UNIVERSITY POLICY

SUBJECT:	ADMINISTRATION	**TITLE:**	SELECT BIOLOGICAL AGENTS & TOXINS and BIOSAFETY LEVEL 3 LABORATORIES		
CODING:	00-01-10-10:00	**ADOPTED:**	07/10/02	**AMENDED:**	05/20/08
				LAST REVIEWED:	05/20/08

I. PURPOSE

The purpose of this policy is to: (a) ensure that select biological agents and toxins are handled safely and secured properly, (b) establish procedures to promote the safe operation of Biosafety Level 3 laboratories, and (c) provide a safe and secure environment for faculty, staff, students, visitors, patients, and the surrounding community.

II. ACCOUNTABILITY

Under the direction of the President, the Executive Vice President for Academic and Clinical Affairs, the Senior Vice President for Administration, and the Vice President for Research shall ensure compliance with this policy. The Executive Director of the Office of Emergency Management and Occupational Health and Safety (EMOHS), along with the Director of the Department of Environmental and Occupational Health and Safety Services (EOHSS), shall implement this policy in conjunction with the Senior Vice Presidents, Deans, Vice Presidents, Presidents/CEOs of the Healthcare Units, and Department Chairpersons.

The Executive Director of Emergency Management and Occupational Health and Safety (or equivalent) has been granted the authority to approve the use and occupancy of all University owned, operated, and/or occupied select agent and BSL-3 laboratories. Such laboratories shall not be constructed, stocked, occupied, or used without prior approval of the Executive Director. The director of Facilities Planning and Construction Department shall notify the Executive Director or designee upon commencement of design or renovation of a BSL-3 laboratory.

III. APPLICABILITY

The policy applies to University faculty, staff, students, and/or any individual who wish to receive, possess, utilize, transfer, or otherwise have access to select agents and toxins in University owned, operated, and/or occupied facilities. This policy also applies to University faculty, staff, students, and/or any individual who wish to work in a University owned, operated, and/or occupied Biosafety Level 3 (BSL-3) laboratory for any reason and for any length of time.

VI. REFERENCES

A. Possession, Use, and Transfer of Select Agents and Toxins; Final Rule: 42 CFR Parts 72 and 73

B. Agricultural Bioterrorism Protection Act of 2002: 7 CFR Part 331

C. Possession, Use, and Transfer of Select Agents and Toxins; Final Rule: 9 CFR Part 121

D. USA Patriot Act of 2001: Public Law 107-56

E. New Jersey Emergency Health Powers Act: P.L. 2005 c. 222

F. UMDNJ Laboratory Safety Plan

G. Biosafety in Microbiological and Biomedical Laboratories (BMBL), CDC

VI. POLICY

The University will comply with all requirements of the regulation entitled "Possession, Use, and Transfer of Select Agents and Toxins: Final Rule" (42 CFR parts 72 and 73, 7 CFR Part 331, and 9 CFR Part 121) as promulgated by the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA), as well as all other applicable laws and regulations relating to select biological agents and toxins and Biosafety Level 3 laboratories. The term "select agents and toxins," for the purposes of this policy, means those items defined and listed in 42 CFR 73.3, 73.4; 7 CFR 331.1; and/or 9 CFR 121.3, 121.4.

A. Additional Requirements:

1. Each school/unit acquiring, possessing, utilizing, transferring, or otherwise having access to select agents and toxins shall comply with the Select Biological Agents and Toxins Compliance Program document that appears in EXHIBIT A of this policy.

2. Select agent research shall be conducted at a reasonably minimum number of locations. Resources dedicated to safety, security, and compliance can thus be focused on creating a maximally compliant facility where multiple users can conduct select agent experiments.

3. Each school/unit acquiring, possessing, utilizing, transferring, or otherwise having access to select agents and toxins shall designate two (2) individuals to be the Responsible and Alternate Responsible Officials. The Alternate Responsible Official shall be the individual authorized to act for the Responsible Official in his/her absence. The Alternate Responsible Official must meet all the qualifications for a Responsible Official.

4. The Responsible and Alternate Responsible Officials must not be individuals actually using, working with, or transferring or receiving select agents or toxins.

B. Responsibilities:

The Responsible Official must:

1. Successfully complete a security risk assessment by the U.S. Department of Justice (DOJ) and be approved for access to biological agents and toxins by the Centers for Disease Control and Prevention (CDC)/Department of Health and Human Services (DHHS). The Responsible Official must also meet all the requirements of this policy for access.

2. Be familiar with the requirements of applicable select agent regulations and UMDNJ relevant policies.

3. Have the authority and responsibility to act on behalf of the school/unit.

4. Ensure compliance with select agent regulations and UMDNJ policies.

5. Review the safety, security and emergency response plans for select agent laboratories under their supervision on an annual basis after any incident or "near miss" incident, as well as in after exercises conducted to test those plans.

6. Ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with applicable regulations and UMDNJ policies.

7. Ensure that the results of annual inspections are appropriately documented and any identified deficiencies are corrected.

