Chapter 34: Biosafety

Quick Start Summary

1 Who needs to know about these requirements

The requirements of Biosafety apply to researchers, principal investigators, laboratory managers, ESH coordinators, the biosafety program manager, the Occupational Health Center, and the Stanford biosafety representative and Stanford Administrative Panel on Biosafety.

2 Why

Biohazardous materials present a potential risk to human and animal health and the environment. The purpose of this program is to ensure work with such materials can be performed safely and in compliance with government regulations and the Stanford biosafety program.

3 What do I need to know

Work involving biohazardous materials and/or recombinant DNA (rDNA) is classified by risk group and biosafety safety level (BSL 1 through 4). Only work classified as BSL 1 or 2 is currently permitted at SLAC. Work classified as BSL 3 or 4 is not permitted at SLAC as the site currently does not have the appropriate facilities to manage the hazards associated with this level of work.

All such work requires the development, review, and approval of experimental protocols and standard operating procedures (SOPs). BSL 1 work is reviewed and approved by the laboratory manager and ESH coordinator. BSL 2 work must in addition be submitted by the principal investigator to the Stanford Administrative Panel on Biosafety (APB) for approval. All work involving biohazardous materials must be performed following approved protocols and SOPs and materials used and their status tracked.

4 When

These requirements take effect 10 May 2019.

5 Where do I find more information

SLAC Environment, Safety, and Health Manual (SLAC-I-720-0A29Z-001)
- Chapter 34, “Biosafety”

Or contact the program manager.
Chapter 34

Biosafety

1 Purpose

The purpose of this program is to ensure work with biohazardous materials is performed safely. It covers the review and approval of such work, and their use, storage, transportation, and disposal. It applies to researchers, principal investigators, laboratory managers, ESH coordinators, the biosafety program manager, the Occupational Health Center, and the Stanford biosafety representative and Stanford Administrative Panel on Biosafety.

This program does not cover safe handling of human material (blood and body fluids). For those requirements, see Chapter 46, “Blood-borne Pathogens”. Moreover, this program does not apply to non-research work with or exposure to biological materials commonly experienced by the general public and not resulting from assigned job duties.

2 Roles and Responsibilities

Functional roles and general responsibilities for each are listed below. More detailed responsibilities and when they apply are provided in the procedures and requirements.

The roles may be performed by one or more individuals and one individual may play more than one role, depending on the structure of the organizations involved. Responsibilities may be delegated.

2.1 Researcher

- Supports the principal investigator in the development and approval of protocols and standard operating procedures (SOPs)
- Completes all appropriate training and medical surveillance before beginning work with biohazardous material
- Conducts all experiments in accordance with approved protocols, SOPs, and standard biosafety work practices
- Ensures decontamination of any equipment and removal of any biohazardous material after completion of the experiment
- Notifies SLAC Site Security (ext. 5555), supervisor, laboratory manager, and the ESH coordinator of any incident or near miss resulting in injury or release of biohazardous materials
Tracks biohazardous materials and ensures that they are either destroyed in the experiment, chemically inactivated or autoclaved and properly disposed of, properly stored on-site per approved SOP, or properly packed and shipped off-site

2.2 Principal Investigator

The principal investigator is ultimately responsible for safety within his or her laboratory environment but can delegate duties listed below to an assigned laboratory manager or other member of the group.

