Memorandum of Understanding
Between Human Research Protection Programs at
University of California Campuses and Lawrence Berkeley National Laboratory for IRB Review of Multi-Campus Human Subject Research
May, 2012

1. **Agreement** - This Memorandum of Understanding (MOU) sets forth the agreement between the Human Research Protection Programs at the ten campuses of the University of California and the Lawrence Berkeley National Laboratory. This MOU concerns reliance by a Human Research Protection Program (HRPP) at a UC campus or at the Berkeley Lab (hereafter referred to as "the campuses") on the review and approval, or determination of exemption, of human subject research by an HRPP at another UC campus.

2. **Types of Research Covered by this Agreement** – This MOU applies to human subject research as defined by federal and state statutes and regulations that is determined to be exempt, that is eligible for IRB review, or requires full board review and that:
   a. Will be a collaborative or multi-site research effort involving two or more of the campuses;
   b. Involves obtaining individually identifiable data or samples from two or more UC campuses, on which one or more other UC campuses will conduct analyses; and/or
   c. Involves obtaining samples that are not identifiable for research subject to oversight by the Food & Drug Administration (FDA).

3. **Compliance with Agency Guidance** - This MOU meets the federal requirements for designation of another institution's IRB as the reviewing IRB, as set forth in Office for Human Research Protections' (OHRP) guidance, *Terms of the Federalwide Assurance*, March 20, 2002.

4. **Definitions**
   a. **Human Subject Research** - The definition of human subject research is that set forth in *45 CFR § 46.102* and *21 CFR § 50.3*, *§102*, *§312.3* and *§812.3*, and as required by California law.
   b. **Exempt Human Subject Research** – The definition of exempt human subject research is that set forth in 45 CFR section 46.101(b).
   c. **Expedited Human Subject Research** – The definition of expedited human subject research is that set forth in 45 CFR section 46.110 and 21 CFR 56.110.
   d. **Institutional Official** – The Institutional Official is the Signatory Official on the Federalwide Assurance (FWA) filed with OHRP to assure compliance with regulations governing protection of human subjects. OHRP requires the Institutional Official to be a high-level official who has the authority to represent the institution named in the FWA.

5. **Reliance on Another UC IRB; Training** – The Institutional Officials signing below agree that the HRPP at his or her campus may accept and rely on the determination of exemption or the review and approval by the HRPP of another UC campus named in this MOU of research involving human subjects meeting the definition in paragraph 4 above. The one exception to this is that studies in which individuals involved in the design, conduct or reporting of research at either the relying or reviewing campus have not undergone training on subject protection will not be eligible to utilize this MOU.

6. **Compliance with Federal and State Law** – A determination of exemption or review and approval of human subject research under this agreement will be conducted in accordance with all relevant federal and state statutes and regulations governing the protection of human subjects, and with all relevant University of California policies pertaining to the protection of human subjects participating in research for which the University of California is responsible.

7. **Informed Consent** – Research subject to this agreement that is not eligible for a determination of exemption will employ a consent process, including a consent form, consent waiver, or alteration of consent that meets all federal and state requirements and that is approved by the IRB of the reviewing campus. The Relying campus shall be permitted, without approval of the Reviewing campus, to make minor changes in the consent form to reflect local administrative requirements (such as phone number, headers, etc.).

8. **Determining the Reviewing IRB**
   a. The reviewing IRB shall be at either:
      i. The campus that is the prime recipient of the research award (or, in studies where the research is not funded by an external award, the campus with which the PI is primarily affiliated), or
      ii. The UC location where subject contact, recruitment, and/or interactions or interventions, shall entirely or substantially take place.
   b. Exceptions to this provision shall be determined by the Director of the HRPP at the campus that is the prime recipient of the research award (or, in studies where the research is not funded by an external award, the campus with which the PI is primarily affiliated).