8. Have a defined and direct report structure to a senior University administrator, such as the Executive Director for Emergency Management and Occupational Health and Safety (or equivalent)

C. Enforcement:

1. Each school/unit owning, operating, and/or occupying a BSL-3 laboratory facility, as defined in the CDC publication entitled "Biosafety in Microbiological and Biomedical Laboratories" (BMBL) shall comply with the Biosafety Level 3 Laboratory Compliance Program that appears in EXHIBIT B of this policy.

2. Each CDC/USDA-registered select agent laboratory and BSL-3 laboratory approved by the UMDNJ Executive Director for Emergency Management and Occupational Health and Safety (or equivalent) shall have a clearly identified facility director and facility manager. It is strongly recommended that the facility director and facility manager be two different individuals. The facility director shall be responsible for long term strategies, budgeting, fund-raising, as well as assisting with policy decisions relating to laboratory safety, security, and emergency response. The facility manager shall be responsible for day-to-day operations, maintenance, and management; ensuring compliance with existing safety, security and emergency response plans; and interfacing with the Responsible Official (and Biosafety Officer(s), as appropriate) to implement new compliance initiatives and monitor compliance with the regulations cited above.

3. The Responsible Official(s) (and Biosafety Officer(s), as appropriate) shall work with BSL-3 and select agent directors and managers to create consistency across all safety, security, and emergency response plans and procedures.

4. To ensure University-wide consistency of policy and operation between various select agent and BSL-3 facilities, the Responsible Officials or Alternate Responsible Officials shall report to a senior University administrator such as the Executive Director for Emergency Management and Occupational Health and Safety (or equivalent). This individual shall be the decision maker regarding uniformity in select agent and BSL-3 policymaking and enforcement. The Executive Director for Emergency Management and Occupational Health and Safety shall review existing policies, procedures, and records and provide for a University-wide format for documentation. In evaluating BSL-3 and select agent policies, the Executive Director for Emergency Management and Occupational Health and Safety will consider comments from EOHSS, Public Safety, Responsible Officials, Alternate Responsible Officials, Research Deans, Facility Directors, Facility Managers, Physical Plant, Facilities Planning and Construction, and others as necessary. The Responsible Officials and Alternate Responsible Officials will also consult with and accept technical assistance from the Department of Environmental & Occupational Health & Safety Services on all safety, emergency response, and regulatory compliance considerations.

5. All incidents and "near-miss" incidents must be immediately reported to the Executive Director of Emergency Management and Occupational Health and Safety and the Responsible Official/Alternate Responsible Official (for incidents/near-miss incidents involving select agents), in addition to any other relevant and/or required individuals and UMDNJ organizations, such as the Biosafety Officer, Public Safety, EOHSS, Risk and Claims, Dean's Office, etc. Any condition/situation that results in or has the potential to cause serious consequences (e.g., injury/illness, security breach, property damage, loss of material, exposure to infectious agents, etc.) shall be considered an incident, and therefore subject to immediate reporting. "Near-miss" incidents also have the potential to

result in serious consequences, however prior to any adverse event occurring, the situation is mitigated; nevertheless, such incidents also must be immediately reported in the same fashion as incidents. Examples of "near-miss" incidents include, but are not limited to, non-compliance with established procedures/work practices, communications breakdowns, redundant safety system failure, and technology malfunctions.

6. Each select agent and BSL-3 facility shall create and maintain a Risk Assessment Committee. Using the risk assessment guidance set out in the Centers for Disease Control and Prevention (CDC) Biosafety in Microbiological and Biomedical Laboratories (BMBL) publication, this committee will verify that risk has been minimized wherever possible and that documentation prepared by each facility has considered all of the necessary factors when preparing their facility specific plans and policies. This committee shall be responsible for reviewing policies, procedures and detailed experimental standard operating procedures (SOPs) for safety, security, and emergency response considerations for their facility. The committee shall consist of the school Associate Dean for Research (or equivalent) or designee, facility director, facility manager, Responsible Official (and/or Biosafety Officer, as appropriate), a representative from the Department of EOHSS, a user representative, and others as necessary. The committee can be convened at the request of any member. Also, a Risk Assessment Committee may oversee more than one select agent or BSL-3 facility, however the scope of review for each Committee must be clearly defined. The Risk Assessment Committee function may be carried out by an existing campus Institutional Biosafety Committee, so long as the complete intent of the Risk Assessment Committee is met.

VI. Sanction

Noncompliance with any component of this policy will result in immediate removal of access to select agents and/or the BSL-3 laboratory. The Vice President for Research and the Associate Deans for Research (or equivalent) may implement additional sanctions for non-compliance. Federal law also provides that in the case of violations of the law, individuals are subject to federal criminal and civil penalties, including prison and fines.

VI. EXHIBITS

A. SELECT BIOLOGICAL AGENTS AND TOXINS COMPLIANCE PROGRAM

B. BIOSAFETY LEVEL 3 (BSL-3) LABORATORY COMPLIANCE PROGRAM

By Direction of the President:

_____

Executive Vice President for Academic and Clinical Affairs

EXHIBIT A

SELECT BIOLOGICAL AGENTS AND TOXINS COMPLIANCE PROGRAM

1. DEFINITIONS

A. Alternate Responsible Official – the designated individual who may act for the Responsible Official in his/her absence. The Alternate Responsible Official must have the authority and control to ensure compliance with the select biological agent and toxin regulations and UMDNJ policies when acting as the Responsible Official.

