Human Subjects Research

Brief

<table>
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<tr>
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<tbody>
<tr>
<td>Publication date</td>
<td>1/23/2013</td>
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BRIEF

Policy Summary

All Berkeley Lab research involving human participants must safeguard participants’ welfare, privacy, and rights as specified under the guiding federal regulation, 45 CFR 46, known as the Common Rule.

Who Should Read This Policy

- Employees, affiliates (formerly known as “guests”), visitors, and subcontractors whenever they propose or conduct research that involves human participants (or human-derived data, tissues, fluids, or other materials)
- The Institutional Official for human research; members of the Institutional Review Board, known at Berkeley Lab as the Human Subjects Committee (HSC); and the staff of the Human and Animal Regulatory Committees (HARC) Office

To Read the Full Policy, Go To:

The POLICY tab on this wiki page

Contact Information

Human and Animal Regulatory Committees Office
HARC@lbl.gov
(510) 486-5399

Policy

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POLICY

A. Purpose

All research at Lawrence Berkeley National Laboratory (Berkeley Lab) involving human participants must safeguard participants’ welfare, privacy, and rights as specified under the guiding federal regulation, 45 CFR 46, known as the Common Rule.

B. Persons Affected

- Berkeley Lab employees, affiliates (formerly known as “guests”), visitors, and subcontractors whenever they propose or conduct research that involves human participants (or human-derived material such as data, tissues, or fluids)
- The Institutional Official for human research; members of the Institutional Review Board, known at Berkeley Lab as the Human Subjects Committee (HSC); and the staff of the Human and Animal Regulatory Committees (HARC) Office, which supports the HSC and the Human Subjects Protection Program as a whole

C. Exceptions

Not applicable
D. Policy Statement

All Berkeley Lab research involving human participants must safeguard participants’ welfare, privacy, and rights as specified under the guiding federal regulation, 45 CFR 46, known as the Common Rule, including, where applicable, Subparts B, C, and/or D. This requirement derives from a Department of Energy (DOE) order and Department of Health and Human Services policy. To ensure that this requirement is met:

1. All protocols for research involving human participants performed at or funded through Berkeley Lab must be submitted to and formally approved by the HSC prior to initiation, and
2. All work with human participants must follow the approved protocol.

The Laboratory can terminate research that is not conducted in accordance with HSC decisions, conditions, and requirements or that has been associated with unexpected serious harm to subjects.

E. Roles and Responsibilities

<table>
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<tr>
<th>Role</th>
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| Human subjects researcher, including employees, affiliates (formerly known as “guests”), visitors, and subcontractors who propose or conduct research that involves human participants or human-derived material such as data, tissues, or fluids | • Safeguards the welfare, privacy, and rights of human subjects who take part in the research experiment  
• Completes required training: EHS0740  
• Develops protocols for and obtains HSC approval  
• Ensures that staff working under the protocol(s) are trained  
• Follows approved protocols, files renewals in a timely fashion, and promptly reports adverse/unexpected/reportable events to the HSC |
| Human Subjects Committee (HSC) | • Establishes and maintains a Federalwide Assurance of Compliance  
• Under the direction of the Chair, determines whether a given project constitutes human subjects research  
• Reviews research proposals to ensure the protection of human subjects  
• Monitors ongoing human subjects research for participant safety and fair treatment  
• Educates Berkeley Lab human subjects researchers as needed  
• Reports unanticipated problems and adverse events to the Institutional Official and Laboratory Director  
• Recommends changes in Laboratory policy relevant to human subjects research to the Institutional Official  
• Certifies to funding agencies, the Office of Sponsored Partnerships & Industry Partnerships, and/or DOE that research has been reviewed and approved by the Institutional Review Board  
• Provides a contact for subjects of approved studies to answer their questions and address their concerns |
| Institutional Official for Human Subjects Protection | • Signs the Federalwide Assurance of Compliance on behalf of the Laboratory  
• Appoints members to the HSC  
• Suspends or terminates research that is not conducted in accordance with HSC decisions, conditions, and requirements or that has been associated with unexpected serious harm to subjects  
• Approves changes in Laboratory policy relevant to human subjects research  
• Ensures support to the HSC and HARC Office sufficient to carry out their responsibilities |
| Human and Animal Regulatory Committees (HARC) Staff | • Facilitate and support the HSC, researchers, and the Institutional Official in carrying out their responsibilities  
• Oversees the HARP database |