9. **Duties and Responsibilities of Principal Investigators**
   a. The Principal Investigator (PI) at the **Relying Campus** shall:
      i. Complete and sign a Notice of Intent to Rely on Another UC IRB and forward it to the PI at the Reviewing Campus before the study is submitted to the Reviewing Campus HRPP for initial review, amendment, and/or continuing review; and
      ii. Follow the standards and guidelines of the HRPP of the Relying IRB for the reporting of any post-approval events, including adverse events, other safety information, and/or protocol violations or incidents.
   b. The PI at the **Reviewing Campus** shall:
      i. Submit with his or her IRB Application a Notice of Intent to Rely on Another UC IRB (NOITR) that has been completed and signed by the PI at the relying campus; and
      ii. Actively communicate with all study investigators at all relying campuses to make sure that the necessary and required coordination of any research activities including notification of post-approval events takes place.
   c. Upon the occurrence of a post-approval event requiring notification, the PI shall report to his/her local campus IRB, pursuant to local standard procedures.

10. **Duties and Responsibilities of the Reviewing IRB** –
    a. Review and Oversight – The reviewing IRB will conduct initial and continuing reviews, and will review amendments to approved protocols and reports of unanticipated problems and serious and/or continuing noncompliance. The reviewing IRB shall have the authority to suspend or terminate the research. The HRPP of the reviewing IRB will notify relying HRPPs of any determinations of unanticipated problems, serious or continuing noncompliance, and suspensions and terminations.

b. Approval Letter – The HRPP of the reviewing IRB shall make a copy of its Approval Letter available to the HRPPs of relying IRB(s) and to the Office of Research & Graduate Studies (ORGS) at the University of California Office of the President (UCOP)

c. Right to Decline to Be IRB of Record – A campus HRPP may decline, on a case-by-case basis, to be the reviewing IRB for research conducted at another UC location. If this occurs, the HRPP of the IRB being asked to review will notify all relevant parties, i.e., the PI at the campus of the reviewing IRB, the HRPP and PI at the campus seeking to rely, and ORGS at UCOP.

d. Record Keeping – The HRPP of the reviewing IRB will keep records of studies subject to this MOU. The records will include at a minimum the date the application is submitted, review determinations, dates of approval, location of research activity, and oversight actions.

e. Review Rates – Standard rates for cost of IRB review shall apply to both Reviewing and Relying campus IRBs on each study.

11. Duties and Responsibilities of the Relying HRPP

a. Acknowledgment Letter – The HRPP of the relying IRB will issue an Acknowledgment Letter to the PI of the relying campus informing him or her of its decision to rely on another campus' review and will send a copy of the Acknowledgment Letter to the HRPP of the reviewing IRB and to ORGS at UCOP.

b. Compliance and Oversight - The HRPP of the relying IRB will monitor compliance with the terms and conditions of the reviewing IRB's approval of research being conducted at the relying UC campus. The HRPP of the relying IRB will advise the HRPP of the reviewing IRB of any incidents of noncompliance or unanticipated problems of which it becomes aware including, but not limited to, violations of human research protection regulations.

c. Right to Decline to Rely – A campus HRPP may decline, on a case-by-case basis, to rely on IRB review conducted by another campus. If this occurs, the HRPP of the relying IRB will notify the PI seeking to rely, the HRPP at the reviewing campus, and ORGS at UCOP of its decision not to rely.

d. Record Keeping – The HRPP of the relying IRB will keep records of studies subject to this MOU. The records will include at a minimum the date the Notice of Intent to Rely was submitted, administrative review determinations, dates of approval by the Reviewing IRB, and location of research activity, as well as oversight actions.