B. Responsible Official – the designated individual with the authority and control to ensure compliance with the UMDNJ policies and "Possession, Use, and Transfer of Select Agents and Toxins: Final Rule" (42 CFR parts 72 and 73, 7 CFR Part 331, and 9 CFR Part 121) as promulgated by the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA).

C. Restricted Person – is defined by the USA Patriot Act of 2001 as an individual who:

i. is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;

ii. has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;

iii. is a fugitive from justice;

iv. is an unlawful user of any controlled substance;

v. is an alien illegally or unlawfully in the United States;

vi. has been adjudicated as a mental defective or has been committed to any mental institution;

vii. is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State has made a determination (that remains in effect) that such country (as of the date of this policy Iran, Syria, Libya, Cuba, North Korea, and Sudan have been identified) has repeatedly provided support for acts of international terrorism; or

viii. has been discharged from the Armed Services of the United States under dishonorable conditions.

D. Select Biological Agent or Toxin - unless otherwise specified, means all of the biological agents listed in 42 CFR 73.3, 73.4, 7 CFR 331.3, 9 CFR 121.3, or 121.4. As of the date of this policy, the list included in this policy (Table 1) shows the agents which are currently considered to be select biological agents or toxins. As described by the above referenced CDC and USDA regulations, select biological toxins are regulated only above certain threshold levels (Table 2). Quantities of select biological toxins below the thresholds are not regulated by CDC or USDA but must still comply with the applicable sections of this policy.

Modifications made to federal list of select biological agent and toxin will be incorporated into this policy by default.

EXHIBIT A (continued)

TABLE 1 Select Biological Agents and Toxins (42 CFR 73.3, 73.4; 7 CFR 331.3; 9 CFR 121.3, 121.4)		
Viruses	**Viruses (continued)**	**Fungi**
Akabane virus	Swine vesicular disease virus	*Coccidioides immitis*
African swine fever virus	Tick-borne encephalitis complex (flavi) viruses	*Coccidioides posadasii*
African horse sickness virus	Central European tick-borne encephalitis	
Avian influenza virus (highly pathogenic)	Far Eastern tick-borne encephalitis	**Toxins**
Blue tongue virus (exotic)	Russian Spring and Summer encephalitis	Abrin
Bovine spongiform encephalopathy agent	Reconstructed 1918 influenza virus	Botulinum neurotoxins
Camel pox virus	Kyasanur Forest disease	Conotoxins
Classical swine fever virus	Omsk Hemorrhagic fever	*Clostridium perfringens* epsilon toxin
Crimean-Congo hemorrhagic fever virus	Variola major virus (Smallpox virus)	Diacetoxyscirpenol
Eastern Equine Encephalitis virus	Variola minor virus (Alastrim)	Ricin
Ebola viruses	Venezuelan Equine Encephalitis virus	Saxitoxin
Foot and mouth disease virus	Vesicular stomatitis virus (exotic)	Shigatoxin
Goat pox virus		Shiga-like ribosome inactivating proteins
Cercopithecine herpesvirus 1 (Herpes B virus)		Staphylococcal enterotoxins
Japanese encephalitis virus	**Bacteria**	T-2 toxin
Lassa fever virus	*Bacillus anthracis*	Tetrodotoxin
Lumpy skin disease virus	*Brucella abortus*	
Malignant catarrhal fever virus (exotic)	*Brucella melitensis*	
Marburg virus	*Brucella suis*	**Plant Pathogens**
Menangle virus	*Burkholderia mallei (*formerly *Pseudomonas mallei)*	*Liberobacter africanus*
Monkeypox virus	*Burkholderia pseudomallei*	*Liberobacter asiaticus*
Newcastle disease virus (VVND)	Botulinum neurotoxin producing species of *Clostridium*	*Peronosclerospora philippinensis*
Nipah and Hendra complex viruses	*Cowdria ruminantium* (Heartwater)	*Phakopsora pachyrhizi*
Peste Des Petits Ruminants virus	*Coxiella burnetti*	Plum Pox Potyvirus
Rift Valley fever virus	*Francisella tularensis*	*Ralstonia solanacearum* race 3, biovar 2
Rinderpest virus	*Mycoplasma capricolum*/ M.F38/*M. mycoides capri*	*Schlerophthora rayssiae* var *zeae*
Sheep pox virus	*Mycoplasma mycoides mycoides*	*Synchytrium endobioticum*
South American Hemorrhagic fever viruses	*Rickettsia prowazekii*	*Xanthomonas oryzae*
Junin	*Rickettsia rickettsii*	*Xylella fastidiosa* (citrus variegated chlorosis strain)
Machupo	*Yersinia pestis*	
Sabia		
Flexal		
Guanarito		

