Immunization against Biosafety Hazards

Brief

<table>
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BRIEF

Policy Summary

Berkeley Lab encourages and promotes the safe use of vaccines to prevent occupational infections. The goal is to increase the safety of research with biological etiologic agents.

Note:

1. Bloodborne pathogens are covered in PUB-3000, Chapter 26, Section 26.5.4, Bloodborne Pathogens and Human Materials, due to different regulatory requirements. Immunizations against bloodborne pathogens are also offered under that policy.
2. Immunizations are also offered through the work-related Travel Medicine Program, which is part of the Health Promotion Program at Berkeley Lab.

Who Should Read This Policy

- All Laboratory employees at risk of infection with biological etiologic agents
- Members of the Laboratory’s Institutional Biosafety Committee (IBC)
- The Laboratory Biosafety Officer
- The Laboratory Medical Director
- Laboratory work leads or managers conducting research with biological etiologic agents, or using environmental samples reasonably suspected of containing biological etiologic agents

To Read the Full Policy, Go To:

The POLICY tab on this wiki page

To Read the EH&S Program Details, Go To:

- http://www.lbl.gov/ehs/pub3000/CH03.html

Contact Information

Laboratory Medical Director
Pedro Estacio, MD
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or

Health Services Program Manager
Sue Broadway
Policy

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POLICY

A. Purpose

Lawrence Berkeley National Laboratory (Berkeley Lab) encourages and promotes the safe use of vaccines to prevent occupational infections. The goal is to increase the safety of research with biological etiologic agents.

Note:

1. Bloodborne pathogens are covered in PUB-3000, Chapter 26, Section 26.5.4, Bloodborne Pathogens and Human Materials, due to different regulatory requirements. Immunizations against bloodborne pathogens are also offered under that policy.
2. Immunizations are also offered through the work-related Travel Medicine Program, which is part of the Health Promotion Program at Berkeley Lab.

B. Persons Affected

- All Laboratory employees at risk of infection with biological etiologic agents
- Members of the Laboratory's Institutional Biosafety Committee (IBC)
- The Laboratory Biosafety Officer
- The Laboratory Medical Director
- Laboratory work leads or managers conducting research with biological etiologic agents, or using environmental samples reasonably suspected of containing biological etiologic agents

C. Exceptions

None

D. Policy Statement

1. See the Biosafety Manual for:
   a. Pre-approval of work with biological agents
   b. Internal procedures of the Institutional Biosafety Committee (IBC)
2. The IBC is required to:
   a. Invite the Laboratory Medical Director to all IBC meetings
   b. Solicit immunization recommendations of the Laboratory Medical Director.
      i. When the SOMD or his/her designee is not present at IBC meetings, the Laboratory Biosafety Officer is responsible for getting the SOMD's recommendations.
3. The following events trigger an appointment with Health Services to evaluate an employee's exposure to biohazards:
a. A vaccine is recommended by the SOMD as potentially protective for a given exposure.

b. Medical evaluations are needed to determine whether immunizations are appropriate or personal medical conditions are contraindicated for working with biological etiologic agents.

4. Principal investigators or employees should call Health Services to schedule the appointment for 3.a or 3.b, above. At that appointment, Health Services will determine whether the risks of exposure are sufficient to warrant vaccination.

5. Health Services will provide information to the employee about the characteristics of the vaccine and whether the vaccine's potential benefits outweigh its risks.

6. The recommendation for vaccine usage may only apply to subgroups of employees, based on their health status and/or the contraindications of the vaccine.

