Memorandum of Understanding
Between
Hebrew Union College and the
University of Southern California

Effective March 20, 2014 ("Effective Date")

1) Agreement

Hebrew Union College, a California nonprofit public benefit institution ("HUC"), and the University of Southern California, a California nonprofit public benefit corporation ("USC"), are each engaged in human subjects research (each, an "Institution"). This MOU allows the University Park Institutional Review Board ("UPIRB") of USC to review, approve, and maintain oversight of designated research studies conducted by HUC. USC agrees that it will make its UPIRB available for such reviews. IRB reviews are made in the interests of protecting human subjects. No compensation will be paid by either Institution for such reviews. Researchers at HUC are required to adhere to USC IRB Policies and procedures as well as all Federal and state regulations pertaining to human subjects research.

2) Reliance on IRB approval hereunder may be requested: (a) all human subjects research

This MOU meets the federal requirements for designation of another Institution's IRB as the Reviewing IRB, as set forth in the Office for Human Research Protections' (OHRP) guidance Terms of the Federalwide Assurance, March 20, 2002 ("Assurance"). The Reviewing IRB shall adhere to the requirements set forth in the Assurance.

HUC and USC represent, each on its own behalf, that it has a valid and approved FederalWide Assurance ("FWA") by the HHS Office for Human Research Protections ("OHRP"), and that it will maintain that FWA as valid and approved throughout the term of this MOU. Each Institution's existing FWA is attached hereto as Exhibit A. In the event that either Institution files a new or revised FWA that changes the voluntary choice as to whether 45 CFR 46 applies to all Human Subject Research at that Institution, or that materially alters the coverage or other significant feature of the FWA, then that Institution shall notify the other Institution before such change is made.

As required by the Assurance, HUC must name the UPIRB as the IRB of record in its FWA.

3) 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:

   i) 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 each Institution's 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) **Reportable Events** – Any events, including adverse events, unanticipated problems, protocol violations, noncompliance with applicable laws and regulations, incidents, concerns, injuries to subjects related to a protocol intervention, and/or complaints that are required to be reported to the Reviewing IRB in accordance with its policies and guidelines.

4) Reliance on Another IRB Review and Approval

The Institutional Officials signing below agree that HUC may rely on the review and approval by the UPIRB for research that has been referred under this MOU.

5) Compliance with Federal and State Law

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

6) Informed Consent Form

Research under this MOU 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 UPIRB.

In instances where informed consent is required, the UPIRB will be responsible for reviewing, approving, and releasing for use with human subjects, a consent document that incorporates all requirements under 45 CFR 46.

7) Duties and Responsibilities of the University Park IRB

a) **Review and Oversight** – The UPIRB shall conduct initial and continuing reviews, and shall review amendments to approved protocols and reportable events. The UPIRB shall have the authority to suspend or terminate the research and shall notify HUC of any suspension or termination of research. The UPIRB shall notify HUC of any determinations resulting from review of unanticipated problems, serious or continuing noncompliance, and other noncompliance with approved protocols. In the event that the UPIRB receives an inquiry from any governmental official related to research for which the UPIRB is the IRB of record the UPIRB shall inform HUC immediately, and shall provide any new information to the HUC during the course of such an inquiry.

b) **Approval Letter** – The UPIRB shall provide the IRB Approval Letter and the approved submission documents to the Principal Investigator (PI). The UPIRB shall also provide the PI any continuing review approvals as well as any approvals of changes to a study that has been referred to the UPIRB.

c) **Record Keeping** – The UPIRB will keep records of all 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, all study documents released with the approval, as well as oversight actions. The UPIRB shall make these records available to HUC upon request. The UPIRB shall retain these records for the period of time required by all relevant federal and state laws, statutes and regulations and the UPIRB Institutional policy.

8) Duties and Responsibilities of HUC

a) **Compliance and Oversight** – HUC shall monitor compliance with the terms and conditions of the UPIRB's approval of research being conducted at the HUC. HUC shall advise the UPIRB of any Reportable Events of which it becomes aware including, but not limited to, violations of human research

protection regulations. In the event that HUC receives an inquiry from any governmental official related to research for which the UPIRB is the IRB of record, HUC shall inform the UPIRB immediately, and shall provide any new information to the UPIRB during the course of such an inquiry.

b) **Record Keeping** – HUC will keep records of any Acknowledgement Letters and any oversight actions. HUC shall retain these records for the period of time required by all relevant federal and state laws, statutes and regulations and the HUC's Institutional policy. The office responsible for keeping such records, as well as renewing the MOU every five years, is HUC Dean's Office.

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

a) **Protocol and Grant Comparison** – In the event that HUC has received a federal grant or contract with respect to any study referred under this MOU, HUC shall ensure that the protocol for such study is consistent with the activities described under the federal grant or contract.

b) **Reporting Unanticipated Problems and/or Any Serious and/or Continuing Noncompliance** – HUC shall immediately report to the UPIRB any Reportable Events. This reporting duty is in addition to, but does not replace, the investigator's duty to report Reportable Events to his or her Institution as required by regulation, IRB directive, and/or Institutional policies and procedures. The HUC Dean's Office shall serve as the destination for reported problems, to be documented on consent forms.

i) **Investigation** – The UPIRB will coordinate the investigation of the Reportable Event with HUC and the two will work collaboratively in the fact-finding process. When appropriate, HUC must forward a summary and corrective action plan to the UPIRB as soon as the inquiry has been completed, to allow the UPIRB 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 or indicates other reportable noncompliance.

ii) **Reporting to Oversight Agencies** – The UPIRB 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 or funding agencies and entities. Copies of any such reports made to the federal government or other oversight or funding agencies and entities shall be promptly forwarded by UPIRB to HUC. Where such reporting may result in media attention, the involved Institutions will seek to coordinate their public relations responses but in no event shall HUC use or reference the name(s), logos, or other marks of USC without USC's express written permission. Email correspondence shall meet the writing requirement.

iii) **Complaints** – Complaints from subjects, investigators or others about a protocol that has been referred under this MOU must be reported by all investigators and any Institution promptly to the UPIRB.

c) **Cooperation** – The UPIRB and HUC shall cooperate fully with the operation of this MOU. Relevant documentation to support review, compliance and oversight will be made available to the reciprocal Institution upon request. Each Institution will make available records applicable to regulatory and accrediting agency activity if and when the reciprocal Institution requires such records. Each Institution 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.

d) **Confidentiality** – Each Institution is obligated to maintain the confidential or proprietary nature of review information; will hold such information in confidence and restrict access to those within the Institution on a need-to-know basis; and will advise UPIRB members and staff of this requirement.

e) **MOU on File** – This MOU must be kept on file at each Institution named in this MOU and must be provided to OHRP upon request.

f) **Standard Operating Procedures** – While operating under this Agreement, the Institutions agree to abide by the terms of the Standard Operating Procedures ("SOP") to be collaboratively developed by the Institutions. SOPs may be changed to reflect current practices and will not require revision of the MOU, unless the changes alter the terms of this Agreement.

10) Human Research Subject Injuries

Each Institution's Human Research Protections 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 site where the research occurred. Each Institution shall adhere to its own policies concerning research subject injuries, if any, that may result from research-related interventions that occur at its site. In any protocol that has been referred under this MOU, the reviewing IRB and relying IRB shall notify one another immediately, in the event of receiving a report of an injury to a human subject reportedly or apparently caused by a research intervention.

Because HUC researchers are not conducting medical research, HUC does not need to purchase additional insurance above and beyond its preexisting insurance plans, which cover injuries on the HUC campus (see below).

11) Conflicts of Interest

If the relying Institution determines that a protocol has a potential institutional conflict of interest as well as an investigator conflict of interest (following USC's policy, as indicated here: http://policies.usc.edu/p4acad_stud/conflic_interest_research.html), the relying Institution will require its investigators to provide sufficient information to the reviewing IRB (including completion of conflict of interest disclosure forms) to allow it to consider the applicable conflict of interest issues in addressing the relevant IRB approval criteria. For all these purposes, the term "investigators" shall include the principal investigator, co- investigators, and key research personnel. The reviewing IRB will adhere to the confidentiality provisions set forth in Section 11(e) hereof to maintain the confidential nature of the conflict of interest information.

12) Indemnification and Limitation on Damages

Each Institution shall defend, indemnify and hold the other's faculty, officers, employees, agents and unaffiliated IRB members 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, faculty, or IRB members (in the course and scope of their employment or Institutional service) (the "Indemnifying Parties"), (b) the breach by any Indemnifying Party of this MOU or the Standard Operating Procedures mutually agreed upon by the Institutions, or (c) the breach by any Indemnifying Party of relevant federal and state laws, statutes and regulations, as such proportionate liability has been determined by the final and binding determination of an arbitrator selected by the mutual agreement of the involved entities, who can be from 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.

Notwithstanding anything to the contrary contained herein, to the maximum extent permitted by law, in no event will either USC or HUC be responsible for any incidental, consequential, indirect, special,

punitive, or exemplary damages of any kind, including damages for lost goodwill, lost profits, lost business or other indirect economic damages, whether such claim is based on contract, negligence, tort (including strict liability) or other legal theory, as a result of a breach of any warranty or any other term of this MOU, and regardless of whether a party was advised or had reason to know of the possibility of such damages in advance.

13) Insurance

Each Institution 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. Each Institution agrees to name the other Institution as additional named insured, but only in proportion to and to the extent of the negligent or intentional acts of the primary insured Institution.

14) Termination

The term of this MOU shall be for a period of (5) years following the Effective Date. Thereafter, the Institutions shall have the right to extend the term pursuant to their mutual written agreement. Each Institution shall have the right to terminate this MOU at any time during the term hereof for any reason by giving at least ninety (90) days' advance notice in writing to the other Institution, provided that the Institutions 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.

15) Execution

The undersigned Institutional officials at Hebrew Union College and the University of Southern California have read and agreed to all of the terms above.

16) Assignment

Neither Institution shall have the right to assign or transfer any right or obligation under this MOU to any third party, and such assignment is expressly prohibited.

17) Amendment

No provision of this MOU may be waived, changed, modified or amended except by the mutual written agreement of the Institutions.

By and on behalf of:

The University of Southern California

By: _____

Title: Michael W. Quick
Executive Vice Provost

Date: _____

Hewbrew Union College

By: Sandra M. Miller

Title: Chief Financial Officer

Date: April 10, 2014