TABLE 2 Maximum Select Biological Toxin Amounts Excluded from Regulation	
HHS Toxins	**Amount**
Abrin	100 mg
Conotoxin	100 mg
Diacetoxyscirpenol (DAS)	1000 mg
Ricin	100 mg
Saxitoxin	100 mg
Shiga-like ribosome inactivating proteins	100 mg
Tetrodotoxin	100 mg
Overlap Toxins	
Botulinum neurotoxins	0.5 mg
Staphylococcal enterotoxins	5.0 mg
Clostridium perfringens epsilon toxin	100 mg
Shigatoxin	100 mg
T-2 toxin	1000 mg

EXHIBIT A (continued)

2. APPROVALS REQUIRED FOR RESEARCH WITH SELECT BIOLOGICAL AGENTS AND TOXINS

Scientifically based justifications for the use of select biological agents or toxins shall be required from researchers. Various levels of review will be required based on the type of manipulations planned with the select biological agent or toxin. Any required approvals from the Centers for Disease Control and Prevention (CDC), United States Department of Agriculture (USDA), UMDNJ Department of Environmental and Occupational Health and Safety Services (EOHSS), UMDNJ Institutional Biosafety Committee (IBC), UMDNJ Institutional Animal Care and Use Committee (IACUC), and other research committees as described below must be acquired prior to obtaining the select biological agent or toxins.

A. Use of select biological agent organisms in the laboratory will require approval of the CDC/USDA and the applicable campus UMDNJ IBC.

B. Use of regulated quantities of select biological toxins in the laboratory will require approval of the CDC/USDA and EOHSS.

C. Use of select biological agent organisms in animal models will require approval of the CDC/USDA, the applicable campus UMDNJ IBC and the applicable campus UMDNJ IACUC.

D. Use of select biological agent organism genetic elements or cell extracts will require approval of the UMDNJ IBC and EOHSS. This shall include materials that may be exempt from CDC and/or USDA regulatory oversight.

E. Use of regulated quantities of select biological toxins in animal models will require approval of the CDC/USDA, EOHSS and the applicable UMDNJ IACUC.

F. Use of select biological toxins below the regulatory threshold will require approval of EOHSS.

Researchers at UMDNJ must begin the appropriate approval process by notifying the intent to obtain select biological agents or toxins with the Executive Director of Emergency Management and Occupational Health and Safety (or equivalent). Once the researcher has received approval from the Executive Director, the researchers must contact the Responsible Official and EOHSS to register the researcher's intent to obtain select biological agents or toxins. To register, the registration form, accessible at the website of the Department of Environmental & Occupational Health & Safety Services (EOHSS) should be completed. In Newark or Scotch Plains, the registration form can be accessed at: http://www2.umdnj.edu/eohssweb/nsp/nsp_registry.htm. In Piscataway, New Brunswick, Camden or Stratford, the registration form can be accessed at http://www2.umdnj.edu/eohssweb/pisc/pisc_registry.htm.

Prior to being approved to use select biological agents or toxins, any person who will have unrestricted access to the agents or toxins must attest that they are not a restricted person as defined in section 1 (Definitions) of this document and must successfully complete a U.S. Department of Justice (DOJ) background check. Individuals who are identified as restricted persons or who do not successfully complete the DOJ background check will be denied access to select biological agents and toxins.

3. GENERAL PROCEDURES

A. Procedures for Possession, Use or Storage of Regulated Select Biological Agents or Toxins

i. Researchers are required to report possession of any select agents or toxins to the Executive Director for Emergency Management and Occupational Health and Safety, EOHSS, and the Responsible Official. Irrespective of quantity, researchers are required to contact the Executive Director for Emergency Management and Occupational Health and Safety (EMOHS), EOHSS, and the Responsible Official before acquiring any select agents or toxins.

EXHIBIT A (continued)

ii. Once notified of an intention to obtain select biological agents or toxins, the Executive Director for EMOHS will contact the appropriate Dean of Research or other senior management representative for the Dean of the school/unit/department. The Dean of Research or other senior management representative must approve each new proposed acquisition of select agent or regulated toxin certifying that the requestor of the agent is officially affiliated with their facility/school/unit.

iii. Researchers are required to contact the Responsible Official, the Biosafety Officer, and EOHSS when transferring select agents or toxins inside or outside the University.

iv. Researchers are required to contact the Responsible Official, the Biosafety Officer, and EOHSS several months in advance of beginning any work with select biological agents or toxins.

v. The Responsible Official, in coordination with the Biosafety Officer and EOHSS, will assist the researcher with obtaining the required CDC or USDA approvals.

vi. Each person who will have unrestricted access to select biological agents or toxins must successfully complete the DOJ background check affirming that the individual is not a restricted person. The Responsible Official will review and approve each application for DOJ clearance. The Responsible Official will also assist researchers with their DOJ applications.

vii. Individuals who grant access to select agent facilities (by providing PIN numbers for entry, activating ID cards, providing keys, etc) must successfully complete the DOJ background check.

