

Ceded IRB Review among Institutions Engaged in Research at Los Angeles County Department
of Health Services Facilities

Memorandum of Understanding

The Human Research Protection Programs at:
Charles R. Drew University of Medicine and Science (FWA00002736)
Los Angeles BioMedical Research Institute at Harbor-UCLA Medical Center (FWA00001992)
Harbor-UCLA Medical Center (FWA00002334)
LAC+USC Medical Center (FWA00005905)
Los Angeles County Public Health Department, Ambulatory Care Network,
and Health Services Administration (FWA00000071)
Olive View-UCLA Education and Research Institute (FWA00000495)
Rancho Research Institute at Ranchos Los Amigos National Rehabilitation Center
(FWA00002950, FWA00003200)
University of Southern California (FWA00005906, FWA00007099)

Effective Date: May 18, 2018

1) Agreement

As part of the collaboration with Los Angeles County Department of Health Services (DHS) facilities, this Memorandum of Understanding (MOU) sets forth the express agreement among the Human Research Protection Programs (HRPP) at Charles R. Drew University of Medicine and Science; Los Angeles BioMedical Research Institute at Harbor-UCLA Medical Center; Harbor-UCLA Medical Center; LAC+USC Medical Center; Los Angeles County Public Health Department, Ambulatory Care Network, and Health Services Administration; Olive View-UCLA Education and Research Institute; Rancho Research Institute at Ranchos Los Amigos National Rehabilitation Center; and University of Southern California (each referred to as an "Institution"). This MOU concerns the ability of an Institutional Review Board (IRB) at one Institution to rely on the review and approval by the IRB at another Institution, in accordance with the criteria set forth in this MOU. This MOU allows the IRB of one Institution ("Relying IRB") to rely on the IRB of another Institution ("Reviewing IRB") for the review and continuing oversight of the research that is identified in section 2. This MOU does not replace a subcontract if required.

2) Types of Research Covered by this Agreement

The following type of research and related activities covered by this Agreement, and the conditions under which they are covered, are as follows:

1. A research, quality improvement, or similar project that involves human subjects that is verified as *Exempt* from human subject regulations, or approved via an *Expedited* process, by the IRB affiliated with the primary site of the work or the work location of the primary investigator, may be conducted at all DHS facilities, provided:

- a) A copy of the research protocol and the primary approval is provided to the IRB(s), if any, affiliated with the other DHS facilities;
- b) A period of 30-days for review is provided for the relying IRBs, as above;
- c) No questions or concerns are communicated by the relying IRB to the primary IRB or the investigator;
- d) Annual reviews, if any, as required by the primary IRB will be provided to relying IRBs as well; and
- e) If any change is to be made to the project at one or more sites, all IRBs will be notified prior to the modification, unless the modification is required to protect human subjects from harm. If a modification is made to protect human subjects, that will be communicated to all IRBs as quickly as practical.

2. Research that, under applicable federal laws, requires *full IRB review* and that:

- a) Will be a collaborative effort between or among any of the Institutions; and
- b) Involves obtaining personally identifiable data or samples from any one or more of the Institutions, and any one or more of the Institutions will conduct analyses of the data/samples; or
- c) Involves obtaining samples that are not identifiable for research in which the FDA is providing oversight.

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 Code of Federal Regulations (CFR) § 46.102(f) and 21 CFR § 50.3(g), §56.102(e), §312.3(b) and §812.3(p).
- b) Exempt Human Subject Research – The definition of exempt human subject research is set forth in 45 Code of Federal Regulations § 46.101(b).
- c) Expedited Human Subject Research – The definition of expedited human subject research is that set forth in 45 Code of Federal Regulations § 46.110 and 21 CFR § 56.110.
- d) Full Board Review – Review of proposed research at a convened IRB meeting at which the majority of the members are present as set forth in 45 Code of Federal Regulations § 46.108 and 21 CFR § 56.108.
- e) Institutional Official – The Institutional Official is the Signatory Official on the Federal wide 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.
- f) Lead Principal Investigator (PI) – For the purpose of this MOU, a Lead PI is the investigator who is responsible for submitting a new protocol, amendments, continuing

review reports, and post-approval reportable events to the Reviewing IRB. See the definition of reportable events below.