7. Recommended vaccines are provided at no cost to the employee.

8. Medical records must be maintained for vaccinated employees in accordance with medical record guidelines.

E. Roles and Responsibilities

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<th>Responsibility</th>
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| Work leads or safety line managers (conducting research using biological etiologic agents) | • Ensure that research with biohazardous materials or agents is documented, reviewed, and preauthorized by the Institutional Biosafety Committee prior to beginning work  
• Ensure that workers complete the Job Hazards Analysis process  
• Ensure that safety controls (e.g., immunizations) are implemented prior to the start of work  
• Direct their workers to attend appointments in Health Services for health evaluations and/or immunization when advised by the Biological Use Authorization  
• Assist Health Services in arranging appointments for affected managers and their workers  
• Prevent workers, students, and affiliates from working with biological etiologic agents until the employees are approved for such work by Health Services |
| Institutional Biosafety Committee (IBC)            | • Reviews proposed work with biohazardous materials and/or biological etiologic agents in accordance with PUB-3000 Chapter 26 and the Laboratory Biosafety Manual  
• Seeks input from the Laboratory Medical Director or the Laboratory Medical Director designee on ways to reduce the risk of infection, when protocols anticipate work with biological etiologic agents or unknown environmental samples reasonably suspected of containing biological etiologic agents. This input includes the availability and advisability of the use of vaccines in preventing occupational infections. Normally, this input is received during the Institutional Biosafety Committee meeting. |
| Biosafety Officer                                  | • Ensures that every protocol reviewed by the Biosafety Committee is reviewed by the Laboratory Medical Director or Laboratory Medical Director designee for consideration of the use of vaccines to protect the workers  
• Refers to the SOMD and applicable Institutional Biosafety Committee standards or guidelines regarding vaccination relative to the proposed work |
| Laboratory Medical Director                       | • Consults with the Laboratory Biosafety Officer, Institutional Biosafety Committee, and others to evaluate the risk of occupational infection from Laboratory research using biohazardous materials or biological etiologic agents  
• Identifies and reviews applicable standards or guidelines regarding vaccination relative to the proposed work  
• Recommends for or against the use of vaccination for some or all workers as a means to reduce the risk of occupational infection  
• Serves as the Laboratory Subject Matter Expert on health aspects of the Laboratory’s vaccination policy and its application to specific work and workers  
• Recommends other means, as appropriate, for reducing the risk of occupational infection |
F. Definitions/Acronyms

See PUB-3000 Chapter 3 and Chapter 26 for technical terms related to the details of this policy and its implementation.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Biological Etiologic Agent</td>
<td>A microorganism, virus, or toxic protein (biologic toxin or prion) known to cause human disease</td>
</tr>
<tr>
<td>Biohazardous Material</td>
<td>Environmental materials reasonably suspected of containing biological etiologic agent(s)</td>
</tr>
<tr>
<td>Workers at Risk of Infection with Biological Etiologic</td>
<td>Laboratory employees, affiliates, or students working with biological etiologic agents in a manner</td>
</tr>
<tr>
<td>Agents</td>
<td>that may expose them to the risk of infection from the organism/protein</td>
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G. Recordkeeping Requirements

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<tr>
<td>Health Services</td>
<td>Maintains medical records for vaccinated employees in accordance with medical record guidelines</td>
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<tr>
<td>Biosafety Officer</td>
<td>Records that immunization recommendations have been developed during the biosafety protocol review. The immunization recommendations will be attached to the approved protocol.</td>
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H. Implementing Documents

<table>
<thead>
<tr>
<th>Document Number</th>
<th>PUB-3000 Reference</th>
<th>Title</th>
<th>Type</th>
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<td>02.13.002.001</td>
<td>Chapter 3</td>
<td>Health Services</td>
<td>Program</td>
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<tr>
<td>07.07.004.001</td>
<td>Chapter 26</td>
<td>Biosafety</td>
<td>Program</td>
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I. Contact Information

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J. Revision History
Document Information

DOCUMENT INFORMATION

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<tr>
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<td>11/30/2008</td>
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<td>Next review date:</td>
<td>7/24/2016</td>
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<td>Health Services Programs</td>
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<td>ESH</td>
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<td>Functional Division</td>
<td>EH&amp;S</td>
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<td>PUB-3000, Chapters 3 and 26</td>
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Source Requirements Documents

10 CFR 851, Appendix A, Worker Safety and Health Functional Areas

Implementing Documents

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