

# University of California

## Memorandum of Understanding Between and Among Human Research Protection Programs at University of California Campuses and Lawrence Berkeley National Laboratory for IRB Review of Multi-Campus Human Subject Research May 21, 2009

1. **Agreement** - This Memorandum of Understanding (MOU) sets forth the agreement between and among 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 a 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 or is eligible for IRB review and that:
  - a. Will be a collaborative research effort between one or more of the campuses;
  - b. Involves obtaining individually identifiable data or samples from one 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, §103, §312.3 and §812.3. In addition, California law requires IRB review and approval for research that relies on individually identifiable information from death data files held by local registrars, county recorders and the State Registrar. (*California Health & Safety Code § 102231(a)(5)*)
  - b. **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 at one or more UC campuses named in this MOU of research involving human subjects meeting the definition in paragraph 4 above with the exception that studies in which individuals involved in the design, conduct or reporting of research at either the relying or reviewing campus who have not undergone training on subject protection shall not be eligible to rely on this MOU.

6. **Compliance with Federal and State Law** – A determination of exemption or review and approval of human subject research under this agreement shall 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 shall 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.
8. **Determining 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 Reviewing 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 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.
10. **Duties and Responsibilities of the Reviewing IRB** –
  - a. **Review and Oversight** – The reviewing IRB shall conduct initial and continuing reviews, and shall 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 shall 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 send a copy of its Approval Letter 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.

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

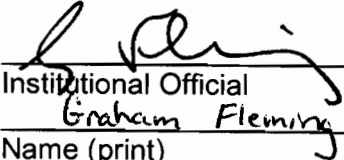
- a. Acknowledgement Letter – The HRPP of the relying IRB will issue an Acknowledgement Letter to the PI of the relying campus informing him or her of its decision to rely on another campus’ review and will send a copy of the Acknowledgement Letter to the HRPP of the reviewing IRB and to ORGS at UCOP.
- b. Compliance and Oversight - The HRPP of the relying IRB shall 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 shall 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 shall 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 shall 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 shall 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 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.

13. **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 shall remain in effect unless or until revoked or superseded by a revised Memorandum of Understanding.

**UC BERKELEY**

 5/21/09  
 Institutional Official Date  
 Name (print) Graham Fleming

FWA00006252  
 Federalwide Assurance Number  
Vice Chancellor for Research  
 Institutional Title

**UC DAVIS**

\_\_\_\_\_  
 Institutional Official Date  
 Name (print)

FWA00004557  
 Federalwide Assurance Number  
 \_\_\_\_\_  
 Institutional Title

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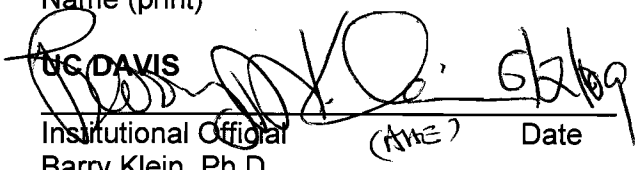
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**UC BERKELEY**

\_\_\_\_\_  
Institutional Official    Date

Name (print)



UC DAVIS  
 Institutional Official (Name)    Date

Barry Klein, Ph.D.

Name (print)

FWA00006252

Federalwide Assurance Number

\_\_\_\_\_  
Institutional Title

FWA00004557

Federalwide Assurance Number

Vice Chancellor for Research

\_\_\_\_\_  
Institutional Title

**UC IRVINE**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

Susan V. Bryant  
Name (print) \_\_\_\_\_

FWA00004071  
Federalwide Assurance Number  
*Susan V. Bryant*  
Vice Chancellor for Research  
Institutional Title \_\_\_\_\_

**UC LOS ANGELES**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

Name (print) \_\_\_\_\_

FWA00004642  
Federalwide Assurance Number  
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Institutional Title \_\_\_\_\_

**UC MERCED**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

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Institutional Title \_\_\_\_\_

**UC RIVERSIDE**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

Name (print) \_\_\_\_\_

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Federalwide Assurance Number  
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Institutional Title \_\_\_\_\_

**UC SAN DIEGO**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

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**UC SAN FRANCISCO**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

Name (print) \_\_\_\_\_

FWA00000068  
Federalwide Assurance Number  
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Institutional Title \_\_\_\_\_