The researcher is required to fill out, sign, and submit the Registration Form (see item 2 above) to the Responsible Official prior to beginning research with select biological agents or toxins. The form must be reviewed and approved by Responsible Official, the appropriate Institutional Biosafety Committee, and the Department of Environmental and Occupational Health and Safety Services (EOHSS) prior to the start of research. Any other committees (e.g., IACUC) that are required to review the Registration Form must also issue approval prior to the start of research.

viii. Each individual who will be participating in the research with select biological agents or toxins must read and sign the registration form prior to beginning work.

ix. The designated Responsible Official, in coordination with the Biosafety Officer, EOHSS, Physical Plant, and Facilities Planning and Construction, must certify before receiving any new select agent or toxin that the laboratory meets standards for working with the requested agent or toxin and the receiving facility holds a currently valid registration.

x. Researchers are responsible for sending the original signed select agent Registration Form to the Responsible Official and keeping a copy for their records.

xi. The Responsible Official and the researcher (or designee) will be required to review, and update where necessary, each active select biological agent and toxin protocol on an annual basis.

xii. Each individual who will have access to select agents or toxins must be up to date on all applicable laboratory safety training requirements.

xiii. Researchers will be required to maintain a current and accurate select agent inventory as required in the relevant regulation.

EXHIBIT A (continued)

xiv. Clinical and diagnostic laboratories that collect and identify samples potentially containing select agents or toxins are required to establish procedures to report and refer isolates and samples as required by the New Jersey Department of Health and Senior Services (NJDHSS) and the CDC. These laboratories must immediately notify the Executive Director of Emergency Management and Occupational Health and Safety and the Responsible Official if samples containing select biological agents or toxins are identified. In addition, other relevant and/or required individuals and UMDNJ organizations, such as the Biosafety Officer, Public Safety, EOHSS, Dean's Office, etc. should be notified as necessary.

xv. All select agent documentation, including both paper and electronic files, must be maintained in a secure and confidential manner. This documentation must be used for official purposes only.

xvi. The Responsible Official will maintain files on all registrations and other select biological agent and toxin documents for at least three years.

B. Procedures for Possession, Use or Storage of Exempt Select Biological Agents and Toxins

i. Laboratory directors possessing, using, or storing quantities of select agent below the regulatory threshold are required to report possession of these toxins to the Executive Director for Emergency Management and Occupational Health and Safety, the Responsible Official, the Biosafety Officer, and the Department of EOHSS.

ii. Facilities using exempt strains of select biological agents are required to report possession of these toxins to the Executive Director for Emergency Management and Occupational Health and Safety, the Responsible Official, the Biosafety Officer and the Department of EOHSS.

iii. The Responsible Official or Biosafety Officer will communicate with the Principal Investigator regarding regulatory thresholds and exemptions under select agent regulations.

iv. Regardless of exemption status, laboratory directors are required to contact the Responsible Official, Biosafety Officer, and the Department of EOHSS when transferring select biological agents and toxins inside or outside the University.

v. Irrespective of exemption status, researchers are required to contact the Responsible Official, Biosafety Officer and the Department of EOHSS <u>before</u> acquiring any select biological agents or toxins.

vi. Laboratory directors are required to contact the Responsible Official, Biosafety Officer and the Department of EOHSS several months in advance of beginning any work with select biological toxins.

vii. Laboratories using exempt strains of select agents must perform quality control testing to ensure the strains are indeed those exempted by the federal regulations. If the testing is not conducted, the strains must be handled at the level of containment required for regulated strains.

viii. All laboratories using unregulated quantities of select biological toxins are required to comply with the UMDNJ Laboratory Safety Plan, especially with respect to implementing the safety controls necessary to protect employees from exposure to hazardous materials.

ix. The laboratory director is required to submit an experimental standard operating procedure (SOP) to the Responsible Official, Biosafety Officer, and the Department of EOHSS prior to

beginning research with unregulated quantities of select biological agents or toxins. The Department of EOHSS will provide a format and outline for the SOP. Any committees (e.g., IACUC) that are required to review the SOP must also issue approval prior to the start of work.

x. Each individual who will be participating in the manipulation of select biological agents or toxins must read and sign the SOP prior to beginning work.

xi. Each individual who will have access to select biological agents or toxins must be up to date on all applicable laboratory safety training requirements.

xii. The laboratory director (or designee) will be required to annually review, and update where necessary, each active select biological agent or toxin SOP. Once this annual review is completed, the laboratory director is required to submit a signed copy to the Responsible Official, Biosafety Officer, and Department of EOHSS.

xiii. Laboratory directors will be required to maintain a current and accurate select biological agent and toxin inventory. The "Select Biological Agent/Toxin Inventory Notification Form" shall be provided by EOHSS and completed and submitted to the Responsible Official, Biosafety Officer, and the Department of EOHSS on at least an annual basis.

xiv. If at any time a researcher exceeds the regulatory threshold quantity of select biological toxin, the laboratory director must immediately notify the Responsible Official, Executive Director of Emergency Management and Occupational Health and Safety, and the Biosafety Officer.

xv. If at any time a select biological agent or toxin is identified in a clinical laboratory, the Laboratory Director must immediately notify the Responsible Official, Executive Director of Emergency Management and Occupational Health and Safety and the Biosafety Officer.

