INTRODUCTION & PREMISE

- The rapid advance of the COVID-19 pandemic has created a dire need for critical research to better understand and manage the coronavirus (SARS-CoV-2) causing this pandemic.
- A number of SLU researchers have expressed interest in applying for funding and ramping up research to work with this high risk pathogen.
- Risk assessments are essential to properly classifying SARS-CoV-2 research containment as BSL-2 or BSL-3 (and/or ABSL-2 or ABSL-3) based on protocols submitted to the SLU Institutional Biosafety Committee (IBC) for review and approval.
- An integral factor in approving protocols requiring BSL-3 and/or ABSL-3 containment is the training and experience of the principle investigator (PI) and their staff in being safe and proficient at working in BSL-3 and/or ABSL-3 laboratories.
- The safety of our SLU researchers and the community at large is of paramount concern and importance to the IBC in reviewing and approving work with high risk pathogens like SARS-CoV-2. Further complicating work with SARS CoV-2 is that traditional worker health surveillance programs may not be able to detect laboratory acquired versus community spread COVID-19. To that end, minimum training and experience requirements for BSL-3 and/or ABSL-3 work with SARS-CoV-2, and any other high risk pathogens, are essential to minimizing the risks of accidental exposures, releases and increased disease transmission.

The following requirements (designated A and B below) are hereby formalized and adopted:

A. Minimum Experience Requirements for All BSL-3 / ABSL-3 Personnel

1. Past Experience Working at BSL-3 and/or ABSL-3
   (a) Past experience will be considered on a case by case basis.
   (b) Evidence of past experience will include review of C.V. and in-person interview by the Biological Safety Officer (BSO) or his/her designee. This includes work with Risk Group 2 (RG2) and Risk Group 3 (RG3) biological agents in a BSL-3 and/or ABSL-3 facility.
   (c) If past BSL-2/ABSL-3 experience is deemed insufficient during the past three years, additional BSL-3/ABSL-3 training may be required. (See A. 2. Below)
   (d) In the case of a PI, laboratory inspections and incident reports for that PI’s laboratory over the past three years will also be reviewed.
   (e) Summary report prepared by BSO to be reviewed by IBC.

2. New BSL-3 and/or ABSL-3 User (Including New PI and Lab Group)
   (a) For new BSL-3/ABSL-3 users, in addition to the didactic component outlined in B. below, there is a hands-on immersion experience in the BSL-3 (and/or ABSL-3 laboratory) provided by the BSO or his/her designee.
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(b) New BSL-3/ABSL-3 users must demonstrate to the BSO (or designee) proficiency in safely and competently functioning in a BSL-3 or ABSL-3 high containment laboratory, including donning and doffing PPE, and performing some routine procedures (possibly using lower risk RG2 biological materials or mock inconsequential non-infectious materials) while wearing required PPE, including respiratory protection. Procedures covered by the BSO include:

Entry Procedures
- Donning PPE
- Security (access control systems)
- Verify negative directional airflow

Working in High Containment
- Proper use of Biosafety Cabinet
- Safe sharps use and disposal
- Proper pipetting technique
- Proper use of centrifuge
- Transporting infectious materials within the lab
- Decontaminating work area
- Incident response

Exit Procedures
- Decontamination
- Doffing PPE

(c) The BSO (or designee) must certify the new BSL-3/ABSL-3 user has successfully demonstrated mastery of safe practices and procedures in the BSL-3/ABSL-3 laboratory delineated in A.2.(b) above and is familiar with the BSL-3/ABSL-3 facility plans and procedures and demonstrates an understanding of facility engineering controls.

(d) Training of lab group members on the research procedures specific to the research to be conducted in the BSL-3/ABSL-3 laboratory is the responsibility of their experienced BSL-3/ABSL-3 supervising PI.

B. Minimum Training Requirements for All BSL-3/ABSL-3 Personnel

1. Select Agent and High Containment (BSL-3/ABSL-3) Awareness Training (provided by BSO):

(a) The BSL-3/ABSL-3 candidate (whether experienced or not) must successfully complete BSL-3 training course. Currently, this consists of a PowerPoint presentation provided by the SLU Biological Safety Officer (BSO) or designee.

(b) This training is required to be completed annually to maintain BSL-3/ABSL-3 access.

2. ABSL-3 Training (provided by Comparative Medicine (CM)):

(a) Personnel planning to do only ABSL-3 work (whether experienced or not) must successfully complete ABSL-3 training course provided by the SLU CM Manager or designee.
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(b) This course includes a PowerPoint presentation and a tour of the ABSL-3 facility.

(c) This training is required to be completed annually to maintain ABSL-3 access.

3. Powered Air Purifying Respirator (PAPR) Training (provided by BSO or Comparative Medicine):
   If work in BSL-3/ABSL-3 will require use of a PAPR respirator, the following training must be provided as stated below.
   
   (a) If the BSL-3/ABSL-3 user’s work will require use of a PAPR in both the BSL-3 and ABSL-3 laboratories, then training is provided by the BSO.
   
   (b) If the BSL-3/ABSL-3 user’s work requires PAPR use only in the ABSL-3 laboratories, then training will be provided by the CM Manager.
   
   (c) This training course consists of a PowerPoint presentation, viewing a series of training videos (optional) provided by vendor, and a hands-on experience with BSO or CM Manager that includes donning, doffing, and maintenance of the PAPR unit.
   
   (d) This training is required to be completed annually to maintain BSL-3 and/or ABSL-3 access for which PAPR use is required.

C. Requirements for IBC and IACUC Protocol Applications (PI New to BSL-3/ABSL-3)

A PI who is not experienced working in BSL-3/ABSL-3 labs and who wishes to submit a new IBC and/or IACUC protocol requiring BSL-3/ABSL-3 containment is required to complete the training outlined in Section B.1.a. above and to also review the applicable BSL-3 and/or ABSL-3 Biosafety Plans prior to developing and submitting their IBC and IACUC protocol application.

APPROVALS

These training and experience requirements for BSL-3/ABSL-3 work with SARS-CoV-2 and other high risk pathogens have been approved by the following:

Institutional Biosafety Committee (IBC): (signed copy on file) 
   Laurie Shornick, Ph.D. 
   IBC Chair 
   (Date)

Vice President for Research: (signed copy on file) 
   Kenneth A. Olliff 
   (Date)

Dean, School of Medicine 
Vice President for Medical Affairs: (signed copy on file) 
   Robert Wilmott, M.D. 
   (Date)