- Is adequately trained in good microbiological practices
- Develops protocols and SOPs for the safe handling, storage, and disposal of biohazardous materials
- In collaboration with the Stanford biosafety representative, determines the risk group for biohazardous materials and assigns a biosafety level for each proposed experimental protocol based on the risk group, handling practices, and other factors (all biosafety level 2 assignments must be reviewed by the Stanford biosafety representative)
- Submits all SOPs for review and approval by the laboratory manager and ESH coordinator
- Submits protocols for biosafety level 2 agents, or where there is a particular health concern, to the Stanford Administrative Panel on Biosafety (APB), using the Stanford eProtocol system
- Ensures all conditions of APB approval are met before work may begin
- Maintains necessary biosafety protocol documentation outside of APB protocol
- Ensures researchers complete all required medical surveillance and training before allowing work to begin
- Ensures adherence to approved protocols, SOPs, and work practices
- Provides laboratory staff with protocols and SOPs describing potential biohazards and necessary precautions
- Incorporates lessons learned into SOPs
- Instructs and trains laboratory staff in the practices and techniques required to ensure safety, including procedures for dealing with spills and other incidents
- Informs laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (for example, vaccinations or antibody titer)
- Supervises laboratory staff to ensure that the required safety practices and techniques are employed
- Corrects work errors and conditions that may result in the release of biohazardous materials
- Ensures integrity of physical and biological containment
- Ensures SLAC Security (ext. 5555) and the ESH coordinator are notified of any incident, or near miss, resulting in injury or release of biohazardous materials
- Ensures that biohazardous materials are tracked per SLAC policies
- Ensures that proper biohazardous waste streams are established in consultation with the Waste Management Group
- Complies with shipping requirements for biohazardous materials
2.3 Laboratory Manager

- Reviews and approves SOPs
- Verifies that all biosafety level 2 protocols have been approved by the Stanford APB before work is allowed to begin
- Ensures that all personnel within his or her assigned areas who may come in contact with biohazardous materials receive appropriate training per the requirements of this program and the SOP
- Performs any duties delegated to him or her by the principal investigator

2.4 ESH Coordinator

- Reviews and approves SOPs
- Verifies that all biosafety level 2 protocols have been approved by the Stanford APB before work is allowed to begin
- Arranges for specific training as outlined in Section 4.2
- Evaluates training of visiting researchers
- Works with researchers to ensure that all the required controls stemming from approved protocols and the standard biosafety work practices are implemented
- Verifies researchers follow approved protocols, SOPs, and work practices
- Submits, before the end of the calendar year, reports describing the status and inventory of biohazardous materials used in his or her areas over the previous year to the biosafety program manager

2.5 Biosafety Program Manager

- Is responsible for SLAC’s overall biosafety program and ensuring it aligns with the Stanford’s biosafety program
- Attends meetings of Stanford’s Administrative Panel on Biosafety (APB) as SLAC’s representative to facilitate protocol approval for materials handled at SLAC, if needed
- Is available to provide input for biosafety level determination and other safety issues for proposed protocols
- Gathers information from individual directorates and compiles records of biological etiological agents into an annual report and submits report to the DOE Bay Area Site Office and the Occupational Health Center along with any changes to this program from the previous year.
- Conducts random field audits to verify compliance to approved protocols
- Ensures all biosafety cabinets (BSCs) are maintained properly and certified annually by a certified vendor

2.6 Stanford Biosafety Representative at SLAC

- Serves as the Stanford University liaison to SLAC
Assists principal investigator with the proper assignment of the risk group and biosafety level for biohazardous materials. Reviews all biosafety level 2 assignments to confirm proper assignment.

- Assists principal investigator with eProtocol submittal process
- Conducts regular visits to assess areas that may use biological materials and provides assistance, clarification, and/or training in the safe use of these materials with the appropriate researchers
- Provides on-site SLAC support at least two days a week

2.7 Stanford Administrative Panel on Biosafety

- Reviews protocols for planned biosafety level 2 work, or for work with recombinant DNA (rDNA) that falls under the NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules. May also review protocols where there is a particular health concern from the researcher or researcher’s designee.
- Provides approval to proceed with research outlined in submitted protocols
- Performs an annual review of submitted protocols

2.8 Occupational Health Center

- Provides medical surveillance to researchers working with biohazardous materials
- Provides immunizations for researchers working with biological agents as needed, based on the evaluation of risk and benefit of immunization
- Performs titer checks, or similar blood testing, as indicated, based on the evaluation of risk related to bioagent work
- Treats personnel exposed to biohazardous materials or refers them out for appropriate care. (Exposure can result from skin punctures or inhalation of aerosols or direct contact with mucous membranes.)

