Research with Radioactive Drugs in Human Subjects

Brief

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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, the Common Rule. Research involving experimental radioactive drugs in humans must additionally follow the guiding regulations laid out at 21 CFR 361.1, *Radioactive Drugs for Certain Research Uses*.

Who Should Read This Policy

- Employees, affiliates (formerly known as "guests"), visitors, and subcontractors whenever they propose or conduct research that involves the use of applicable experimental radioactive drugs in human participants
- The Institutional Official for human research, members of the Radioactive Drug Research Committee (RDRC), 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

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

Policy

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POLICY

A. Purpose

All Lawrence Berkeley National Laboratory (Berkeley Lab) research involving human participants must safeguard participants' welfare, privacy, and rights as specified under the guiding federal regulation, 45 CFR 46, the Common Rule. Research involving experimental...
radioactive drugs in humans must additionally follow the guiding regulations laid out at 21 CFR 361.1, *Radioactive Drugs for Certain Research Uses*.

**B. Persons Affected**

- Employees, affiliates (formerly known as "guests"), visitors, and subcontractors whenever they propose or conduct research that involves the use of experimental radioactive drugs in human participants
- The Institutional Official for human research, members of the Radioactive Drug Research Committee (RDRC), and the staff of the Human and Animal Regulatory Committees (HARC) Office, which supports the RDRC and the Human Subjects Protection Program as a whole

**C. Exceptions**

Research involving experimental radioactive drugs in human subjects where all the drugs used in the research are either approved by the Food and Drug Administration (FDA), or listed in the current *United States Pharmacopeia*, or are covered by an FDA-approved Investigational New Drug (IND) exemption

**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, the Common Rule. Research including the administration to humans of experimental radioactive drugs not subject to the exception noted above in Section C, Exceptions, must additionally follow the guiding regulations laid out in 21 CFR 361.1. These requirements derive from a Department of Energy (DOE) order and Department of Health and Human Services regulations. To ensure that these requirements are 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 Human Subjects Committee (HSC) and, when applicable, the RDRC 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 and RDRC decisions, conditions, and requirements, or that has been associated with unexpected serious harm to subjects.

**E. Roles and Responsibilities**

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibility</th>
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</table>
| Human subjects researcher, including employees, affiliates (formerly known as "guests"), visitors, and subcontractors who propose or conduct research that includes the use of experimental radioactive drugs in human participants | • Safeguards the welfare, privacy, and rights of human subjects who take part in the research experiment  
• Completes required training: EHS0740, *Human Subjects Research Training*  
• Develops protocols for and obtains HSC and RDRC approval  
• Ensures that staff working under the protocol(s) are trained  
• Follows approved protocols, files quarterly reports and renewals in a timely fashion, and promptly reports adverse/unexpected/reportable events to the HSC and RDRC |
<table>
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<tr>
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<tr>
<td>Human Subjects Committee (HSC)</td>
<td>- In addition to their responsibilities under the Human Subjects Research policy, verifies that RDRC approval has been obtained for studies involving the administration of radioactive drugs to human participants</td>
</tr>
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</table>
| Institutional Official for Human Subjects Protection | - Appoints members to the RDRC  
-Suspends or terminates research that is not conducted in accordance with RDRC decisions, conditions, and requirements, or that has been associated with unexpected serious harm to subjects  
- Approves changes in Laboratory policy relevant to research involving the use of experimental radioactive drugs in human participants  
- Ensures support to the RDRC and HARC Office sufficient to carry out their responsibilities |
| Radioactive Drug Research Committee            | - Determines whether a given project falls within the purview of the RDRC  
- Reviews protocols for research with radioactive drugs in human participants  
- Ensures compliance with 21 CFR 361.1  
- Reviews the quarterly dose summaries for individual subject-studies  
- Reports annually and more often when needed to the Food and Drug Administration about activities carried out under the authority of 21 CFR 361.1 |
| RDRC Chair                                     | - Signs annual and special reports to the FDA on behalf of the RDRC |
| Human and Animal Regulatory Committees (HARC) Staff | - Facilitates and supports the RDRC, researchers, and the Institutional Official in carrying out their responsibilities  
- Oversees the Human/Animal Research Protocol Management System (HARP) database  
- Maintains physical files of RDRC records |

