This form documents that University of California, Irvine (UCI) will serve as Reviewing Institutional Review Board (IRB) for the research noted below; and the following Relying Institution has agreed to cede IRB review to UCI. Flexible implementation applies.

IRB Review will be ceded under the [**SMART IRB Agreement**](https://smartirb.org/agreement/) **Version 3.0**. Questions regarding this reliance arrangement should be directed to SMART IRB institutional [Points of Contact](https://smartirb.org/participating-institutions/) (POC).

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| Reviewing IRB Institution |  |
| Relying Institution |  |
| Research Study Title(s) |  |
| Reviewing Institution Principal Investigator (PI) |  |
| Relying Institution Site Investigator |  |

This reliance arrangement is effective on the date that the last official signs and may be terminated by either party at any time. If the arrangement is terminated prior to the completion of the research, the Relying Institution will need to obtain alternative IRB review.

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| **This Letter of Acknowledgment was completed by the following institutional representatives:** |
| Reviewing Institution Designee | ***(Signature to be Obtained by UCI Human Research Protections Staff)*****Signature:****Name:****Role:****Date:** |
| Relying Institution POC/Designee | **Signature:****Name:****Role:****Date:** |

**Flexible Implementation Apply**

*[For items with multiple options, delete the option that does not apply]*

**1. Standard Operating Procedures:
Reviewing IRB SOPs Will Apply**

The Participating Institutions will follow the Reviewing IRB SOPs (<https://research.uci.edu/wp-content/uploads/all-hrp-policies.pdf>) with respect to the identified research.

**2. HIPAA Determinations and Actions:
Relying Institution or 3rd Party Will Provide Determination**

The Relying Institution or a third party named by Relying Institution will make any HIPAA determinations or perform any HIPAA Actions in connection with the research.

**Reviewing IRB Will Provide Determination (Rare for UCI)**The Reviewing IRB will review in accordance with 45CFR164.512(i)(1)(i) and (i)(2) a request for HIPAA Waiver/Alteration of Authorization in Connection with the Research.

**3. HIPAA Authorization Language and Consent Forms:**
**Not Applicable**

HIPAA Authorization will not be obtained. A HIPAA Waiver/Alteration of Authorization is requested.

**Relying Institution Will Provide Reviewing IRB with Separate HIPAA Authorization**

The Reviewing IRB is under no obligation to ensure HIPAA Authorization language meet the requirements of 45 CFR 164.508(b) and (c).

**Reviewing IRB Will Provide Separate HIPAA Authorization Form (Rare for UCI)**

Reviewing IRB will provide separate HIPAA authorization form on behalf of the Relying Institution meeting the requirements of 45 CFR 164.508(b) and (c) as necessary to permit the use and disclosure of PHI.

**4. Conflicts of Interest:
Relying Institution Will Perform Conflict of Interest Analyses Under Their Policies**

The Relying Institution will perform their own analyses under their relevant policy with respect to disclosure and management of their Research Personnel’s conflicts of interest in connection with the identified research. The Relying Institution’s resulting determinations, prohibitions, management plans, and any updates will be provided to the Reviewing IRB. Note that the Reviewing IRB has the right to impose additional prohibitions or conflict management requirements.

**5. For-Cause Audits:
Relying Institution Will Conduct Any IRB-Initiated, For-Cause Audits or Investigations**

The Reviewing IRB will request Relying Institution conduct any IRB-initiated audits or investigations of matters relating to the Ceded Review of the identified research.

**6. IRB Notifications (of Decisions, Changes, Lapses in Approval, Problems, Noncompliance)
Reviewing IRB Will Provide Notifications Through Another Party**

The Reviewing IRB will provide notifications through the UCI PI to the Overall PI, Site Investigator(s), and Relying Institution(s) of decisions, changes, lapses in approval, problems, and non-compliance.

**7. IRB-Initiated External Reporting:
Reviewing IRB Will Draft and Submit Reports to External Recipients**

The Reviewing IRB will draft and submit to external parties (e.g., regulatory agencies, other oversight authorities) any reports of unanticipated problems, serious or continuing noncompliance, and suspension or termination of IRB approval that the IRB determines are required in connection with the identified research. Note that the Relying Institution have the right to review/ comment on the draft report(s) and to make/submit their own report(s) in addition to the Reviewing IRB’s report(s).

 **8. Congruence of Federal Grant Applications/Contract Proposals:
Another Party Will Review Congruence**
The Reviewing IRB will delegate responsibility for review of the congruence of any federal grant application(s) or contract proposal(s) supporting the identified research to the UCI PI.

**9. Financial Agreements:
Reviewing IRB/Institution Will Not Charge Relying Institution for Review Costs**

The Relying Institution will not be responsible for financial support of the costs of review of the identified research. The Reviewing IRB may charge the sponsor or other third parties for those costs.
 **10. Quality Assurance/Quality Improvement (“QA/QI” Function or Program):
Program Access Required - Relying Institution Has an IRB or is an Independent IRB Organization**

Each Participating Institution must have or have access to a human subjects research QA/QI program or service (or an alternate means of monitoring) that can conduct and report to that institution the results of for-cause and not-for-cause audits of the institution’s and its Research Personnel’s compliance with human subjects protections and other relevant requirements.

**Program Access Not Required - Relying Institution Does Not Have an IRB and is Not an Independent IRB Organization**Participating Institutions engaged in or conducting the identified research are not required to have or have access to a human subjects’ research QA/QI program or service.

**11. Insurance:
Insurance Required – Non-Public Participating Institution**

Each Non-Public Participating Institution must maintain insurance coverage of sufficient type(s) and in reasonable amount(s) to cover its activities with respect to the identified research, including coverage of its IRB/IRB members when acting as a Reviewing IRB. Participating Institutions may request from one another an insurance certificate or equivalent documentation of the relevant coverage (including any sponsor-provided coverage).

**Insurance Not Required – Public Participating Institution**

Participating Institutions are not required to maintain insurance coverage to cover activities with respect to the identified research.

**Relying Institution Site Investigator Certifications:**

1. I understand that individuals are engaged in human research whenever: (a) an individual intervenes or interacts with human subjects for research purposes; or (b) the individual obtains identifiable private information about human subjects for research purposes.
2. I accept responsibility for safeguarding the rights and welfare of each research subject I interact with on this project, and I understand that the subject’s rights and welfare must at all times come before the goals and requirements of the research.
3. I will maintain evidence of human research educational training at my institution for myself and my study team, or I / they will complete the UCI Human Research Protections educational training and maintain evidence of completion prior to initiating research covered under this Agreement.
4. I will conduct the research as approved by the UCI IRB and I will not make any changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to participants.
5. I will report immediately to the UCI IRB any unfavorable occurrence or any unanticipated problems involving risks to participants or others in research covered under this Agreement.
6. If I am responsible for enrolling subjects, I will obtain, document, and maintain records of informed consent for each such subject or each subject’s legally authorized representative following the methods described in the approved study. Upon conclusion of the study, these records will be maintained as per UCI recordkeeping standards.
7. I will promptly report to the UCI IRB any noncompliance with the standards or requirements reference in this Agreement, whether by the Investigator, any co-investigators, research staff, or others, regardless of fault or intent.
8. I will abide by all determinations of the UCI IRB and provide all information requested by the IRB or the Principal Investigator in a timely manner.
9. I will provide the names of any individuals engaged in the research who are working under my direction to the UCI IRB.
10. I will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.
11. I will abide by all determinations of the IRB designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

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| **Relying Institution Site Investigator** |
| **Signature:****Name:****Date:** |