3 Procedures

These documents list the core requirements for this program and describe how to implement them:

- **Biosafety: General Requirements** (SLAC-I-730-0A21S-061). Describes general requirements for working with biohazardous materials
- **Biosafety: Review Procedure** (SLAC-I-730-0A21C-035). Describes process for review and approval of work with biohazardous materials

4 Training

SLAC currently uses Stanford University’s biosafety training courses or equivalent for visiting researchers from other institutions.
4.1 Researcher

Per the Stanford biosafety program, all researchers and all potentially exposed research personnel must complete the required biosafety training courses:

- Stanford Course EHS-1500, Biosafety (Stanford EHS-1500)
- Stanford Course EHS-PROG-1600, Bloodborne Pathogens (Stanford EHS-PROG-1600). (This course replaces ESH Course 258, Blood-borne Pathogens Awareness [ESH Course 258] for biosafety work.)

Once training is completed, a printout of completion must be provided to the ESH coordinator.

Note: A SUNET ID is required to complete Stanford training course.

4.2 ESH Coordinator

ESH coordinators must complete the same training as researchers (see Section 4.1).

4.3 Other SLAC Training

In addition to the Stanford training courses above, SLAC employees (researchers and other personnel) who work with or may come in contact with biohazardous materials must receive appropriate training as arranged by their ESH coordinator. The content of the training will be specific to the nature of the material used, type of experiments being conducted, and the equipment used.

4.4 Visiting Researcher

Visiting researchers, including Stanford researchers, must have the appropriate level of training to safely handle the biohazardous materials planned for in the experiment.

For Stanford researchers, completion of the appropriate tier level training is required before work is allowed to be initiated. (See Stanford’s Biosafety Manual for details on appropriate tier level.)

For visiting researchers from other institutions, their ESH coordinator must evaluate and ensure that they have the appropriate level of training.

5 Definitions

Administrative Panel on Biosafety (APB). The Stanford University committee that reviews all university and SLAC research and teaching activities involving the use of biohazardous agents, recombinant DNA molecules, and synthetic nucleic acid molecules that require approval per the National Institutes of Health (NIH Guidelines). Such a committee is commonly referred to an institutional biosafety committee.

Biohazardous materials. Hazardous biological materials and organisms, including

- infectious organisms (bacteria, fungi, parasites, prions, rickettsias, viruses, etc.) that can cause disease in a healthy human and/or significant environmental or agricultural impact
human or primate tissues, fluids, cells, or cell culture
- recombinant DNA (rDNA) molecules
- animals known to be vectors of zoonotic diseases
- synthetic nucleic acid molecules

Biosafety level (BSL). The sum of the risk group of the agent being used and the work to be done. The biosafety level assigned to work determines the containment required. Biosafety level is rated from 1 to 4, with 1 requiring the least stringent containment conditions and 4 the most stringent. Work at SLAC is limited to biosafety level 2 and below.

Containment. Combination of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations to be performed, the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons and the environment to potentially hazardous agents. Containment is classified based on the biosafety level of the work to be done.

- BSL 1 containment. Area where work controls are in place to safely manage well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. More information on the practices, safety equipment, and facilities requirements can be found in the Stanford Biosafety Manual.
- BSL 2 containment. Area where work controls are in place to safely manage agents that pose moderate hazards to personnel and the environment. More information on the practices, safety equipment, and facilities requirements can be found in the Stanford Biosafety Manual.