F. Definitions/Acronyms

<table>
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<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Human subject</td>
<td>A living person about whom a researcher obtains (1) data through intervention or interaction or (2) identifiable private information</td>
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<tr>
<td>Common Rule</td>
<td>45 CFR 46, the section of the Code of Federal Regulations that lays out the federal policy for the protection of human subjects</td>
</tr>
<tr>
<td>Institutional Review Board</td>
<td>A board or committee authorized by a federal assurance to review research with human participants. The HSC is the Berkeley Lab Institutional Review Board.</td>
</tr>
<tr>
<td>Institutional Official for human subjects research</td>
<td>The Berkeley Lab official who signs the Federalwide Assurance of Compliance committing the institution to following the regulations laid out at in 45 CFR 46 (known as the Common Rule) and Subparts B, C, and D</td>
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<tr>
<td>Federalwide Assurance of Compliance</td>
<td>The written, binding agreement submitted to the Department of Health and Human Services in which the institution commits to complying with regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved</td>
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Human/Animal Research Protocol Management System (HARP)  
The system housing online "smart" forms that lead researchers through protocol application, renewal, amendment, and adverse/unexpected event reporting processes

### G. Recordkeeping Requirements
None

### H. Implementing Documents

<table>
<thead>
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<th>Document Number</th>
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<th>Document Title</th>
<th>Type</th>
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<tr>
<td>n/a</td>
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<td>Human/Animal Research Protocol (HARP)</td>
<td>Web site</td>
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<tr>
<td>03.02.002.001</td>
<td>PUB-3000 Chapter 22</td>
<td>Research with Human and Animal Subjects</td>
<td>Program</td>
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<tr>
<td>n/a</td>
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<td>Human Subjects Committee Charter</td>
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<tr>
<td>n/a</td>
<td>n/a</td>
<td>Human Subjects Protection Program, Federalwide Assurance of Compliance</td>
<td>Compliance document</td>
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### I. Contact Information

Human and Animal Regulatory Committees Office  
HARC@lbl.gov  
(510) 486-5399

### J. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision</th>
<th>By whom</th>
<th>Revision Description</th>
<th>Section(s) affected</th>
<th>Change Type</th>
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<tr>
<td>1/2/2012</td>
<td>0</td>
<td>C. Byrne</td>
<td>Brief for wiki</td>
<td>All</td>
<td>Minor</td>
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<tr>
<td>1/23/2013</td>
<td>1</td>
<td>C. Byrne</td>
<td>Full policy reformatted</td>
<td>All</td>
<td>Minor</td>
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### Document Information

**DOCUMENT INFORMATION**

- **Title:** Human Subjects Research
- **Document number:** 03.02.002.000
- **Revision number:** 1
- **Publication date:** 1/23/2013
- **Effective date:** 12/2001
- **Next review date:** 1/23/2016
- **Policy Area:** Human and Animal Subjects Research
- **RPM Section (home):** Conduct of R&D
- **RPM Section (cross-reference):** None
- **Functional Division:** Office of Institutional Assurance
- **Prior reference information (optional):** PUB-3000, Section 22.1

### Source Requirements Documents

- *DOE O 443.1B, Protection of Human Research Subjects*

### Other Driving Requirements

- *The Belmont Report*
Implementing Documents

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Other References

- Criteria for the Approval of Human Subjects Research
- Full or Initial Review Process
- Expedited Protocol Review Process
- Continuing Review, or Renewal Process
- Changing, Amending, Modifying an Approved Protocol
- Treatment and Compensation for Research-Related Injury
- Dealing with Adverse Events