Memorandum of Understanding
Between Human Research Protection Programs at University of California Campuses and UC-Managed Laboratories for IRB Review of Multi-Campus Human Subject Research

Effective Period: March 21, 2006 - March 21, 2007

1) Agreement - This Memorandum of Understanding (MOU) sets forth the agreement between the human research protection programs at University of California campuses and at the national laboratories under University of California (UC) management. This MOU concerns reliance by a UC human research protection program (HRPP) on the review and approval by another UC campus or lab’s HRPP of human subject research that is deemed exempt from Institutional Review Board (IRB) review or that is eligible for expedited IRB review under federal regulations.

2) Types of Research Covered by this Agreement –
   a) This MOU applies to human subject research that is determined to be exempt by a campus or lab’s HRPP or that is eligible for expedited review by the campus or lab’s IRB and that:
      i) Will be conducted concurrently at more than one UC location; or
      ii) Involves personally identifiable data or samples from one or more UC location on which investigators at another UC location will be conducting analyses.
   b) This MOU does not apply to:
      i) Human subject research that requires full committee IRB review; or
      ii) Research regulated by the Food and 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 guidance issued by the Office for Human Research Protections (OHRP), Terms of the Federalwide Assurance, March 20, 2002.

4) Definitions and Terms
   a) Human Subject Research - The definition of human subject research is that set forth in 45 Code of Fed. Regs. § 46.102.
   c) Expedited Human Subject Research - The definition of expedited human subject research is that set forth in 45 Code of Fed. Regs. § 46.110.
   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 Review and Approval** - The Institutional Officials signing below agree that the HRPP at their campus or lab may accept and rely on the determination of exemption, or review and approval, by a HRPP at another UC campus or lab of research involving human subjects that is eligible to be exempt from IRB review as set forth in 45 Code of Fed. Regs. § 46.101(b) or that is eligible for expedited review as set forth in 45 Code of Fed. Regs. § 46.110.

6) **Compliance with Federal and State Law and UC Policy** – A determination of exemption or expedited review of human subject research under this agreement shall be conducted in accordance with all applicable federal and state statutes and regulations governing the protection of human subjects, and with all applicable University of California policies pertaining to the protection of human subjects participating in research conducted at or by employees of the University of California.

7) **Informed Consent Form** – Research subject to this agreement shall employ a consent process, including a consent form, consent waiver, or alteration of consent, approved by a UC campus or lab IRB or the Model UC Consent Form issued with this agreement.

8) **Reviewing IRB** – The reviewing IRB shall be at either the UC location 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 the UC location where subject contact shall entirely or substantially take place. Exceptions to this provision shall be determined by the institutional official at the UC location 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 the Principal Investigator** –
   a) **Notice to Reviewing IRB** - The investigator must request at the time of application that the reviewing IRB be the IRB of record for exempt or expedited research involving more than one UC location.
   b) **Notice to Relying IRB** - The investigator must file a Notice of Intent to Rely on Another UC IRB, issued with this MOU, with any other campus HRPP where the research will take place.
   c) **Filing with the Relying HRPP** - When the investigator obtains a determination of exemption or an expedited approval from an HRPP at another UC location, he or she shall file with each relying HRPP a copy of the exempt determination or a copy of the expedited approval together with the final application and all supporting documentation, including the protocol and consent documents, and a copy of any modification, annual review application, withdrawal notice, adverse event report, and/or termination notice.
   d) **Additional Notices to Relying IRBs** - The investigator must file an additional Notice of Intent to Rely on Another UC IRB for each annual review and/or protocol modification, with any relying campus HRPP where the research is continuing to take place.

10) **Duties and Responsibilities of the Reviewing HRPP**
a) **Review and Oversight** – The reviewing HRPP shall conduct initial and continuing reviews, and shall review amendments to approved protocols and unanticipated problems or adverse events that may arise. The reviewing HRPP shall have the authority to suspend the research for failure to comply with conditions of approval or regulatory requirements. The reviewing HRPP shall notify the relying HRPPs of any adverse events, unanticipated problems, or suspension of research.

b) **IRB Review of Applications for HHS Support** – The reviewing HRPP is responsible for confirming that, where applicable, the application or proposal for human subject research submitted to the federal Department of Health and Human Services (HHS) matches the protocol submitted for IRB approval, as required under Federal regulations (45 CFR 46.103(f)). See OHRP guidance, *IRB Review of Applications for HHS Support*, May 31, 2000.

c) **Right to Refuse to be IRB of Record** – A campus or lab HRPP may refuse, on a case-by-case basis, to be relied upon as the IRB of record for research involving another UC location.

d) **Central Database** – The UCOP Office of Research will maintain a central database of studies that are subject to this MOU. The reviewing HRPP shall list a study in the central database when the application is submitted and shall update the database with information on determination of exemption, expedited review, and oversight activity.