Near miss. An incident where no barrier or only one barrier prevented an event from having a reportable consequence

Recombinant DNA (rDNA). Recombinant DNA molecules are either: 1) molecules that are constructed in vitro outside living cells by joining natural or synthetic DNA segments to in vivo-competent DNA molecules 2) DNA molecules that result from the replication of those described in 1

Risk group (RG). Numerical risk value from 1 to 4 given to an agent based on the pathogenicity of the organism, mode of transmission and host range, availability of effective preventive measures, availability of effective treatment, and other factors. See Appendix A of the Stanford Biosafety Manual for more information. (Note the Stanford Biosafety Manual uses the term BSL rather than risk group to refer to agents.)

- RG 1. Agents not associated with disease in healthy adult humans.
- RG 2. Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are often available.
6 References

6.1 External Requirements

The following are the external requirements that apply to this program:


- Centers for Disease Control and Prevention and National Institutes of Health (CDC-NIH). Biosafety in Microbiological and Biomedical Laboratories (BMBL), fifth edition. 2009


- National Institutes of Health (NIH). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

- Federal Select Agent Program. Select Agents and Toxins List

- International Air Transportation Association (IATA). Dangerous Goods Regulations (IATA DGR)


6.2 Related Documents

SLAC Environment, Safety, and Health Manual (SLAC-I-720-0A29Z-001)

- Chapter 16, “Spills”
- Chapter 17, “Hazardous Waste”
- Chapter 46, “Blood-borne Pathogens”

Other SLAC Documents

- Biological Safety Program (SharePoint)
- SLAC Occupational Health Center
- Field Services Department - Hazardous Waste Management
Other Documents

- Stanford University. Administrative Panel on Biosafety (APB) Review
- Stanford University. eProtocol Biosafety
- American Biological Safety Association (ABSA). Risk Group Database
Chapter 34: Biosafety

General Requirements

1 Purpose

The purpose of these requirements is to ensure work with biohazardous materials is performed safely. They cover use, storage, transportation, and disposal of biohazardous materials. They apply to researchers, principal investigators, laboratory managers, ESH coordinators, the biosafety program manager, and the Occupational Health Center.

2 Requirements

Work involving biohazardous materials and/or recombinant DNA (rDNA) is classified by risk group and biosafety safety level (BSL). Only work classified as BSL 1 or 2 is currently permitted at SLAC. Work classified as BSL 3 or 4 is not permitted at SLAC as the site currently does not have the appropriate facilities to safely manage the hazards associated with this level of work.

2.1 Review and Approval

All work with biohazardous materials and/or recombinant DNA (rDNA) must be reviewed and approved following the Biosafety: Review Procedure before work may begin. This includes the development and approval of standard operating procedures (SOPs) and protocols.

2.2 Standard Work Practices

At a minimum, all researchers working with biohazardous materials must adhere to the following standard biosafety work practices:

- Long pants and closed-toe shoes must be worn at all times.
- Hands must be washed with soap after handling materials, after removing gloves and before leaving the laboratory.
- Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in the work areas.
- Mouth pipetting is prohibited.
- Work surfaces must be decontaminated at least once a day and after any spill of biological materials.
- A biohazard sign must be posted at the entrance to the laboratory. The sign must include the name of the material in use and the name and phone number of the researcher.
2.3 Transportation

Transportation of biohazardous materials on-site, including transportation between laboratories and buildings, requires the use of leak-proof secondary containment with a tight-fitting cover. Off-site transportation requires the use of tertiary containment. The outside of the largest containment container must be labeled with a biohazard sticker, biosafety level, and contact information. (See the Stanford Biosafety Manual.)

All biohazardous materials being shipped from SLAC must be performed under the supervision of a trained Department of Transportation (DOT) or International Air Transport Association (IATA) handler and shipper. Contact SLAC Shipping and Receiving for more details. Non-trained researchers can assist in packing their own biohazardous materials as long as the packing is supervised by a trained shipper and handler.

2.4 Material Storage

All biohazardous materials stored on-site must be in a storage area approved via the SOP and protocol. Areas must be labeled with a biohazard sign. Refrigerators and freezers used to store materials and samples must be labeled with a biohazard sign, current emergency contact information, and NOT FOR FOOD. Secondary containment is needed for sample storage.