- g) Reviewing IRB (IRB of Record) – The Reviewing IRB is the IRB at the Institution which is responsible for reviewing a new protocol, amendments, continuing review reports, and post-approval reportable events in compliance with Federal and State laws, statutes and regulations.
- h) Relying PI – For the purpose of this MOU, a Relying PI is the investigator who requests his/her local IRB to rely on the review and approval of the Reviewing IRB for a collaborative protocol involving more than one participating institution in this MOU.
- i) Relying IRB – Local IRB which relies on the review and approval of the Reviewing IRB.
- j) Reportable Events – Any events, including adverse events, unanticipated problems, protocol violations, incidents, concerns, and/or complaints, which are required to be reported to the Reviewing IRB in accordance with its policies and guidelines.
- k) Ceded Review – Reliance on the IRB of another institution named in this MOU for review and approval of research involving human subjects.

5) Reliance on another IRB Review and Approval

The goal of the Ceded IRB review is to reduce duplicative IRB review and in that way, promote and accelerate collaborative research efforts among investigators at the institutions named in this MOU conducting research at DHS facilities. The Institutional Officials signing below agree that an IRB at his or her Institution may accept and rely on the review and approval by an IRB at any other signatory Institution for research involving human subjects described in Section #2 above.

6) Compliance with Federal and State Law

Review of Human Subject Research under this agreement shall be conducted in accordance with all relevant federal and state laws, statutes and regulations governing the protection of human subjects.

7) Informed Consent Form

Research under the agreement shall comply with the requirements for consent including a consent form or, where applicable, a consent waiver, or alteration of consent that meets all federal and state requirements and is approved by the Reviewing IRB.

8) Reviewing IRB (IRB of Record)

The Reviewing IRB shall be identified as:

- a) The IRB at the Institution that is the prime recipient of the research award (or, in studies where the research is not funded by an external award, the Institution with which the Lead PI is primarily affiliated); or
- b) With the written notification and agreement of the funding institution (prime recipient of the award), the IRB at the Institution where subject contact, recruitment, and/or interactions and/or interventions shall entirely or substantially take place; or

- c) If both the Reviewing and the Relying IRBs agree, an exception to the above can be made on a case-by-case basis.

9) Duties and Responsibilities of the Lead PI and the Relying PI

- a) The Lead PI will include the Relying PI in his or her study once the collaboration is established. He/she will submit the completed submission material to the Reviewing IRB. He/she will make the Reviewing IRB aware that they are reviewing the project for the other sites under this MOU.
- b) The Relying PI will follow the Relying Institution's guidelines for submitting the appropriate materials to the Relying IRB.
- c) The Lead PI will be responsible for ensuring that necessary and required coordination of any IRB protocol submission and research activities occurs between or among Institutions.
- d) The Lead PI will follow the policies and guidelines of the Reviewing IRB for the reporting of any post-approval events. These include amendments, continuing review reports, and other reportable events including unanticipated problems, SAEs and protocol deviations from all sites.
- e) The Relying PI will, i) inform the Lead PI of any reportable events (unanticipated problems, SAEs and protocol deviations) originating in the Relying PI's Institution so that the Lead PI can forward these to the Reviewing IRB, and ii) also follow the standards and guidelines of the Relying IRB for the submission and reporting of such events that occur at the Relying Institution.

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 reportable events. The Reviewing IRB shall have the authority to suspend or terminate the research. The Reviewing IRB shall notify the Relying IRBs of any determinations resulting from review of unanticipated problems, serious or continuing noncompliance, and suspensions and terminations.
- b) Approval Letter – The Reviewing IRB shall provide the IRB Approval Letter and the approved submission documents.
- c) Right to Refuse to Be the Reviewing IRB – Any Institution's IRB may refuse, on a case-by-case basis, to serve as the Reviewing IRB for research involving the other Institutions. If this occurs, the IRB will notify both the Lead and Relying PIs, as well as the Relying IRB.
- d) Record Keeping – The Reviewing IRB will keep records of studies that are subject to this MOU. The records will include, at a minimum, the date the application was submitted, the application and all related correspondence, including revised applications, correspondence between the IRB and the investigator, review determinations, dates of approval, location of research activity, minutes related to review activities, as well as oversight actions. The Reviewing IRB shall make these records available to the Relying IRB upon request. The Reviewing IRB shall retain these records for the period of time

required by all relevant federal and state laws, statutes and regulations and the Reviewing IRB's institutional policy.

11) Duties and Responsibilities of the Relying Institution

- a) Acknowledgement Letter – The Relying IRB will screen each research study under this MOU to determine whether it will agree to accept the review of the Reviewing IRB for that study. The Relying IRB shall notify the Reviewing IRB and the Relying PI of its decision by issuing an Acknowledgement Letter.
- b) Compliance and Oversight – The Relying Institution shall monitor compliance with the terms and conditions of the Reviewing IRB's approval of research being conducted at the Relying Institution. The Relying Institution shall advise the Reviewing IRB of any events related to compliance of which it becomes aware including, but not limited to, violations of human research protection regulations.
- c) Right to Refuse to Rely – An IRB may refuse, on a case-by-case basis, to rely on the review by another IRB. If this occurs, the IRB shall notify both the Lead and Relying PIs and the Reviewing IRB.
- d) Record Keeping – The IRB of the Relying Institution will also keep records of any oversight actions. The Relying IRB shall retain these records for the period of time required by all relevant federal and state laws, statutes and regulations and the Relying IRB's institutional policy.

