CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE (CTSI)
Amended and Restated Memorandum of Understanding
Among the Human Research Protection Programs at
Cedars-Sinai Medical Center (FWA 00000468)
Charles Drew University of Medicine and Science (FWA00002736)
Los Angeles BioMedical Research Institute at Harbor-UCLA Medical Center (FWA00001992)
and the University of California, Los Angeles (FWA00004642),

Effective March 26, 2012 to March 26, 2017

1) Agreement – As part of the collaboration established by their CTSI, this Amended and
Restated Memorandum of Understanding (MOU), which amends and restates the original MOU
among the parties effective as of September 1, 2008, sets forth the express agreement
between the Human Research Protection Programs (HRPP) at the University of California Los
Angeles, Los Angeles BioMedical Research Institute at Harbor-UCLA Medical Center, Cedars-
Sinai Medical Center and Charles Drew University of Medicine and Science (each of the above
referred to as a CTSI “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, as part of the CTSI. 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.

2) Types of Research Covered by this Agreement
This MOU applies to the following types of human subject research as defined by federal
regulations and state laws: research that is eligible for expedited review; or research that
requires full board review and that:
   a) Will be a collaborative effort between or among any of the four 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). In addition, California law requires IRB approval for any research
      involving
         (1) Derivation and use of human embryonic stem cells, human embryonic germ cells and
             human adult stem cells from any source, including somatic cell nuclear transplantation,
(2) Any research using individually identifiable information from death data files held by the State Registrar, local registrars, and county recorders.

b) 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.

c) 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.

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.

e) 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.

f) 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.

g) Reportable Events – Any events, including adverse events, unanticipated problems, protocol violations, incidents, concerns, and/or complaints, that are required to be reported to the Reviewing IRB in accordance with its policies and guidelines.

5) Reliance on Another IRB Review and Approval - 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 this 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 of the funding institution, 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 UCLA CTSI IRB Protocol Registration Notice and the completed submission material to the Reviewing IRB.
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.
e) The Relying PI will
   i) inform the Lead PI of any reportable events 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 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 enter appropriate data to the CTSI Portal and also upload 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 reportable events 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 enter the appropriate data into the CTSI Portal as well as upload a copy of the Acknowledgement Letter. It 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 the local institutional review 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 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. 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 immediately report to the reciprocal IRB any required reportable events using the CTSI portal. 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** – The Reviewing IRB will coordinate the investigation of the reportable event 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 as described in Section 12d 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 agreement and must be provided to OHRP upon request.

j) Notification of OHRP – Each Institution must include the other Institution named 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 MOU for any reason by giving at least ninety (90) days 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 University of California Los Angeles, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, Cedars-Sinai Medical Center and Charles R. Drew University of Medicine and Science and 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.

**UNIVERSITY OF CALIFORNIA LOS ANGELES**

Institutional Official Signature Date

Economou

FWA00000068

Federalwide Assurance Number

**LOS ANGELES BIOMEDICAL RESEARCH INSTITUTE AT HARBOR-UCLA MEDICAL CENTER**

Institutional Official Signature Date

D. Meyer

FWA00001992

Federalwide Assurance Number

**CEDARS-SINAI MEDICAL CENTER**

Institutional Official Signature Date

Shlomo Melmed, M.D.

FWA00000468

Sr. Vice President, Academic Affairs, Dean of the Medical Faculty

**CHARLES DREW UNIVERSITY OF MEDICINE AND SCIENCE**

Institutional Official Signature Date

David M. Carlisle

FWA00002736

President and CEO
Joinder Agreement

Name: University of Southern California

This Joinder Agreement, which is effective as of July ___, 2015 (the "Effective Date") is intended to establish that the University of Southern California ("Joining Institution") shall become a party to the Amended and Restated Memorandum of Understanding Among the Human Research Protection Programs at Cedars-Sinai Medical Center, Charles R. Drew University of Medicine and Science, Los Angeles BioMedical Research Institute at Harbor-UCLA Medical Center and the University of California, Los Angeles, dated as of March 26, 2012 (the "Agreement").

1. Definitions. Capitalized terms used but not defined herein shall have the meanings set forth in the Agreement.

2. Joinder; Binding Provisions of Agreement. Joining Institution hereby agrees to join the Agreement and become a participating Institution thereunder. Joining Institution hereby accepts, assumes and agrees to be bound by all of the obligations and to enjoy all of the rights of an Institution under the Agreement.

3. Consent of Participating Institutions. The participating Institutions hereby consent to the addition of the Joining Institution to the Agreement.

IN WITNESS WHEREOF, the undersigned Institutional Officials of the HRPP at each Institution has executed this Joinder Agreement as of the Effective Date first above written.

Joining Institution:

UNIVERSITY OF SOUTHERN CALIFORNIA

[Signature]
Institutional Official Signature

[Date]
Date

Randolph W. Hall, Ph.D
Name (print)

FWA00005906, FWA00007099
Federalwide Assurance Number

Vice President of Research
Institutional Title

 Participating Institutions:

UNIVERSITY OF CALIFORNIA LOS ANGELES

[Signature]
Institutional Official Signature

[Date]
Date

Name (print)

FWA00000068
Federalwide Assurance Number

Institutional Title
### LOS ANGELES BIOMEDICAL RESEARCH INSTITUTE AT HARBOR-UCLA MEDICAL CENTER

<table>
<thead>
<tr>
<th>Institutional Official Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

**Name (print)**

<table>
<thead>
<tr>
<th>Federalwide Assurance Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>FWA00001992</td>
</tr>
</tbody>
</table>

**Institutional Title**

### CEDARS-SINAI MEDICAL CENTER

<table>
<thead>
<tr>
<th>Institutional Official Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

**Name (print)**

<table>
<thead>
<tr>
<th>Federalwide Assurance Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>FWA00000468</td>
</tr>
</tbody>
</table>

**Institutional Title**

- Senior Vice President, Academic Affairs & Dean of the Medical Faculty
- **Salomo Melmed, M.D.**

### CHARLES R. DREW UNIVERSITY OF MEDICINE AND SCIENCE

<table>
<thead>
<tr>
<th>Institutional Official Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

**Name (print)**

<table>
<thead>
<tr>
<th>Federalwide Assurance Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>FWA00002736</td>
</tr>
</tbody>
</table>

**Institutional Title**