### F. Definitions/Acronyms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<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>
</tr>
<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>
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<tr>
<td><strong>Institutional Review Board</strong></td>
<td>A board or committee authorized by a federal assurance to review research with human participants. The Human Subjects Committee (HSC) is the Berkeley Lab Institutional Review Board.</td>
</tr>
<tr>
<td><strong>Radioactive Drug Research Committee</strong></td>
<td>A board or committee authorized by the Food and Drug Administration responsible for the review and approval of research protocols involving the administration or use of radioactive drugs in human subjects.</td>
</tr>
<tr>
<td><strong>Institutional Official for human subjects research</strong></td>
<td>The Berkeley Lab official who signs the Federal-wide Assurance of Compliance committing the institution to following the regulations laid out in 45 CFR 46 (known as the Common Rule) and Subparts B, C, and D.</td>
</tr>
<tr>
<td><strong>Federal-wide Assurance of Compliance</strong></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>
</tr>
<tr>
<td><strong>Human/Animal Research Protocol Management System (HARP)</strong></td>
<td>The Berkeley Lab system housing online &quot;smart&quot; forms that lead researchers through protocol application, renewal, amendment, and adverse/unexpected event reporting processes.</td>
</tr>
<tr>
<td><strong>Drug</strong></td>
<td>(1) Articles recognized in the <em>United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States</em>, or the <em>National Formulary</em>, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.</td>
</tr>
<tr>
<td><strong>Radioactive drug or radiotracer</strong></td>
<td>Radioactive drugs or biological products labeled with a radionuclide.</td>
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<tr>
<td><strong>Experimental radioactive drug</strong></td>
<td>A radioactive drug not listed in the <em>United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States</em>, or the <em>National Formulary</em>, or any supplement to any of them.</td>
</tr>
<tr>
<td><strong>Subject-study</strong></td>
<td>An instance of a radioactive drug being administered to a subject under an approved protocol.</td>
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### G. Recordkeeping Requirements

| **FDA Form 2914** | Radioactive Drug Research Committee Membership Summary: Prepared by the HARC staff and filed by the RDRC Chair annually (as part of the Annual Report) and whenever there is a membership change on the Committee. |
| **FDA Form 2915** | Radioactive Drug Research Committee Report on the Research Use of Radioactive Drugs Study Summary: Filed quarterly by investigators with the RDRC to detail the actual subject-studies conducted during the previous quarter under each protocol approved for the use of experimental drugs. Filed by the RDRC with the FDA whenever the RDRC approves a research protocol meeting certain conditions established in 21 CFR 361.1. |
| **Annual Report** | An annual summary filed with the FDA by the RDRC Chair, containing a written summary of approved protocols, Form 2914, and Form(s) 2915 detailing the subject-studies conducted under each protocol approved for the use of experimental drugs at any time during the calendar year of the report. |

### H. Implementing Documents

- Protocols for research with experimental radioactive drugs in human subjects are submitted through the Human and Animal
Research Protocol (HARP) on-line 'smart' protocol form that leads researchers through the application process. Details on getting started in HARP, including the initial step of establishing an account, can be found on the Human Subjects Committee website at [http://www.lbl.gov/ehs/health_services/harc/hsc.shtml](http://www.lbl.gov/ehs/health_services/harc/hsc.shtml)

- ES&H Manual Research with Human and Animal Subjects program
- Human Subjects Committee (HSC) Guidelines — Reviewing Protocols Involving the Use of Ionizing Radiation
- Assurance of Compliance

I. Contact Information

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

J. Revision History

<table>
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<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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<td>3/21/2014</td>
<td>1</td>
<td>C. Byrne</td>
<td>Full policy reformatted</td>
<td>All</td>
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Document Information

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<tbody>
<tr>
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<tr>
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<td>3/21/2014</td>
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<td>Effective date:</td>
<td>12/2001</td>
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<td>3/21/2017</td>
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<td>Human and Animal Subjects Research</td>
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<td>Conduct of R&amp;D</td>
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<td>Functional Division</td>
<td>Office of Institutional Assurance</td>
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Source Requirements Documents

- 21 CFR 361.1, Radioactive Drugs for Certain Research Uses

Other Driving Requirements

Lawrence Berkeley National Laboratory. The official or current version is located in the online LBNL Requirements and Policies Manual. Printed or exported versions are not official. Users are responsible for working with the latest approved revision.
### Implementing Documents

<table>
<thead>
<tr>
<th>Document Number</th>
<th>Other Reference Number</th>
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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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<td>Human Subjects Committee (HSC) Guidelines</td>
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<td>Reviewing Protocols Involving the Use of Ionizing Radiation</td>
<td>Procedure</td>
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<td>n/a</td>
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<td>Human and Animal Research Protocol (HARP) system online “smart” protocol form</td>
<td>Website</td>
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<tr>
<td>FDA Form 2914</td>
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<td>Radioactive Drug Research Committee (RDRC) Report on Research Use of Radioactive Drugs — Membership Summary</td>
<td>Form</td>
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<tr>
<td>FDA Form 2915</td>
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<td>Radioactive Drug Research Committee (RDRC) Report on Research Use of Radioactive Drugs — Study Summary</td>
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### Other References

- Assurance of Compliance