12) Duties and Responsibilities of Both the Reviewing and the Relying IRB(s)

- a) Local Institutional Review Committees – Both the Reviewing and Relying IRBs will ensure that any additional local institutional review or committee reviews and approvals are in place before the research commences at each site. This includes, but is not limited to, review and management, where applicable, of conflict of interest, Institutional Biosafety review, radiation safety review and others as locally required.
- b) Protocol and Federal Grant Comparison – Comparison of the protocol and federal grant or contract application to ensure consistency will be done by the IRB of the Institution which receives the federal funding for those studies that are federally funded. If this is the Relying IRB, evidence of this comparison will be forwarded to the Reviewing IRB and considered at the time of IRB review. Other sponsor protocols will be included with the application for review by the Reviewing IRB.
- c) Reporting Unanticipated Problems and/or Any Serious and/or Continuing Noncompliance – The Reviewing and Relying IRBs shall report to the reciprocal IRB in a timely fashion (within 2 weeks of the determination). This reporting duty is in addition to, but does not replace, the investigator's duty to report reportable events as required by regulation and Institutional policies and procedures.
- d) Investigation of unanticipated problems and/or serious and/or continuing noncompliance – The Reviewing IRB will coordinate the investigation of the unanticipated problems and/or serious and/or continuing noncompliance with the Relying IRB and the two IRBs will be expected to work collaboratively. Where appropriate, the Relying IRB must forward a summary and corrective action plan to the Reviewing IRB as soon as the inquiry has been completed to allow the Reviewing

IRB to make a final determination regarding whether the event is an unanticipated problem involving risks to subjects or others and/or serious and/or continuing noncompliance.

- e) Reporting to Oversight Agencies – The Reviewing IRB is responsible for the reporting of any reportable events (including unanticipated problems and/or serious and/or continuing noncompliance) that are required to be made to the federal government or other oversight agencies. The Relying IRB may also make such reports and shall forward copies of any such reports to the appropriate persons or offices in its own institution. Copies of any such reports made to the federal government or other oversight agencies shall be promptly forwarded to the other IRBs that are involved in such study. Where such reporting may result in media attention, the involved institutions will be expected to coordinate their public relations responses.
- f) Complaints – Complaints from subjects, investigators or others about a study under the MOU must be reported promptly to the other IRBs that are involved in such study. The Reviewing and Relying IRBs will apply the coordinated process to handle complaints.
- g) Cooperation – The Reviewing and Relying IRBs shall cooperate fully with the reciprocal IRB concerning the operation of this agreement. Relevant documentation to support review, compliance and oversight by the respective IRBs will be made available to the reciprocal IRB upon request. Each IRB will make available records applicable to regulatory and accrediting agency activity if and when the reciprocal IRB requires such records. Each IRB shall retain such records for the period of time required by all relevant federal and state laws, statutes and regulations and such IRB's institutional policy.
- h) Confidentiality – Each institution is obligated to maintain the confidential or proprietary nature of review information and will hold such information in confidence and restrict access to those within the institution on a need-to-know basis.
- i) MOU on File – This MOU must be kept on file at the IRBs of each Institution named in this MOU and must be provided to OHRP upon request.
- j) Notification of OHRP – Each Institution named in this MOU must include the other Institutions named in this MOU in its FWA on file with OHRP.

13) Human Research Subject Injuries

Each Party's Human Research Protection Program shall have policies and procedures in place for addressing the issue of human research subject injuries, and detailing whether any compensation or medical treatments are available if injury occurs related to a research study. Each Institution is responsible for inserting in the consent form a description of whether any compensation or medical treatments are available in the event of an injury at the local site. Each Party shall adhere to its own policies concerning research subject injuries, if any, that may result from research-related procedures that occur at its site.