**UC SANTA BARBARA**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

Name (print) \_\_\_\_\_

FWA00006361  
Federalwide Assurance Number  
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**UC SANTA CRUZ**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

Name (print) \_\_\_\_\_

FWA00002797  
Federalwide Assurance Number  
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Institutional Title \_\_\_\_\_

**LAWRENCE BERKELEY NATIONAL LABORATORY**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

Name (print) \_\_\_\_\_

FWA00006253  
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**UC DAVIS**

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**UC IRVINE**

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**UC LOS ANGELES**

Roberto Pecece                                  6/4/09  
Institutional Official                                  Date

Roberto Pecece  
Name (print)

FWA00004642 \_\_\_\_\_  
Federalwide Assurance Number

Vice Chancellor for Research  
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**UC IRVINE**

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**UC LOS ANGELES**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

Name (print) \_\_\_\_\_

**UC MERCED**

*Samuel Justin Traina* \_\_\_\_\_ *5/27/09* \_\_\_\_\_  
Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

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**UC RIVERSIDE**

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**UC SANTA BARBARA**

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**UC SANTA CRUZ**

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**LAWRENCE BERKELEY NATIONAL LABORATORY**

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FWA00005105

Federalwide Assurance Number

*Vice Chancellor for Research*  
Institutional Title

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**UC RIVERSIDE**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

*Charles F. Louis* *6-2-09*  
Name (print) \_\_\_\_\_ Research

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**UC SAN DIEGO**

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**UC SANTA BARBARA**

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**UC SANTA CRUZ**

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**LAWRENCE BERKELEY NATIONAL LABORATORY**

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**UC IRVINE**

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**UC SAN DIEGO**

  
Institutional Official \_\_\_\_\_ Date \_\_\_\_\_  
GARY FIRESTEIN, MD 6/3/09  
Name (print) \_\_\_\_\_

FWA000004495  
Federalwide Assurance Number

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Institutional Title

**UC SAN FRANCISCO**

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**UC IRVINE**

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**UC LOS ANGELES**

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**UC MERCED**

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Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

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**UC SAN FRANCISCO**

Institutional Official \_\_\_\_\_ Date *6-1-09* \_\_\_\_\_

*[Signature]*  
A. Eugene Washington, MD, MSc

Name (print) \_\_\_\_\_

**UC SANTA BARBARA**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

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**LAWRENCE BERKELEY NATIONAL LABORATORY**

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Federalwide Assurance Number

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FWA00000068  
Federalwide Assurance Number  
Executive Vice Chancellor and Provost  
Institutional Title

FWA00006361  
Federalwide Assurance Number

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FWA00002797  
Federalwide Assurance Number

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FWA00006253  
Federalwide Assurance Number

\_\_\_\_\_ Institutional Title

**UC IRVINE**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

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**UC LOS ANGELES**

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Name (print) \_\_\_\_\_

**UC SANTA BARBARA**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

Name (print) \_\_\_\_\_

**UC SANTA CRUZ**

*Bruce H. Margon* \_\_\_\_\_ *6-2-09* \_\_\_\_\_  
Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

Bruce H. Margon

Name (print) \_\_\_\_\_

**LAWRENCE BERKELEY NATIONAL LABORATORY**

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Institutional Title

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Federalwide Assurance Number  
Vice Chancellor for Research

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Institutional Title

FWA00006253  
Federalwide Assurance Number

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Institutional Title

**UC IRVINE**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

Name (print) \_\_\_\_\_

**UC LOS ANGELES**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

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Name (print) \_\_\_\_\_

**LAWRENCE BERKELEY NATIONAL LABORATORY**

Institutional Official \_\_\_\_\_ Date \_\_\_\_\_

Name (print) \_\_\_\_\_

FWA00004071  
Federalwide Assurance Number

\_\_\_\_\_  
Institutional Title

FWA00004642  
Federalwide Assurance Number

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Institutional Title

FWA00005105  
Federalwide Assurance Number

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Institutional Title

FWA00001965  
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FWA000004495  
Federalwide Assurance Number

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FWA00000068  
Federalwide Assurance Number

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FWA00006361  
Federalwide Assurance Number

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Institutional Title

FWA00002797  
Federalwide Assurance Number

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Institutional Title

FWA00006253  
Federalwide Assurance Number

Institutional Official  
Institutional Title

*Joe W. Gray*  
*6/10/09*  
*JOE W. GRAY, Ph.D.*