Research with Vertebrate Animals

Brief

<table>
<thead>
<tr>
<th>Title:</th>
<th>Research with Vertebrate Animals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publication date:</td>
<td>10/3/2013</td>
</tr>
<tr>
<td>Effective date:</td>
<td>10/3/2013</td>
</tr>
</tbody>
</table>

BRIEF

Policy Summary

All Berkeley Lab research involving vertebrate animals must be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, and the Animal Welfare Act.

Who Should Read This Policy

- Employees, affiliates (formerly known as "guests"), visitors, and subcontractors whenever they propose or conduct research that involves vertebrate animals (or vertebrate-animal-derived materials such as antibodies or tissues)
- The Institutional Official for animal welfare, members of the Institutional Animal Care and Use Committee (IACUC) known at Berkeley Lab as the Animal Welfare and Research Committee (AWRC), 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

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

Policy

<table>
<thead>
<tr>
<th>Title:</th>
<th>Research with Vertebrate Animals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publication date:</td>
<td>10/3/2013</td>
</tr>
<tr>
<td>Effective date:</td>
<td>10/3/2013</td>
</tr>
</tbody>
</table>

POLICY

A. Purpose

All Berkeley Lab research involving vertebrate animals must be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, and the Animal Welfare Act.

B. Persons Affected

- Berkeley Lab employees, affiliates (formerly known as "guests"), visitors, and subcontractors whenever they propose or conduct research that involves vertebrate animals (or vertebrate-animal-derived materials such as antibodies or tissues)
- The Institutional Official for animal welfare; members of the Institutional Animal Care and Use Committee (IACUC) known at Berkeley Lab as the Animal Welfare and Research Committee (AWRC); and the staff of the Human and Animal Regulatory Committees (HARC) Office, which supports the AWRC

C. Exceptions
D. Policy Statement

All Berkeley Lab research involving vertebrate animals must be conducted in accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), the Guide for the Care and Use of Laboratory Animals, and the Animal Welfare Act. This requirement derives from Department of Health and Human Services policy and federal law.

To ensure that this requirement is met:

1. All protocols for research involving vertebrate animals performed at or funded through Berkeley Lab must be submitted to and formally approved by the Animal Welfare and Research Committee prior to initiation and
2. All work with vertebrate animals must follow the approved protocol

The Laboratory can terminate research that is not conducted in accordance with AWRC decisions, conditions, and requirements, or that has been associated with pain or distress beyond the level anticipated in the protocol and/or unanticipated experimental outcomes.

E. Roles and Responsibilities

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibility</th>
</tr>
</thead>
</table>
| Researchers using animals (including employees, affiliates (formerly known as "guests"), visitors, and subcontractors who propose or conduct research that involves animals or animal-derived material such as antibodies or tissues) | - Safeguard the welfare of animals used in their research  
- Complete required Ethical Training for researchers at LBNL  
- Develop protocols for and obtain AWRC approval  
- Ensure that staff working under the protocol(s) are trained  
- Follow approved protocols, file renewals in a timely fashion, and promptly report problems to the AWRC |
| Animal Welfare and Research Committee (AWRC) | - Establishes and maintains an Animal Welfare Assurance with the U.S. Department of Health and Human Services Office of Laboratory Animal Welfare  
- Conducts a semiannual facility inspection and animal welfare program review  
- Reviews research proposals to ensure the protection of animals used in research  
- Monitors ongoing animal research  
- Educates Berkeley Lab researchers using animals as needed  
- Reports unanticipated problems and adverse events to the Institutional Official and Laboratory Director  
- Recommends changes in Laboratory policy relevant to research-animal welfare to the Institutional Official  
- Certifies to funding agencies and/or the Office of Sponsored Partnerships & Industry Partnerships that research has been reviewed and approved by the Institutional Animal Care and Use Committee |
| Attending Veterinarian | - Oversees all activities involving animals at Berkeley Lab  
- Conducts routine inspections and monitors ongoing animal research  
- Consults with and provides training for animal care and research staff as needed  
- Serves as a member of the IACUC  
- Temporarily suspends or interrupts research that is not conducted in accordance with AWRC decisions, conditions, and requirements or that has been associated with unexpected experimental failure or suffering to animals  
- Recommends changes in Laboratory policy relevant to research animal welfare to the AWRC and/or the Institutional Official |
| Institutional Official for animal welfare | - Signs the Animal Welfare Assurance on behalf of the Laboratory  
- Receives the semiannual inspection and program review report from the AWRC  
- With the AWRC Chair, signs the annual report to the Office of Laboratory Animal Welfare  
- Appoints members to the AWRC  
- Suspends or terminates research that is not conducted in accordance with AWRC decisions, conditions, and requirements or that has been associated with unexpected failure or suffering to animals  
- Approves changes in Laboratory policy relevant to research involving animals  
- Ensures support to the AWRC, the Attending Veterinarian and the HARC Office sufficient to carry out their responsibilities |
| Human and Animal Regulatory Committees (HARC) Staff | - Facilitate and support the AWRC, researchers, and the Institutional Official in carrying out their responsibilities  
- Oversees the Human/Animal Research Protocol Management System (HARP) |

F. Definitions/Acronyms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal</td>
<td>Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.</td>
</tr>
<tr>
<td>PHS Policy</td>
<td>Public Health Service Policy on Humane Care and Use of Laboratory Animals; the implementing guidance for federally funded research involving animals</td>
</tr>
</tbody>
</table>
Guide for the Care and Use of Laboratory Animals

The Guide is published by the National Research Council of the National Academies and defines the framework for a compliant animal care and use program.