2.4.1 Biosafety Cabinets

Biosafety cabinets must be maintained properly and certified annually by a certified vendor. The biosafety program manager is responsible for ensuring maintenance and certification.

2.5 Decontamination

Decontaminants are specific to the biohazardous materials within the protocol. Refer to the Stanford Biosafety Manual for the specific decontamination procedure for the biohazardous materials (this information should also be included in the protocol). (See Stanford’s Comparing Different Disinfectants.)

2.6 Biohazardous Waste Disposal

Biohazardous waste includes all laboratory waste that may contain any biohazardous material or were in contact with said material.

2.6.1 Solid Waste

All non-sharps biohazard wastes must be placed in a red bag marked with a biohazard symbol. Arrangements must be made through Waste Management for pickup and disposal. (See Chapter 17, “Hazardous Waste” and Chapter 46, “Blood-borne Pathogens”.)
2.6.1.1 Sharps

Do not throw biohazardous sharps in the red bag or regular trash; instead, sharps containers are available for the proper disposal of these materials. Arrangements must be made through Waste Management for pickup and disposal.

2.6.2 Liquid Waste

Biohazardous liquid waste may be decontaminated and disposed down the sewer with running water if approved in the protocol and SOP. Otherwise, biohazardous liquid waste must be collected into designated waste containers. These containers must have secondary containment and a properly completed waste label on the primary collection container. Arrangements must be made through Waste Management for pickup and disposal.

2.7 Spill Response

The following is the general procedure for biohazardous spill cleanup. For specific situations, refer to the SOP or contact your ESH coordinator for further assistance.

1. Evacuate the area for 30 minutes for the aerosols to settle.
2. Find a spill kit and put on appropriate personal protective equipment (PPE) including safety glasses, lab coat, gloves, and shoe covers.
3. Contain the spill with absorbent sheets or paper towels.
4. Decontaminate the spill with disinfectant (for example, freshly prepared 10 percent bleach). Let it sit for at least 20 minutes.
5. Dispose the absorbent sheets into a biohazard waste bag, and apply fresh absorbent sheets and disinfectants to wipe up the area.
6. Dispose used PPE into the same biohazard waste bag. Arrangements must be made through Waste Management for pickup and disposal.
7. Wash hands with soap before leaving the area.
8. Report the incident to your supervisor (as indicated on the SOP), call ext. 5555, and follow the notification and reporting procedures in Chapter 16, “Spills”.

2.8 Biological Agent Inventory

At the beginning of each calendar year, the biosafety program manager is required to provide the DOE Bay Area Site Office, and the Occupational Health Center, with an inventory of biological etiological agents used at SLAC throughout the year and any updates to this biosafety program. The inventory includes a list of agents, the principal investigator’s or owner’s name, and location(s) of the work.

To assist in this inventory, ESH coordinators are required to submit, before the end of the calendar year, reports describing the status and inventory of biohazardous materials used in their areas over the previous year to the biosafety program manager. Principal investigators are required to maintain this information and to provide it to their ESH coordinator.
Past inventories can be viewed on Biological Safety Program.

2.9 Medical Surveillance and Immunization

Any required medical surveillance must be completed by the Occupational Health Center (OHC) before work may begin. The OHC provides immunizations for persons working with biological agents as needed based on the evaluation of risk and benefit of immunization and performs titer checks, or similar blood testing, as indicated, based on the evaluation of risk related to bioagent work. The OHC also treats personnel exposed to biohazardous materials or refers them out for appropriate care. (Exposure can result from skin punctures or inhalation of aerosols or direct contact with mucous membranes.)