12. Duties and Responsibilities of Both the Reviewing and the Relying HRPP

a. Local Institutional Review Committees – The HRPPs of both the reviewing and relying IRBs will ensure that local institutional committee reviews and approvals are in place before the research commences at each site. This includes, but is not limited to, institutional biosafety review, radiation safety review, review and management of conflict of interest, and others as required.

b. Reporting Unanticipated Problems and/or any Serious and/or Continuing Noncompliance – The HRPPs of the reviewing and relying IRBs will immediately report to the reciprocal HRPP any unanticipated problems involving risks to subjects or others or any incidents of serious and/or continuing noncompliance. This reporting duty is in addition to and does not replace the investigator's duty to report unanticipated problems or serious and/or continuing noncompliance as required by government regulation and institutional policies and procedures.

c. Cooperation – The HRPPs of the reviewing and relying IRBs will cooperate fully with the reciprocal HRPP concerning this agreement. Relevant documentation to support review, compliance and oversight by the respective HRPPs will be made available to

support review, compliance and oversight by the respective HRPPs will be made available to the reciprocal HRPP upon request. Each HRPP will make available records applicable to regulatory and accrediting agency activity if and when the reciprocal HRPP requires such records.

d. MOU on File – This MOU must be kept on file at the HRPPs that are party to this agreement and must be provided to OHRP upon request.

12. **Execution** – The undersigned Institutional Officials of the HRPPs at University of California campuses and at the Lawrence Berkeley National Laboratory have read and agreed to all of the terms above. This MOU will remain in effect unless or until revoked or superseded by a revised Memorandum of Understanding.

UC BERKELEY

Graham Fleming 6/20/12

Institutional Official — Date

FWA00006252
Federalwide Assurance Number

Graham Fleming
Name (print)

Institutional Title

UC DAVIS

Institutional Official — Date

FWA00004557
Federalwide Assurance Number

Name (print)

Institutional Title

UC IRVINE

Institutional Official — Date

FWA00004071
Federalwide Assurance Number

Name (print)

Institutional Title

UC LOS ANGELES

Institutional Official — Date

FWA00004642
Federalwide Assurance Number

Name (print)

Institutional Title

UC MERCED

Institutional Official — Date

FWA00005105
Federalwide Assurance Number

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HARRIS A. LEWIN
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UC IRVINE

Institutional Official	Date	FWA00004071 Federalwide Assurance Number
James W. Hicks Name (print)		Assoc. Vice Chancellor for Research Institutional Title

UC LOS ANGELES

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UC LOS ANGELES

John S Economon 6/2/12

Institutional Official — Date

ECONOMON

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UC Research

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UC MERCED

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Samuel Dustin 5/31/12 Institutional Official Date	FWA00005105 Federalwide Assurance Number
Samuel Dustin Name (print)	Vice Chancellor for Research Institutional Title

UC RIVERSIDE

Institutional Official — Date: 6/11/12

Charles F. Louis
Name (print) Vice Chancellor for Research

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Federalwide Assurance Number

Vice Chancellor for Research
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UC SAN DIEGO

Institutional Official — Date

Name (print)

FWA000004495
Federalwide Assurance Number

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UC SAN FRANCISCO

Institutional Official — Date

Name (print)

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Federalwide Assurance Number

Institutional Title

UC SANTA BARBARA

Institutional Official — Date

Name (print)

FWA00006361
Federalwide Assurance Number

Institutional Title

UC SANTA CRUZ

Institutional Official — Date

Name (print)

FWA00002797
Federalwide Assurance Number

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LAWRENCE BERKELEY NATIONAL LABORATORY

Institutional Official — Date

Name (print)

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Elizabeth A Boyd Institutional Official	5/31/12 Date	FWA00000068 Federalwide Assurance Number
Elizabeth A Boyd Name (print)		Associate Vice Chancellor, Ethics + Compliance Institutional Title

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Michael Witherell	6/1/2012	FWA00006361
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Michael Witherell		
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Bruce Margon	6-1-12	FWA00002797
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BRUCE MARGON		Vice Chancellor, Research
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LAWRENCE BERKELEY NATIONAL LABORATORY

[signature]	6/11/12	FWA00006253	
Institutional Official	Date	Federalwide Assurance Number	
HORST D. SIMON		Deputy Director	
Name (print)		Institutional Title	