Chapter 34: **Biosafety**

## Review Procedure

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URL: [https://www-group.slac.stanford.edu/esh/eshmanual/references/biosafetyProcedReview.pdf](https://www-group.slac.stanford.edu/esh/eshmanual/references/biosafetyProcedReview.pdf)

### 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>
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<tbody>
<tr>
<td>1.</td>
<td>Principal investigator</td>
<td>Identifies the need to use a biohazardous material for an experiment</td>
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<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>
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<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>
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<td>4.</td>
<td>Principal investigator</td>
<td>Develops standard operating procedure (SOP) for the safe handling, storage, and disposal of the biohazardous material to be used. SOPs should cover</td>
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<td>- Training requirements</td>
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<td>- Equipment/PPE requirements</td>
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<td>- Procedure</td>
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<td>- Hazards</td>
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<td>- Handling/storage</td>
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### Step 5
**Principal investigator**
Consults with ESH coordinator and laboratory manager on SOP. The biosafety program manager and Stanford biosafety representative can provide assistance.

### Step 6
**Principal investigator**
Submits SOP to the laboratory manager and ESH coordinator for review and approval.

### Step 7
**Laboratory manager and ESH coordinator**
Review and approve SOP.

### Step 8
**Principal investigator**
For **BSL 1 work**, review is complete, goes to step 14
For **BSL 2 work**, extracts necessary information from approved SOP and submits an application to the Stanford Administrative Panel on Biosafety (APB), using the Stanford eProtocol system (see Administrative Panel on Biosafety (APB) Review for details). The Stanford biosafety representative and the biosafety program manager can provide assistance.

**Important**
- The eProtocol submittal must be performed by a Stanford-approved principal investigator, including a SLAC principal investigator.
- The APB meets monthly, so adequate approval time must be allowed before the experiment. (See the Stanford Research Compliance Office, Panel Meeting Dates and Deadlines and Time Needed for Protocol Approval.)

### Step 9
**Stanford biosafety representative**
Assists with the Stanford eProtocol submittal process.

### Step 10
**Biosafety program manager**
Attends APB meetings as SLAC’s representative to facilitate protocol application approval, if needed.

### Step 11
**APB**
Reviews and approves protocol application
- 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.)
- If an application is denied, the SOP and application must be revised and resubmitted.

### Step 12
**Principal investigator**
Ensures any conditions are met (required medical surveillance, training, et cetera) before work may begin.

### Step 13
**Laboratory manager and ESH coordinator**
Verify that all APB applications have been approved by the APB and all conditions met before work is allowed to begin.

### Step 14
**Principal investigator**
Once SOP or APB application is approved, ensures experiment is performed in accordance with
- SLAC’s work planning and control process (see Chapter 2, “Work Planning and Control”)
- Standard biosafety work practices (see Biosafety: General Requirements)
### 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. 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)