3 Forms

The following forms are required by these requirements:

- SLAC eShipper. System used to document off-site transportation

4 Recordkeeping

The following recordkeeping requirements apply for this procedure:

- The biosafety program manager maintains a record of annual biosafety agent inventories (see Biological Safety Program).
- Principal investigators maintain information describing the status and inventory of biohazardous materials used in their areas.
- The biosafety program manager maintains records of annual biosafety cabinet certification.
- Shipping and Receiving keeps records of off-site transportation of biohazardous materials (using SLAC eShipper).
- The Occupational Health Center maintains medical records for medical surveillance and immunizations.

5 References

SLAC Environment, Safety, and Health Manual (SLAC-I-720-0A29Z-001)

- Chapter 34, “Biosafety”
  - Biosafety: Review Procedure (SLAC-I-730-0A21C-035)
- Chapter 16, “Spills”
- Chapter 17, “Hazardous Waste”
- Chapter 46, “Blood-borne Pathogens”
Other SLAC Documents

- Biological Safety Program (SharePoint)
- Field Services Department - Hazardous Waste Management
- SLAC Occupational Health Center

Other Documents

- Stanford University. Office of Environmental Health and Safety. Comparing Different Disinfectants
Chapter 34: Biosafety

Review Procedure

1 Purpose

The purpose of procedure is to ensure work with biohazardous materials is performed safely. It covers the review and approval of work involving biohazardous materials. It applies to principal investigators, laboratory managers, ESH coordinators, the biosafety program manager, the Occupational Health Center, and the Stanford biosafety representative and Stanford Administrative Panel on Biosafety.

2 Procedures

Work involving biohazardous materials and/or recombinant DNA (rDNA) is classified by risk group and biosafety safety level (BSL). Only work classified as BSL 1 or 2 is currently permitted at SLAC. Work classified as BSL 3 or 4 is not permitted at SLAC as the site currently does not have the appropriate facilities to safely manage the hazards associated with this level of work. All work involving biohazardous material must be reviewed and approved as described below before beginning (with the exception of samples prepared off-site, see Section 2.1).

<table>
<thead>
<tr>
<th>Step</th>
<th>Person</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Principal investigator</td>
<td>Identifies the need to use a biohazardous material for an experiment</td>
</tr>
<tr>
<td>2.</td>
<td>Principal investigator</td>
<td>In collaboration with the Stanford biosafety representative, determines the appropriate risk group, based on the inherent risk of the biohazardous material. For guidance on risk groups, see the ABSA Risk Group Database. The biosafety program manager, ESH coordinator, and laboratory manager can provide assistance.</td>
</tr>
<tr>
<td>3.</td>
<td>Principal investigator</td>
<td>Assigns the biosafety level. Refer to the Biosafety Level Classification and Appendix A of the Stanford Biosafety Manual. The Stanford biosafety representative can provide assistance.</td>
</tr>
</tbody>
</table>
| 4.   | Principal investigator | Develops standard operating procedure (SOP) for the safe handling, storage, and disposal of the biohazardous material to be used. SOPs should cover:  
  - Training requirements  
  - Equipment/PPE requirements  
  - Procedure  
  - Hazards  
  - Handling/storage |
### Chapter 34 | Review Procedure

