

**Reliance Memorandum of Understanding
Between and Among the University of California Campuses, UC Division of Agriculture and Natural
Resources, and Lawrence Berkeley National Laboratory for Institutional Review Board Review of
Multi-UC Campus Human Subject Research**
Updated July, 2016

Purpose

The purpose of this Reliance Memorandum of Understanding (“Reliance MOU”) is to set forth the agreement between and among the Human Subjects Research Programs (HRPP) and Institutional Review Boards at the ten campuses of the University of California, UC Division of Agriculture and Natural Resources (ANR), and the Lawrence Berkeley National Laboratory (“UC Campuses”) to allow an Institutional Review Board (IRB) at any of the UC campuses to rely upon the review and approval, or determination of exemption, of human subject research by an IRB at another of the UC campuses. This MOU is intended to reduce unnecessary duplication of effort and administrative burden by facilitating optional single-IRB review for multi-site human research activities.

Research Covered by this Agreement

The Reliance MOU applies to human subject research as defined by federal and state statutes and regulations involving two or more UC Campuses that involves a federal grant, cooperative agreement, or contract awarded to one UC Campus (the “Prime Awardee”) but pursuant to which one or more other UC campuses engage in Human Subjects Research.

Compliance with Federal and State Law

A determination of exemption or review and approval of human subject research under this Reliance MOU will be conducted in accordance with all applicable federal and state statutes and regulations and UC policies governing the protection of human subjects in research. This agreement meets the requirements of each UC Campus’s Federalwide Assurance. The Reliance MOU shall be kept on file at each of the UC Campuses and shall be provided to OHRP or other federal agencies upon request.

Definitions

Human Subjects Research – The definition of human subject research is that set forth in federal regulations describing humans, research, clinical investigation and other closely related terms promulgated by the Office of Human Subject Protections for Human Subject Research at 45 CFR §46.102, and the Food & Drug Administration regulations of Clinical Investigations at 21 CFR §50.3, §312.3 and §812.3, and as required by California law.

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 authority to represent the institution named in the FWA.

Implementing Procedures

Procedures to Implement the Reliance Memorandum of Understanding Between Human Research Protection Programs at University of California Campuses, UC Division of Agriculture and Natural Resources, and Lawrence Berkeley National Laboratory for IRB Review of Multi-Campus Human Subject Research shall be developed and modified as agreed upon by the HRPP directors of the UC Campuses. Each of the UC Campuses agrees to follow these Procedures for human subject research covered by this Reliance MOU.

Reliance on another UC IRB

The Institutional Officials signing below agree that the HRPP director at his or her campus may elect to accept and rely on the determination of the exemption or the review and approval by the IRB of another. Each of the participating UC Campuses may elect, on a case-by-case basis whether to rely on, or review for another. The Relying Campus remains responsible for assuring compliance with the Reviewing IRB’s determinations and terms of the FWA.

Execution

The undersigned Institutional Officials of the UC Campuses have read and agreed to all of the terms above. This Reliance MOU will remain in effect unless or until revoked or superseded by a revised Memorandum of Understanding.

UC BERKELEY: FWA000006252

Institutional Official (Signature)


Paul Alivisatos

Name (print)

Vice Chancellor for Research

Institutional Title

UC DAVIS: FWA00004557

Institutional Official (Signature)

Harris A. Lewin, Ph.D.

Name (print)

Vice Chancellor for Research

Institutional Title

UC IRVINE: FWA00004071

Institutional Official Designee(Signature)

Bruce Morgan

Name (print)

Associate Vice Chancellor for Research Administration

Institutional Title

UC LOS ANGELES: FWA00004642

 8/22/16

Institutional Official (Signature)

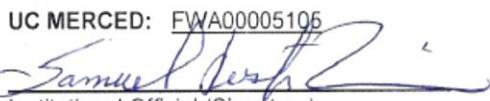
Ann R. Karagozian

Name (print)

Interim Vice Chancellor for Research

Institutional Title

UC MERCED: FWA00005106



Institutional Official (Signature)

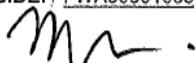
Samuel Justin Trainor

Name (print)

Vice Chancellor for Research

Institutional Title

UC RIVERSIDE: FWA00001965



Institutional Official (Signature)

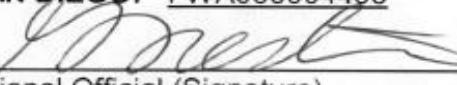
Dr. Michael Pazzani

Name (print)

VC Research & Economic Development

Institutional Title

UC SAN DIEGO: FWA000004495



Institutional Official (Signature)

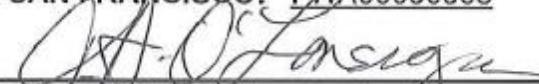
Gary Firestein, MD

Name (print)

Institutional Official

Institutional Title

UC SAN FRANCISCO: FWA00000068



Institutional Official (Signature)

J.A. O'Lonegan

Name (print)

AAC Ethics & Compliance

Institutional Title



UC SANTA BARBARA: FWA00006361



Institutional Official (Signature)

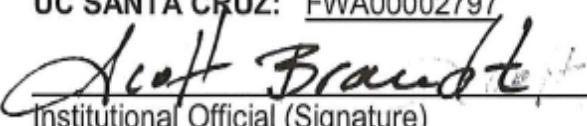
Joseph Incandela

Name (print)

Interim Vice Chancellor for Research

Institutional Title

UC SANTA CRUZ: FWA00002797



Institutional Official (Signature)

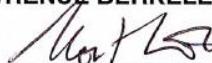
Scott Brandt

Name (print)

Vice Chancellor for Research

Institutional Title

LAWRENCE BERKELEY NATIONAL LAB: FWA00006253



Institutional Official (Signature)

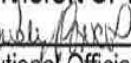
Horst Simon

Name (print)

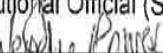
Deputy Director and Chief Research Officer

Institutional Title

UC DIVISION OF AGRICULTURE AND NATURAL RESOURCES:



Institutional Official (Signature)



Name (print)

Associate Vice President

Institutional Title