|  |  |
| --- | --- |
| **or-logo-stacked** | Institutional Authorization  Agreement (IAA) - IRB & HIPAA  *Version 10-04-2022* |

|  |  |
| --- | --- |
| ***Relying Institution/Entity Information*** | |
| ***Lead Researcher Name:*** |  |
| ***Lead Researcher Phone:*** |  |
| ***Lead Researcher E-mail:*** |  |
| ***Name of Institution/Entity Relying on UCI IRB:*** |  |
| ***Institution/Entity Address:*** |  |
| ***Name of Authorized Official for the Institution/Entity:*** |  |
| ***Federalwide Assurance (FWA) #:*** |  |

|  |  |
| --- | --- |
| ***Reviewing Institution/Entity Information*** | |
| ***Name of Institution/Entity Providing IRB Review:*** | University of California, Irvine (UCI) |
| ***IRB Registration #:*** | A: 00000393, B: 00000394, C: 00000395 |
| ***UCI FWA #:*** | 00004071 |
| ***UCI IRB Protocol #*** |  |
| ***UCI Study Title:*** |  |

UCI IRB will serve as the IRB of record for research covered under this agreement; it will review the research as specified above, consistent with the requirements of 45 CFR 46 and 21 CFR 50, 56, 312, and 812, as applicable.

The UCI IRB acts as a Privacy Board for Research per HIPAA to review the use/disclosure of PHI and to determine whether participants should sign an "Authorization" (an addendum to the consent to participate in research) or if a Waiver of HIPAA Authorization (roughly analogous to a Waiver of Consent under the Common Rule) may be granted. Each institution will retain their own Privacy reporting responsibilities should a breach of privacy occur.

UCI will provide the Relying Institution a HIPAA Research Authorization Form template for use by the Relying Institution. UCI makes no guarantee that the template is appropriate for use at the Relying Institution. By UCI providing this template, and as a condition of this agreement, the Relying Institution accepts all responsibility and liability for evaluating the adequacy of such template for the Relying Institution’s own needs.

The UCI IRB will follow written procedures for reporting its findings and actions to appropriate officials at the institution specified above. Relevant minutes of IRB meetings will be made available to the institution specified above, upon request. The institution specified above relying on the UCI IRB remains responsible for ensuring compliance with UCI IRB’s determinations and with the Terms of its OHRP-approved FWA, and all other applicable laws and regulations related to the conduct of research covered under this agreement. This document must be kept on file by both parties and provided to OHRP upon request.

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

**RELYING INSTITUTION’S** **LEAD RESEARCHER 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 provide 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 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 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 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 IRB and provide all information requested by the IRB or the Principle Investigator I 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 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.

|  |
| --- |
| **Relying Institution Lead Researcher** |
| **Signature: ­­­­**  **Title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date:** |

|  |  |  |
| --- | --- | --- |
| **Authorized Official for Relying Institution** |  | **Authorized Official for UCI** |
| **Signature: ­­­­**  **Title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date:** |  | **Signature: ­­­­**    ***(Signature to be obtained by UCI IRB Staff)***  **Title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date:** |