Animal Welfare Act


Institutional Animal Care and Use Committee (IACUC)

A board or committee authorized by a federal assurance to review research involving animals. The AWRC is the Berkeley Lab Institutional Animal Care and Use Committee.

Institutional Official for animal welfare

The Berkeley Lab official who signs the Animal Welfare Assurance, committing the institution to following the Public Health Service (PHS) Policy on Humane Care and Use of Animals.

Animal Welfare Assurance

The written, binding agreement submitted to the Department of Health and Human Services in which the institution commits to complying with regulations governing the use of animals in research and stipulates the procedures through which compliance will be achieved.

Human/Animal Research Protocol Management System (HARP)

The system housing online "smart" forms that lead researchers through protocol application, renewal, modification, and adverse/unexpected event reporting processes.

G. Recordkeeping Requirements

<table>
<thead>
<tr>
<th>Responsible Party</th>
<th>Record</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Welfare and Research Committee (AWRC)</td>
<td>Conducts a semiannual facility inspection and animal welfare program review, and reports the outcome to the Institutional Official</td>
</tr>
<tr>
<td>Institutional Official and AWRC Chair</td>
<td>Reports annually to the PHS Office of Laboratory Animal Welfare on the status of the animal welfare program</td>
</tr>
</tbody>
</table>

H. Implementing Documents

<table>
<thead>
<tr>
<th>Document Number</th>
<th>Document Title</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>n/a</td>
<td>Human/Animal Research Protocol Management System (HARP)</td>
<td>Web site</td>
</tr>
<tr>
<td>n/a</td>
<td>Animal Welfare and Research Committee Short Renewal Form</td>
<td>Form</td>
</tr>
<tr>
<td>n/a</td>
<td>Animal Welfare and Research Committee Protocol Personnel Form (PPF)</td>
<td>Form</td>
</tr>
<tr>
<td>03.02.002.001</td>
<td>Research with Human and Animal Subjects</td>
<td>Program</td>
</tr>
<tr>
<td>n/a</td>
<td>Animal Welfare and Research Committee Charter</td>
<td>Charter</td>
</tr>
<tr>
<td>n/a</td>
<td>Animal Welfare Assurance</td>
<td>Compliance document</td>
</tr>
</tbody>
</table>

I. Contact Information

Animal Welfare and Research Committee
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>
</tr>
</thead>
<tbody>
<tr>
<td>1/2/2012</td>
<td>0</td>
<td>C. Byrne</td>
<td>Brief for wiki</td>
<td>All</td>
<td>Minor</td>
</tr>
<tr>
<td>10/3/2013</td>
<td>1</td>
<td>C. Byrne</td>
<td>Policy for wiki</td>
<td>All</td>
<td>Minor</td>
</tr>
</tbody>
</table>

Document Information

DOCUMENT INFORMATION
Title: Research with Vertebrate Animals

Document number 03.02.003.000

Revision number 1

Publication date: 10/3/2013

Effective date: 10/3/2013

Next review date: 10/3/2013

Policy Area: Human and Animal Subjects Research

RPM Section (home) Conduct of R&D

RPM Section (cross-reference) none

Functional Division OIA

Prior reference information (optional) PUB-3000, Chapter 22, Section 22.3

Source Requirements Documents

- Title 7 U.S.Code, Chapter 54, Transportation, Sale and Handling of Certain Animals, The Animal Welfare Act

Other Driving Requirements

- Public Health Service Policy on Humane Care and Use of Laboratory Animals, 2002
- Guide for the Care and Use of Laboratory Animals, Eighth Edition

Implementing Documents

<table>
<thead>
<tr>
<th>Document Number</th>
<th>Document Title</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>n/a</td>
<td>Human/Animal Research Protocol Management System (HARP)</td>
<td>Web site</td>
</tr>
<tr>
<td>n/a</td>
<td>Animal Welfare and Research Committee Short Renewal Form</td>
<td>Form</td>
</tr>
<tr>
<td>n/a</td>
<td>Animal Welfare and Research Committee Protocol Personnel Form (PPF)</td>
<td>Form</td>
</tr>
<tr>
<td>03.02.002.001</td>
<td>Research with Human and Animal Subjects</td>
<td>Program</td>
</tr>
<tr>
<td>n/a</td>
<td>Animal Welfare and Research Committee Charter</td>
<td>Charter</td>
</tr>
<tr>
<td>n/a</td>
<td>Animal Welfare Assurance</td>
<td>Compliance document</td>
</tr>
</tbody>
</table>