1 Agent

Contact EHS/Biological and Chemical Safety at extension 772-1781 for additional information and assistance prior to commencement of work with a select agent.