<table>
<thead>
<tr>
<th>Step</th>
<th>Person</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Principal investigator</td>
<td>Consults with ESH coordinator and laboratory manager on SOP. The biosafety program manager and Stanford biosafety representative can provide assistance.</td>
</tr>
<tr>
<td>6.</td>
<td>Principal investigator</td>
<td>Submits SOP to the laboratory manager and ESH coordinator for review and approval</td>
</tr>
<tr>
<td>7.</td>
<td>Laboratory manager and ESH coordinator</td>
<td>Review and approve SOP</td>
</tr>
<tr>
<td>8.</td>
<td>Principal investigator</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>For <strong>BSL 1 work</strong>, review is complete, goes to step 14</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For <strong>BSL 2 work</strong>, extracts necessary information from approved SOP and submits an application to the Stanford <em>Administrative Panel on Biosafety (APB)</em>, using the Stanford eProtocol system (see <em>Administrative Panel on Biosafety (APB) Review</em> for details). The Stanford biosafety representative and the biosafety program manager can provide assistance.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Important</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- The eProtocol submittal must be performed by a Stanford-approved principal investigator, including a SLAC principal investigator.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- The APB meets monthly, so adequate approval time must be allowed before the experiment. (See the Stanford Research Compliance Office, <em>Panel Meeting Dates and Deadlines</em> and <em>Time Needed for Protocol Approval</em>.)</td>
</tr>
<tr>
<td>9.</td>
<td>Stanford biosafety representative</td>
<td>Assists with the Stanford eProtocol submittal process</td>
</tr>
<tr>
<td>10.</td>
<td>Biosafety program manager</td>
<td>Attends APB meetings as SLAC’s representative to facilitate protocol application approval, if needed</td>
</tr>
<tr>
<td>11.</td>
<td>APB</td>
<td>Reviews and approves protocol application</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Applications may be approved conditionally (in case additional training, medical surveillance, and other measures are necessary). (In the case of a conditional approval, two notices are sent to the principal investigator, one upon approval and one upon final approval, after conditions have been met. Conditions are documented in the Stanford eProtocol system.)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- If an application is denied, the SOP and application must be revised and resubmitted.</td>
</tr>
<tr>
<td>12.</td>
<td>Principal investigator</td>
<td>Ensures any conditions are met (required medical surveillance, training, et cetera) before work may begin</td>
</tr>
<tr>
<td>13.</td>
<td>Laboratory manager and ESH coordinator</td>
<td>Verify that all APB applications have been approved by the APB and all conditions met before work is allowed to begin</td>
</tr>
<tr>
<td>14.</td>
<td>Principal investigator</td>
<td>Once SOP or APB application is approved, ensures experiment is performed in accordance with</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- SLAC’s work planning and control process (see <em>Chapter 2, “Work Planning and Control”</em>)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Standard biosafety work practices (see <em>Biosafety: General Requirements</em>)</td>
</tr>
</tbody>
</table>
### 2.1 Work Involving Samples Prepared Off-site

Samples of biological material prepared off-site are reviewed as follows:

1. The Stanford biosafety representative working with the relevant ESH coordinator reviews and approves the work to be done before the samples are brought on-site. Approval of work with BSL 2 samples is documented in the Stanford eProtocol system but no APB review is required.

2. The Stanford biosafety representative confirms information about the samples before work begins.

### 3 Forms

The following forms are required by this procedure:

- Stanford eProtocol Biosafety. System used for performing and documenting approval of BSL 2 protocols

### 4 Recordkeeping

The following recordkeeping requirements apply for this procedure:

- The principal investigator maintains approved SOPs and APB protocols and necessary biosafety documentation outside of APB application submittal. The approved SOPs and protocols must be available to the laboratory manager and laboratory personnel.

### 5 References

- [SLAC Environment, Safety, and Health Manual](SLAC-I-720-0A29Z-001)
  - Chapter 34, “Biosafety”
    - [Biosafety: General Requirements](SLAC-I-730-0A21S-061)
  - Chapter 2, “Work Planning and Control”

Other SLAC Documents

- [Biological Safety Program](SharePoint)
Other Documents

- Stanford University. Office of Environmental Health and Safety. *Biosafety Manual*
- Stanford University. *Administrative Panel on Biosafety (APB) Review*
- Stanford University. Stanford Research Compliance Office. *Panel Meeting Dates and Deadlines*
- Stanford University. Stanford Research Compliance Office. *Time Needed for Protocol Approval*
- American Biological Safety Association (ABSA). *Risk Group Database*
- Centers for Disease Control and Prevention and National Institutes of Health (CDC-NIH). *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, fifth edition. 2009
- National Institutes of Health (NIH). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*)