

involving SARS-CoV. The anterooms to the BSL-3 labs house PAPR charging stations, lab and safety supplies, and a changing area. For both the BSL2 and BSL3 select agent spaces, access to the select agents is restricted by the hallway to anteroom door, which requires swipe card and punch codes for entry, the door between the anteroom and the BSL-3 (BL3 only), and freezer locks.

NEIDL: The select agent work to be carried out will be performed in the National Emerging Infectious Diseases Laboratories (NEIDL). The NEIDL is fully permitted for Select Agent work at BSL-3 and ABSL-3, as well as BSL-4 and ABSL-4. We will conduct experimental infection studies using Nipah and Hendra (Henipaviruses) and Ebola and Ebola-related viruses at NEIDL using animal models and cell lines within the biosafety level 4 laboratory at NEIDL. No infectious materials will be moved or handled outside of the BSL 4 facility. All science and animal care staff are fully trained and certified to work under BSL 4 conditions.

At Boston University (BU), research with BSAT is focused to combat infectious diseases caused by the agents, with primary concentration on the development of vaccines, therapeutics and diagnostic tests. Work is conducted in highly specialized containment facilities that are specifically designed, verified and maintained to ensure that the materials are secured, contained and handled safely. Research facilities with BSAT at BU have received prior approval from CDC/USDA and other local regulatory agencies prior to the possession, storage and conducting of research work. All BSAT research proposals are first carefully reviewed by the Institutional Biosafety Committee (IBC) and, together with the Environmental Health and Safety (EHS), checks and verifies that the required safety procedures, personal protective equipment, safety equipment, and trainings are in place and implemented prior to initiation of research work.

A senior Scientific Safety Officer serves as the Select Agent Responsible Official (RO) and has oversight for the implementation of the BSAT program. Under this program, the institution implements and maintains a system of control measures to ensure that all personnel are properly screened for security risks and have passed the required background verification checks by Federal agencies and BU. Personnel complete and meet the medical and health screenings required by the Research Occupational Health Program (ROHP); personnel are appropriately trained on the hazards of the materials, safety procedures and their roles and responsibilities. The RO and the Alternate Responsible Officials (ARO) conduct an annual review of the Security, Biosafety and Incident Response Plans and make necessary changes to the plans.

Describe the procedures that will be used to monitor possession, use and transfer of the Select Agent(s):

All personnel who will have access to select agent-regulated materials have been added to the select agent registration following security risk assessments prescribed by the CDC Select Agent Program. Personnel have completed training in all aspects of select agent compliance requirements and have adopted changes to standard operating procedures as applicable to assure that these requirements are met. Personnel will follow all procedures prescribed for accessing and securing the lab, documenting lab activities and materials used, and responding to incidents that could result in theft, loss or release of select agent regulated materials. Transfers of select agent-regulated materials will be coordinated by the Lab Manager and Responsible Official in accordance with standard operating procedure, including obtaining appropriate permits for shipping select agent materials. Lab managers of both facilities are DOT/IATA trained for shipping dangerous goods and will follow all regulations for shipping, both under dangerous goods and select agent regulations. Transfer of select agent RNA in trizol from the BSL3 and BSL2 laboratory is witnessed by UNC and Vanderbilt ARO in a process that has been approved by the CDC.

For NEIDL, all biohazards that are shipped or received for approved projects are mandated to meet the standards of the High Hazard Materials Management policy, which states that BU will meet or exceed all applicable shipping regulations under the requirements of the U.S. Department of Transportation (DOT) and the International Air Transportation Authority (IATA). The RO, the BU Office of Emergency Management and Public Safety have responsibility for overseeing the transportation process for select agents and for contracting appropriate transportation vendors which utilize screened personnel, GPS tracking systems and can provide an all-inclusive chain of custody documentation for each shipment.

Describe plans for appropriate biosafety, biocontainment, and security of the Select Agent(s): Co-I Baric's