C. Exemptions to Select Agent Regulations

i. Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 using select agents for diagnostic, reference, or verification of proficiency testing purposes may be exempt from federal and state regulations described in this policy. However, these laboratories must follow all of the requirements listed in the "Procedures for Possession, Use or Storage of Exempt Select Biological Agents and Toxins" section of this policy.

ii. Laboratories using attenuated strains of select biological agents or toxins approved for human vaccination purposes by FDA or other recognized national or international organizations may be exempt from the federal and state regulations described in this policy. However, these laboratories must follow all of the requirements listed in the "Procedures for Possession, Use or Storage of Exempt Select Biological Agents and Toxins" section of this policy.

EXHIBIT B

BIOSAFETY LEVEL 3 (BSL-3) LABORATORY COMPLIANCE PROGRAM

As per the Centers for Disease Control and Prevention (CDC), Biosafety Level 3 (BSL-3) containment is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through inhalation exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and in the associated safety, security, and emergency response procedures.

Scientifically based justifications for the use of BSL-3 agents shall be required from researchers. Various levels of review will be required based on the type of manipulations planned with the organism. Any required approvals from the UMDNJ Department of Environmental and Occupational Health and Safety Services (EOHSS), UMDNJ Institutional Biosafety Committee (IBC), UMDNJ Institutional Animal Care and Use Committee (IACUC), and other research committees must be acquired prior to obtaining the BSL-3 materials. Use of BSL-3 organisms in the laboratory will require approval of the applicable campus UMDNJ IBC. Use of BSL-3 organisms in animal models will require approval of the applicable campus UMDNJ IBC and the applicable campus UMDNJ IACUC.

NOTE: Select Agent laboratories that are concurrently BSL-3 laboratories are required to comply with Appendix A of this policy as well as this Appendix (B).

The following standard and special safety practices, equipment, and facility requirements apply to BSL-3 facilities.

I. General Laboratory Safety

A. Each BSL-3 laboratory shall comply with the UMDNJ Laboratory Safety Plan. The Laboratory Safety Plan contains minimum UMDNJ safety standards which apply to all University laboratories.

B. Research with pathogens, human or primate cell lines, human or primate body fluids or tissues, or recombinant DNA at BSL-3 must be approved by the Institutional Biosafety Committee and Institutional Animal Care and Use Committee, as appropriate.

C. Additional requirements for BSL-3 Laboratories are described in the Standard Microbiologial Practices, Special Practices, Safety Equipment, Laboratory Facilities and Emergency Planning and Preparedness sections of this appendix.

II. Standard Microbiological Practices

A. The BSL-3 Director and/or the BSL-3 Manager must enforce the UMDNJ access control policies for the laboratory.

B. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.

C. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.

D. Mouth pipetting is prohibited; mechanical pipetting devices must be used.

E. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Plasticware must be substituted for glassware whenever possible. Use of sharps and glassware must be approved by the Risk Assessment Committee.

F. Precautions must always be taken with sharp items. These include, but are not limited to:

1. Careful management of needles and other sharps are of primary importance.
2. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
3. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
4. Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.

5. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps.
6. Plasticware should be substituted for glassware whenever possible.

G. All procedures must be performed to minimize the creation of splashes and/or aerosols.
H. Maximum culture volume limits must be established.
I. All work with infectious materials must be conducted over absorbent towels or pillows.
J. Work surfaces must be disinfected with an appropriate disinfectant after completion of work and after any spill or splash of potentially infectious material.
K. All cultures, stocks, and other potentially infectious materials must be decontaminated using an effective method before disposal. A method for decontaminating all laboratory wastes should be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).
L. Bags and bottles of waste must be labeled with the name of the individual generating the material.
M. Autoclaves must be validated at least monthly using a spore test.
N. Chemical disinfectants must be documented as effective against the organisms being used.
O. The following methods must be used when preparing waste for disinfection outside of the laboratory.
    1. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
    2. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
P. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. Posted information must include the laboratory's biosafety level, the supervisor's name (or other responsible personnel), office and emergency telephone numbers, and required procedures for entering the laboratory. Agent information should be posted in accordance with facility policy. An effective integrated pest management program is required.
Q. The BSL-3 Director and/or Manager, in consultation with the Biosafety Officer and the Department of EOHSS, must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must complete UMDNJ Bloodborne Pathogen, Laboratory Safety, and Respiratory Protection training programs. The Department of EOHSS provides these training courses for all personnel. Additional facility- and procedure-specific hands on training must be provided and documented. Personnel must receive annual updates or additional training when procedural or policy changes occur. Prior to receiving approval to work in the BSL-3 facility, the BSL-3 Director, BSL-3 Manager, Principal Investigator, Biosafety Officer, Department of EOHSS and the user must sign off that all training has been completed. Personal health status may impact an individual's susceptibility to infection or , ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel, particularly women of child-bearing age must be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify themselves to Occupational Medicine Services or Student Health Services for appropriate counseling and guidance.

