**California State University San Bernardino (CSUSB)**

**Institutional Review Board (lRB) Institutional Authorization Reliance Agreement (IARA)**

1. **Primary Institution/Organization Providing IRB Review:**

Institution/Organization name

IRB registration# , FWA# (if applicable): \_\_\_\_\_\_\_\_\_\_\_

Institution/Organization name

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institution/Organization name

IRB contact name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Institution Relying on Primary Institutions/Organizations IRB Review:**

Institution Name: California State University- San Bernardino

Address: 5500 University Parkway, San Bernardino CA 92407

IRB Contact Information: Michael Gillespie, msillesp@csusb.edu

IRB Registration #:00002578, Federal-wide Assurance (FWA) #: 00004865

Study Approval Number (if applicable) #:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Approval Dates (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The officials signing below agree that the California State University, San Bernardino IRB may rely on the primary institutions/organizations IRB for review and continuing oversight of the following human subject research protocol:

Title of Research Project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institution/Organization name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sponsor or Funding Agency/Award Number (if any):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Primary Institutions IRB Signatory Official:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signatory Official Signature: Date:

Signatory Official Full Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional/Organization Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact Information: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Institutional Official Signs for Grant Funded Studies**

Institutional Official Name: Dr. Dorota Huizinga, Associate Provost for Research

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IRB Institutional Signatory Official (IO) Signature Date

**IRB Chair and/or IRB Chair Designee Signs for Non-Grant Funded Studies**

Dr. King Yeung, IRB Chair

California State University, San Bernardino (CSUSB) Institutional Review Board

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IRB Chair Signature Date

or One of the IRB Chair designees

Dr. Brian Heisterkamp, IRB Vice-Chair,

California State University, San Bernardino (CSUSB) Institutional Review Board

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IRB Vice-Chair Signature Date

Mr. Michael Gillespie, Sr. Research Compliance Officer,

California State University, San Bernardino (CSUSB) Institutional Review Board

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IRB Sr. Research Compliance Officer Signature Date

**DEFINITIONS / ROLES AND RESPONSIBILITIES**

Single IRB (sIRB): One IRB of record (or Reviewing IRB), selected on a study-by-study basis, provides the ethical review for all sites participating in a specific multisite study.

Relying IRB: IRB that relies on the reviewing IRB for the regulatory reviews. The relying IRB is still responsible for institutional reviews (COI, Radiation, Biosafety, Privacy, and others).

Reviewing IRB: The selected IRB of record that conducts the ethical review for participating sites of the multi-site study, including initial reviews, modifications, continuing reviews, and reportable events.

Lead PI: Responsible for the communication and overall conduct of the study and regulatory compliance. The Lead PI will be submitting the regulatory IRB submissions on behalf of all the sites relying on the reviewing IRB. (Note: The Lead PI may not always be associated with the reviewing IRB, but the Lead PI’s responsibilities nevertheless remain the same.)

Relying PI: Responsible for providing the Lead PI with necessary information according to the reviewing IRB’s policies and procedures so the reviewing IRB can conduct an IRB review. The relying PI must know what is also required from their local relying IRB. Relying PI responsibilities

Central IRB: IRB of record (also known as the Reviewing IRB) provides the ethical review for all sites participating in more than one multisite study. The sites are usually in a network, consortium or particular program, e.g. NCI’s CIRB.

Commercial IRB: Commercial or independent IRBs are contracted agencies that are not affiliated with specific institutions and are paid to conduct reviews of research with human subjects, e.g., Quorum IRB, Ethical and Independent Review (E&I Review), Western IRB (WIRB).

**HOW TO GET STARTED TO RELY ON ANOTHER IRB**

**The Protocol Director is required to submit an IRB Protocol application to request reliance on an IRB.**

**The following is required to process the submission of the CSUSB IAA**

**a. IRB Authorization Reliance Agreement (IARA) signed by the reviewing IRB Institution**

**b. Federal grant (when CSUSB is the prime awardee)**

**c. Current IRB approved study protocol including interview questions and surveys**

**d. Current IRB approval letter**

**e. Informed consent document(s) with required consent language**

**f. Local context document (as needed at the request of the relying IRB)**

**g. Proof of human subjects training of all investigators on the study (PI, Co-PI, faculty adviser if a student initiated study)**

**WHEN IS THE RELIANCE COMPLETE**

A Reliance Document (IARA) will be issued when the IRB application is complete and the IARA has been fully executed by both parties to this agreement.

The signed Authorization Reliance Agreement (IARA) will also be available once both parties have signed. This document, along with the IRB approval letter, can be provided to OHRP and other agencies upon request and as needed.

Final NIH Policy on Single IRB: <https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm>