Agreement to Transfer IRB Oversight of Human Subject Research under the Reliance Memorandum of Understanding Among the University of California Campuses, UC Division of Agriculture and Natural Resources, and Lawrence Berkeley National Laboratory

June 2020

This agreement has been approved by the Directors of the Human Subjects Protections Program (HRPPs) of the UC campuses, UC Division of Agriculture and Natural Resources (ANR), and the Lawrence Berkeley National Laboratory (hereinafter referred to as "UC Campuses") as authorized under the above-referenced Reliance Memorandum of Understanding (Reliance MOU) and describes the transfer of review responsibility from one UC Campus IRB to another UC Campus IRB.

1. DEFINITIONS

a. Human Subject Research – The definition of human subject research is that set forth in federal regulations describing human subjects, research, clinical trial, intervention and other closely related terms promulgated by the Office of Human Subject Protections for Human Subject Research at 45 CFR §46.102, the Food & Drug Administration regulations at 21 CFR §50.3, §312.3 and §812.3, and as defined by other local law in the jurisdiction where the research is being conducted.

b. Human Research Protections Program – The program operated by the Institution for the protection of human subjects in research, which includes IRB oversight and administration, and may also include conflict of interest identification and management, radiation safety, biosafety, investigational drug compounding and manufacturing, information privacy and security, and similar activities.

c. Institutional Review Board (IRB) – A specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral or social science research.

d. Original IRB – The IRB originally designated to review a human subject research protocol and transfers oversight responsibility to another IRB.

e. Receiving IRB – The IRB that accepts responsibility for oversight of a human subject research protocol.

2. AGREEMENT

The HRPP Directors of the UC campuses agree that the same IRB retains oversight responsibility for a specific research project throughout the life of the project. However, it is sometimes necessary to transfer the review responsibility from one UC Campus IRB to another UC Campus IRB, on a temporary or permanent basis. Transfer is accomplished in an orderly way that assures continuous IRB oversight with no lapse in either IRB approval or the protection of human subjects, with minimal disruption of research activities, and that is compliant with federal regulatory requirements about transfers.

3. TRANSFER PROCESS

a. General Process

Following guidance provided by the Food and Drug Administration (FDA) and the Office for Human Research Protections (ORHP), the general IRB transfer process involves:

i. Identifying the human subject research protocol(s) to be transferred;

ii. Ensuring the availability and retention of pertinent research records;

iii. Establishing an effective date for transfer of IRB oversight;

iv. The Receiving IRB conducting a review of the human subject research protocol(s) (new or continuing review), as appropriate, before accepting responsibility for the protocol(s);

v. Confirming or establishing the date for the next continuing review;

vi. Determining whether the consent form needs to be revised; and

vii. Notifying relevant parties of the transfer of IRB oversight and the IRB review determination.

b. Procedures

i. **Initiation of the Transfer:** The protocol(s) to be transferred may be identified by the HRPP of the Original IRB or another UC HRPP. Transfer requests should generally be initiated due to an emergency or disaster (e.g., nature disaster or public health emergency) or other unforeseen extenuating circumstances. Transfer requests from investigators will not be considered except under justifiable circumstances.

ii. **Terms and Timing of the Transfer:** The HRPP of the Original IRB works with an appropriate individual at Receiving IRB institution to develop an agreement about the terms and timing of the transfer.

iii. **Records:** The HRPP of the Original IRB arranges to provide the Receiving IRB institution with a copy of any records it requests as part of the transfer, in the format requested by the Receiving IRB institution. Documentation of IRB activities, and records relating to research which is conducted, must be retained for at least 3 years after completion of the research.

iv. **IRB Review:** The HRPP of the Receiving IRB performs a pre-review, following standard local procedures, before accepting responsibility for the protocol(s). The HRPP of the Receiving IRB may request the investigator to provide additional information or the Original IRB to provide local context information to the Receiving IRB. The Receiving IRB performs a complete review of the protocol(s), following standard procedures and using the relevant criteria for IRB approval. This may include the requirement for modifications or consent form changes. The Receiving IRB establishes a new approval period, including the frequency of continuing review.

viii. **Notifications:** The HRPP of the Original IRB works with the Receiving IRB institution and the investigator to ensure that all key parties are appropriately notified about the pending, and completed, transfer of IRB oversight. The investigator is responsible for informing any other relevant parties such as the sponsor, clinical research organization and others as applicable, for the transfer of IRB responsibilities and the review determination.

v. **Closure of the IRB File:** When the transfer is completed, the HRPP of the Original IRB ensures that all transfer-related documentation is placed in the IRB file and closed following standard procedures. Should the Original IRB and the Receiving IRB wish to have the study returned to the oversight of the Original IRB at some future time, the transfer process must be repeated.

4. REFERENCES

a. FDA, "Guidance for IRBs, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another IRB", draft guidance; June 2012.

b. OHRP, "Consideration in Transferring a Previously-Approved Research Project to a New IRB or Research Institution", draft guidance; May 23, 2012.

5. Execution

The undersigned UC Campus HRPP Directors have read and agreed to the above, which shall remain in effect until revoked or superseded by revised procedures and policies.

UC Berkeley IRB Director	6/16/2020 Date
UC Davis IRB Director	6/15/2020 Date
UC Irvine IRB Director	6/15/2020 Date
UC Los Angeles IRB Director	6/17/2020 Date
UC Merced IRB Director	6/15/2020 Date
UC Riverside IRB Director	5/30/2020 Date
UC San Diego IRB Director	6/17/20 Date
UC San Francisco IRB Director	5/31/2020 Date
UC Santa Barbara IRB Director	6/17/2020 Date
Laverne Estanol, M.S. UC Santa Cruz Director, Office of Research Compliance Administration	6/15/2020 Date
Lawrence Berkeley National Laboratory HSP Program Manager	6/15/2020 Date
UC Division of Agriculture and Natural Resources	6/15/2020 Date