11) **Duties and Responsibilities of the Relying HRPP**

a) **Compliance and Oversight** - The relying HRPPs shall monitor compliance with the terms and conditions of the reviewing HRPP’s approval of research being conducted at the relying UC location. The relying HRPPs shall advise the reviewing HRPP of any noncompliance of which it becomes aware, including but not limited to violations of human research protection regulations.

b) **Right to Refuse to Rely** – A campus or lab HRPP may refuse, on a case-by-case basis, to rely on an exempt determination or expedited review by another UC HRPP. The HRPP should advise the investigator of its reasons for declining reliance on another UC HRPP’s review.

c) **Central Database** – The UCOP Office of Research will maintain a central database of studies that are subject to this MOU. The relying HRPPs shall update information on studies listed in the database concerning compliance, unanticipated problems and adverse events.

d) **Acknowledgement Letter**. The relying campus or lab HRPP will send the Principal Investigator and the reviewing IRB a letter acknowledging receipt of each exempt determination or expedited approval which falls under this MOU.

12) **Duties and Responsibilities of Both the Reviewing and the Relying HRPP**

a) **Reporting Unanticipated Problems or Adverse Events** – The reviewing and relying HRPPs shall immediately report to the reciprocal HRPP any unanticipated problems or adverse events involving risks to subjects or others. This reporting duty is in addition to and does not replace the investigator’s duty to report unanticipated problems or adverse events as required by regulation, policy and procedure.
b) **Reporting Noncompliance** – The reviewing and relying HRPPs shall immediately advise the reciprocal HRPP of any serious or continuing noncompliance in the conduct of the study with regulations governing the protection of human subjects or with the provisions of this MOU. Each office shall notify the reciprocal office if and when an oversight agency or organization initiates any action regarding such noncompliance.

c) **Cooperation** - The reviewing and relying HRPPs shall cooperate fully with the reciprocal HRPP concerning the operation of this MOU. Relevant documentation 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) **Policies and Procedures** - UC HRPPs shall develop and implement policies and procedures consistent with this MOU.

e) **MOU on File** - This MOU must be kept on file at the HRPPs of both the reviewing and relying HRPPs and must be provided to OHRP upon request.

13) **Execution** - The undersigned Institutional Officials of the HRPPs at University of California campuses and at the national laboratories under University of California management have read and agreed to all of the terms above. This MOU shall remain in effect one year from the date of execution and implementation thereof and shall be reviewed at that time.

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MOU for IRB Review of Multi-Campus Research

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UC BERKELEY

Institutional Official: Beth Burnside
Date: 3/15/06

Name (print)

UC DAVIS

Institutional Official
Date

Name (print)

UC IRVINE

Institutional Official
Date

Name (print)

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**UC LOS ANGELES**

Institutional Official: [Name (print)]

Date

**UC MERCEDES**

Institutional Official: [Name (print)]

Date

**UC RIVERSIDE**

Institutional Official: Charles F. Louie

Date: 3/16/06

**UC SAN DIEGO**

Institutional Official: [Name (print)]

Date

**UC SAN FRANCISCO**

Institutional Official: [Name (print)]

Date

**UC SANTA BARBARA**

Institutional Official: [Name (print)]

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UC SANTA CRUZ
Institutional Official
Robert C. Miller

3/4/06

Date

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LAWRENCE BERKELEY NATIONAL LABORATORY

Institutional Official

FWA00002797
Federalwide Assurance Number
Vice Chancellor for Research

Institutional Title

LAWRENCE LIVERMORE NATIONAL LABORATORY

Institutional Official

FWA00006253
Federalwide Assurance Number

Institutional Title

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MOU for IRB Review of Multi-Campus Research

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Institutional Title: [Title]

LAWRENCE LIVERMORE NATIONAL LABORATORY

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