14) Indemnification

Each Institution shall defend, indemnify and hold the others' faculty, their officers, employees and agents harmless from and against any and all liability, loss, expense (including reasonable attorneys' fees), or claims for injury or damages arising out of the performance of this MOU, but only in proportion to and to the extent that such liability, loss, expense, attorneys' fees or claims for injury or damages ("Liability") are caused by or result from (a) the negligent or intentional acts or omissions of, the indemnifying Institution, its officers, employees, agents, or faculty (in the course and scope of their employment) (the "Indemnifying Parties"), (b) the breach by any Indemnifying Party of this Agreement or the Standard Operating Procedures mutually agreed upon by the parties, or (c) the breach by any Indemnifying Party of relevant federal and state laws, statutes and regulations, as such proportionate Liability has been agreed to by the Entities involved, or in the event that the Entities cannot agree, as determined by the final and binding determination of an arbitrator selected by the mutual agreement of the involved Entities, who can be from Judicial Arbitration and Mediation Services, Inc. ("JAMS") or from any other mutually acceptable source. The involved Institutions shall share equally the fees charged by the arbitrator and any fees that may be charged by the entity that administers the arbitration for the arbitrator.

15) Insurance

All Parties shall maintain Professional Medical and Hospital Liability insurance or programs of self-insurance with limits of two million dollars (\$2,000,000) per occurrence and five million dollars (\$5,000,000) general aggregate. If the insurance is written on a claims-made form, it shall continue for three years following termination of this MOU. The insurance shall have a retroactive date of placement prior to or coinciding with the effective date of this MOU. All Parties agree to name the other Parties as additional named insureds, but only in proportion to and to the extent of the negligent or intentional acts of the insured party.

All Parties shall maintain Comprehensive or Commercial Form General Liability insurance or programs of self-insurance with a limit of one million dollars (\$1,000,000) per occurrence, and two million dollars (\$2,000,000) general aggregate. If the insurance is written on a claims-made form, it shall continue for three years following termination of this MOU. The insurance shall have a retroactive date of placement prior to or coinciding with the effective date of this MOU. All Parties agree to name the other Parties as additional named insureds, but only in proportion to and to the extent of the negligent or intentional acts of the primary insured party.

16) Termination

While the term of this MOU is five years, any party may terminate its own involvement in this Agreement for any reason by giving at least ninety days (90) notice in writing to the other parties, provided that the parties shall, in any event of termination under this section, cooperate to ensure minimal adverse impact to human subject research and protection of human research subjects.

17) Execution

The undersigned Institutional Officials of the HRPPs at the Institutions named in this MOU have read and agreed to all of the terms above. This MOU shall remain in effect for five years from

the date of execution, unless terminated as set forth herein, subject to amendment at the agreement of authorized representatives of the parties.

CHARLES R. DREW UNIVERSITY OF MEDICINE AND SCIENCE

 7/11/2018
Institutional Official Signature Date

STEVE O. MICHAEL
Name (print)

FWA00002736
Federalwide Assurance Number

Provost
Institutional Title

LOS ANGELES BIOMEDICAL RESEARCH INSTITUTE AT HARBOR-UCLA MEDICAL CENTER

 7/18/18
Institutional Official Signature Date

Richard S. Hetzler
Name (print)

FWA00001992
Federalwide Assurance Number

EXEC. VICE PRESIDENT, OPERATIONS
Institutional Title

HARBOR-UCLA MEDICAL CENTER

 5/30/18
Institutional Official Signature Date

Kimberly McKenzie
Name (print)

FWA00002334
Federalwide Assurance Number

CEO
Institutional Title

LAC+USC MEDICAL CENTER


Institutional Official Signature Date

Tony Orozco
Name (print)

FWA00005905
Federalwide Assurance Number

CEO
Institutional Title

LOS ANGELES COUNTY PUBLIC HEALTH DEPARTMENT, AMBULATORY CARE
NETWORK, AND HEALTH SERVICES ADMINISTRATION

John Walton Senterfitt 5/29/18
Institutional Official Signature Date

FWA00000071
Federalwide Assurance Number

John Walton Senterfitt
Name (print)

IRB Chair + Administrator
Institutional Title

OLIVE VIEW-UCLA EDUCATION AND RESEARCH INSTITUTE

Gregory Moran MD 6/7/18
Institutional Official Signature Date

FWA00000495
Federalwide Assurance Number

Gregory Moran MD
Name (print)

IRB Chair
Institutional Title

RANCHO RESEARCH INSTITUTE AT RANCHOS LOS AMIGOS NATIONAL
REHABILITATION CENTER

Susan Shaw 7/24/18
Institutional Official Signature Date

FWA00002950, FWA00003200
Federalwide Assurance Number

Susan Shaw
Name (print)

Chair, IRB
Institutional Title

UNIVERSITY OF SOUTHERN CALIFORNIA

Kristin Craun 8/8/18
Institutional Official Signature Date

FWA00005906, FWA00007099
Federalwide Assurance Number

Kristin Craun
Name (print)

IRB Director
Institutional Title