

Submission#: 25410
FWA#: FWA00006253
Name#: Lawrence Berkeley Natl Lab

OMB No. 0990-0278
Approved for use through May 31, 2011

**Federalwide Assurance (FWA) for the Protection of Human
Subjects for Institutions Within the United States
Update or Renewal for FWA Number: FWA00006253**

1. Institution Filing Assurance

Name of Organization: Lawrence Berkeley Natl Lab

City: Berkeley State: CA

HHS Institution Profile File (IPF) code, if known: 577512

Federal Entity Identification Number (EIN), if known: 942951741

If this Assurance replaces an MPA or CPA, please provide the "M" or "T" number:

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates. The Institution should have available for review by the Office for Human Research Protections (OHRP) upon request a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the Institutional Review Board(s) (IRB), IRB support staff, and investigators in these various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below. Entities that the Signatory Official is not legally authorized to represent may not be listed here without the prior approval of OHRP.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)
Berkeley, LBNL	BERKELEY	CA

3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of the source of support, will be guided by the ethical principles in the following document(s): *(indicate below)*

The Belmont Report

4. Applicability

(a) This Institution assures that whenever it engages in human subjects research conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the Institution will comply with the [Terms of the Federalwide Assurance for Institutions Within the United States (contained in a separate document on the OHRP website),] unless the research is otherwise exempt from the requirements of the Common Rule or a department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance.

(b) Optional: This Institution elects to apply the following to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance:

The Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46

5. Designation of Institutional Review Boards (IRBs)

This Institution designates the following IRB(s)/IEC(s) for review of research under this Assurance (*if the IRB(s)/IEC(s) has not previously registered with HHS or has not provided a membership roster to HHS, please submit to OHRP the appropriate IRB registration materials which are available on the OHRP website*).

NOTE: Reliance on the IRB of another institution or organization or an independent IRB must be documented by a written agreement that is available for review by OHRP upon request. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the parties involved may develop their own agreement. Future designation of other IRBs requires an update of the FWA.

HHS IRB Registration Number	Name of IRB as Registered with HHS
IRB00000172	U of California Los Angeles-MIRB1 General Biomedical IRB #1 - General Biomedical
IRB00000173	U of California Los Angeles-MIRB2 Cancer/Infectious Disease IRB #2
IRB00000174	U of California Los Angeles-North General Social-Behavior IRB #3
IRB00000195	U of California Riverside IRB #1 - Social/Behavioral
IRB00000229	Parnassus Committee IRB #1
IRB00000230	San Francisco General Hosp (SFGH) Committee IRB #2
IRB00000266	U California Santa Cruz IRB #1

IRB00000307 U California Santa Barbara IRB #1
 IRB00000353 U of California San Diego IRB #1B - Committee B
 IRB00000354 U of California San Diego IRB #1A - Committee A
 IRB00000355 U of California San Diego IRB #2 - Committee S
 IRB00000393 U of California, Irvine IRB #1 - Biomedical
 IRB00000394 U of California, Irvine IRB #2 - Biomedical
 IRB00000395 U of California, Irvine IRB #3 - Social Behavioral
 IRB00000425 Clinical Committee A - UC Davis
 IRB00000426 Clinical Committee B - UC Davis
 IRB00000455 U of California Berkeley IRB #1 - CPHS-I
 IRB00002758 U of California San Diego IRB #4 - Committee C
 IRB00003023 Social & Behavioral Committee -C, UC Davis
 IRB00003471 Laurel Heights Committee(Lhts) IRB #3
 IRB00004473 U of California Los Angeles-Neuroscience MIRB3 IRB #4
 IRB00004474 U of California Los Angeles-South General IRB #5
 IRB00005096 U of California San Francisco IRB #4 - Mt. Zion
 IRB00005274 Clinical Committee D - UC Davis
 IRB00005610 U of California Berkeley IRB #2 - CPHS-II
 IRB00006282 U of California, Merced IRB #1
 IRB00006447 Lawrence Berkeley Natl Lab IRB #1

6. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: Christine Middle Initial: E Last Name: Byrne
 Degrees or Suffix: MA, CIP Organizational Title: Lead Compliance Specialist, Human & Animal Research
 Institution: Lawrence Berkeley Natl Lab
 Telephone: 510 486-5507 FAX: 510 486-5499 E-Mail: cebyrne@lbl.gov
 Address: 1 Cyclotron Road
 MS 26R0143
 City: Berkeley State: CA Zip Code: 94720

Submission#: 25410

Assurance#: FWA00006253

7. Signatory Official (i.e., Official Legally Authorized to Represent the Institution)

I understand that the Assurance Training Modules on the OHRP website describe the responsibilities of the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) designated above are to provide review for all research to which this Assurance applies. The designated IRB(s) will comply with the [Terms of the Federalwide Assurance for Institutions Within the United States] and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.

Signature:



Date:

3/28/11

First Name: Horst

Middle Initial: D Last Name: Simon

Degrees or Suffix: PhD

Organizational Title: Deputy Laboratory Director

Institution:

Lawrence Berkeley Natl Lab

Telephone: 510 486-7377

FAX: 510 486-4300

E-Mail: hdsimon@lbl.gov

Address: 1 Cyclotron Road
MS 50B-4320

City: Berkeley

State: CA

Zip Code: 94720

NOTE: Institutions operated by the U.S. Government may need to obtain department or agency clearance prior to submission of the FWA to OHRP. Please contact the relevant department or agency Human Subject Protections Officer before forwarding this Assurance to OHRP.

8. FWA Approval

The Federalwide Assurance for the Protection of Human Subjects for Institutions Within the United States submitted to HHS by the above Institution is hereby approved.

Assurance Number:

Expiration Date:

Signature of HHS Approving Official:

Date:

Subject: Electronic Update/Renewal of FWA Application for Lawrence Berkeley Natl Lab Approved by OHRP as FWA00006253

From: <Jean.Makle@hhs.gov>

Date: Thu, 31 Mar 2011 14:04:12 -0400

To: <cebyrne@lbl.gov>, <hdsimon@lbl.gov>, <cebyrne@lbl.gov>

CC: <Jean.Makle@hhs.gov>

This is an automated message from an unmonitored address. Please do not reply.

Your institution's electronic submission for the update/renewal of its Federalwide Assurance Lawrence Berkeley Natl Lab has been approved by the Office for Human Research Protections (OHRP). The expiration date for your FWA renewal is 3/31/2014 2:04:12 PM. You will find this approval listed on our website at <http://ohrp.cit.nih.gov/search/search.aspx>. Funding agencies use this website to verify that an institution holds an active OHRP-approved FWA.

Whenever information provided to OHRP changes for your institution's FWA, you must submit an update/renewal. You may do this electronically by going to the OHRP Electronic Submission System at <http://ohrp.cit.nih.gov/efile/>. Your FWA must be renewed at least every 3 years.

When an electronic submission is processed, an automatically generated e-mail notifies the Human Protections Administrator and Signatory Official, as well as the person submitting the electronic record, that the FWA document has been approved. This, of course, is dependent upon the electronic file submitted to OHRP providing e-mail addresses as requested.

Sincerely,

Division of Policy and Assurances
Office for Human Research Protections
U.S. Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852(240) 453-6900
Toll-Free within the U.S. (866) 447-4777

FWA.pdf	Content-Type: application/pdf
	Content-Encoding: base64