III. Special Practices

A. All BSL-3 facilities must be secured to restrict access only to approved users who have completed the necessary training requirements.
B. All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.
C. Facility managers and directors, in coordination with Occupational Medicine Services and Student Health Services, must ensure laboratory personnel are provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory. BSL-3 Managers and Directors must consult with Occupational Medicine Services to ensure appropriate prophylaxis is identified and available prior to starting work with agents.
D. Each facility must establish and document policies and procedures describing the collection and storage of serum samples from at-risk personnel.

E. The facility specific sections of the UMDNJ Laboratory Safety Plan and Exposure Control Plan must be completed to reflect the procedures in place for each facility. This document will function as the biosafety manual. The Laboratory Safety Plan must be available and accessible and reviewed at least annually by the BSL-3 Facility Manager.

F. The Department of EOHSS must inspect BSL-3 facilities on at least a quarterly basis to verify compliance with safety, security, and emergency response requirements.

G. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-3 agents. This proficiency must be documented.

H. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility. The CDC and the U.S. Department of Transportation as well as the International Air Transport Association (IATA) have requirements regarding shipment of hazardous materials such as infectious substances. All personnel who package and/or ship infectious materials via US Postal Service or other delivery services must complete IATA training every two years. IATA training is offered by the Department of EOHSS.

I. Laboratory equipment must be decontaminated routinely, as well as after spills, splashes, or other potential contamination.

   1. Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
   2. Procedures must be developed to ensure items are properly decontaminated or contained prior to leaving the containment area.
   3. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory. Facility managers or directors must consult the Biosafety Officer and Department of EOHSS prior to removing equipment from the BSL-3 facility. EOHSS will review the decontamination method and, after removal from the BSL-3, will post signage on the equipment confirming that the equipment is safe to handle outside of containment.

J. Incidents that may have resulted in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the Laboratory Safety Plan. All such incidents must be reported to the laboratory supervisor, Occupational Medicine Services or Student Health Services, the Biosafety Officer, and the Department of EOHSS. Medical evaluation, surveillance, and treatment should be provided and appropriate records (e.g., Incident Report) completed and maintained.

K. Animals and plants not associated with the work being performed must not be permitted in the laboratory.

L. All procedures involving the manipulation of infectious materials must be conducted within a biological safety cabinet (BSC), or other physical containment devices approved by the Biosafety Officer and the Department of EOHSS. No work with open vessels may be conducted on the open bench. When a procedure cannot be performed within a BSC, a combination of personal protective equipment and other containment devices, as determined by the Biosafety Officer and the Department of EOHSS, must be used.

M. Containers of chemicals, reagents, and organisms must be clearly labeled as specified in the UMDNJ Laboratory Safety Plan. The labeling system must be understandable by laypersons.

IV. Safety Equipment (Primary Barriers and Personal Protective Equipment)

A. All procedures involving the manipulation of infectious materials must be conducted within a BSC (preferably Class II or Class III) or other physical containment devices. The BSC must be certified at least annually.

B. Protective laboratory clothing with a solid-front such as tie-back or wraparound gowns, scrub suits, or coveralls must be worn by workers when in the laboratory. Protective clothing may not be worn outside of the laboratory. Reusable clothing must be decontaminated with appropriate disinfectant before being laundered or reused. Protective clothing must be changed when contaminated. Determination of appropriate protective clothing shall be made by the Risk Assessment Committee.

C. Eye and face protection (goggles, mask, face shield, or other splatter guard) must be used for anticipated splashes or sprays of infectious or other hazardous materials. Eye and face protection must

be disposed of with other contaminated laboratory waste or decontaminated before re-use. Persons who wear contact lenses in laboratories must also wear eye protection. Eye, face, and respiratory protection must be used in rooms containing infected animals.

D. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection must be based on an appropriate risk assessment and must be approved by the Risk Assessment Committee. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. In addition, BSL-3 laboratory workers must:
    1. Change gloves when contaminated, integrity has been compromised, or when otherwise necessary.
    2. Wear two pairs of gloves when appropriate.
    3. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
    4. Do not wash or re-use disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

V. Laboratory Facilities (Secondary Barriers)

A. Laboratory doors must be self closing, self latching, and have locks recommended and approved by UMDNJ Public Safety.
B. The laboratory must be separated from areas that are open to unrestricted traffic flow within the building.
C. Access to the laboratory must be restricted to entry by a series of two self-closing doors.
D. A clothing change room (anteroom) may be included in the passageway between the two self-closing doors.
E. Laboratories must have a sink for hand washing. The sink must be hands-free or automatically operated. It should be located near the exit door.
    1. If the facility is segregated into different laboratories, a sink must also be available for hand washing in each zone.
    2. Additional sinks may be required as determined by the risk assessment.
F. The sink must be equipped with soap and paper towels or warm air hand dryer.
G. The laboratory must be designed so that it can be easily cleaned and decontaminated. Carpets and rugs are not permitted. Seams, floors, walls, and ceiling surfaces shall be sealed. Spaces around doors and ventilation openings should be capable of being sealed to facilitate space decontamination.
    1. Floors must be slip resistant, impervious to liquids, and resistant to chemicals. Consideration should be given to the installation of seamless, sealed, resilient or poured floors, with integral cove bases.
    2. Walls shall be constructed to produce a sealed smooth finish that can be easily cleaned and decontaminated.
    3. Ceilings should be sealed and finished in the same general manner as walls.
    4. Decontamination of the entire laboratory should be considered when there has been gross contamination of the space, significant changes in laboratory usage, for major renovations, or maintenance shut downs. Selection of the appropriate materials and methods used to decontaminate the laboratory must be based on the risk assessment of the biological agents in use and in consultation with the Biosafety Officer and the Department of EOHSS. Finishes used in the laboratory must be specified to withstand the decontamination process without damage.
H. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment must be accessible for cleaning.
    1. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
    2. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
I. All windows in the laboratory must be closed and sealed.

J. BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.

K. Vacuum lines must be protected with HEPA filters, or their equivalent. Filters must be replaced as needed. Liquid disinfectant traps may be required.

L. An eyewash station must be readily available in the laboratory. The eyewash must be flushed on at least a monthly basis.

M. A ducted air ventilation system is required. This system must provide sustained directional airflow by drawing air into the laboratory from "clean" areas toward "potentially contaminated" areas. The laboratory shall be designed such that under failure conditions the airflow will not be reversed.

1. Laboratory personnel must be able to verify directional air flow. A visual monitoring device which confirms directional air flow must be provided at the laboratory entry. Audible alarms should be considered to notify personnel of air flow disruption.
2. The laboratory exhaust air must not re-circulate to any other area of the building.
3. The laboratory building exhaust air should be dispersed away from occupied areas and from building air intake locations and/or the exhaust air must be HEPA filtered.

N. HEPA filtered exhaust air from a Class II BSC can be safely re-circulated into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or a direct (hard) connection. Provisions to assure proper safety cabinet performance and air system operation must be verified. BSCs should be certified at least annually to assure correct performance. Class III BSCs must be directly (hard) connected up through the second exhaust HEPA filter of the cabinet. Supply air must be provided in such a manner that prevents positive pressurization of the cabinet.

O. A method for decontaminating all laboratory wastes should be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

P. Equipment that may produce infectious aerosols must be contained in devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory. These HEPA filters should be tested and/or replaced at least annually.

Q. Facility design consideration should be given to means of decontaminating large pieces of equipment before removal from the laboratory.

R. Enhanced environmental and personal protection may be required by the CDC BMBL agent summary statement, risk assessment, or applicable local, state, or federal regulations. These laboratory enhancements may include, for example, one or more of the following; an anteroom for clean storage of equipment and supplies with dress-in, shower-out capabilities; gas tight dampers to facilitate laboratory isolation; final HEPA filtration of the laboratory exhaust air; laboratory effluent decontamination; and advanced access control devices such as biometrics. HEPA filter housings should have gas-tight isolation dampers; decontamination ports; and/or bag-in/bag-out (with appropriate decontamination procedures) capability. The HEPA filter housing should allow for leak testing of each filter and assembly. The filters and the housing should be certified at least annually.

S. The BSL-3 facility design, operational parameters, and procedures must be verified and documented prior to operation. Facilities must be re-verified at least annually. Documentation of annual facility verification shall be maintained by the BSL-3 facility manager.

VI. Emergency Planning and Preparedness

A. Emergency exits and routes of egress must be posted near the exits from the laboratory.

B. Personnel roles, responsibilities and lines of authority in an emergency must be documented and maintained in a current fashion.

C. Emergency notification lists and call trees must be posted near the phones in the laboratory.

D. Emergency plans must address facility responses to various disasters including, but not limited to, power outage, fire, severe weather, ventilation failure, biological spill, chemical spill, radioactive spill, exposure incidents, medical emergency, emergency facility evacuation, emergency personnel decontamination, reporting of unauthorized or suspicious persons, physical security breach, and

theft, loss, or release of agents. Plans must be provided to, and kept on file at, the campus Public Safety office.

E. In addition to fire exit drills, BSL-3 facility safety and emergency plans and procedures must be drilled annually.

F. Facility procedures and plans must be reviewed annually and after any incident or "near miss" incident by the BSL-3 Director, BSL-3 Manager, the Biosafety Officer, the Department of EOHSS, and others as appropriate. Changes or updates to the policy must be shared with all facility users.

G. Facility managers and directors must be available for consultation during emergency conditions.

H. Each laboratory must have a logbook to record the name, supervisor, time of entry, and time of exit for all facility users and visitors.

I. Visitors to the containment areas of the laboratory must be approved to wear respiratory protection. Visitors must have training on the respirator and fit tests as necessary.

J. Individuals under the age of 18 may not enter BSL-3 laboratories.

K. BSL-3 facilities must hold user meetings on a semi-annual basis. The meetings will be a time to update and review policies and procedures as well as to discuss any user issues. The meetings must be documented via meeting minutes.

L. All approved users must complete basic incident command system training.

M. All approved users must complete basic first aid training as required by the facility standard operating procedures. First aid training will comply with current American Heart Association or American Red Cross standards.