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# INSTITUTIONAL REVIEW BOARD (IRB) AUTHORIZATION AGREEMENT

## Purpose

This Authorization Agreement sets forth the agreement between the **University of Las Vegas, Nevada** and [Insert Institution here] concerning the agreed upon arrangements for the Institutional Review Board (UNLV IRB).

1. Designated IRB. The following IRB shall be the “Designated IRB” for purposes of this Agreement:

**University of Nevada, Las Vegas (UNLV) Biomedical IRB**

**IRB Registration Number: IRB00001104**

**FWA Number: 00002305**

1. Reliance on the Designated IRB. The University hereby authorizes the Research Site to rely on the Designated IRB for review and continuing oversight, as more specifically described below, of the human subjects research described in this Section 2 (select one):

\_\_\_\_\_ All human subjects research covered by the Research Site’s Federalwide Assurance (FWA)

\_\_\_\_\_ The specific protocols described below:

 IRB#:

 TITLE OF STUDY:

 NAME OF PI:

 NAME OF SPONSOR (if any):

 GRANT/AWARD NUMBER (if any):

\_\_\_\_\_ Other (Please describe here):

## Compliance with Federal and State Regulations and the University of Nevada, Las Vegas Policy

Review and approval of human subject’s research under this agreement shall be conducted in compliance with the federal regulations, 45 CFR 46, other pertinent federal regulations, state and local regulations and all applicable UNLV policies pertaining to the protection of human subjects participating in research.

## III. Duties and Responsibilities of the Reviewing Institution

1. Provide initial and continuing review in accordance with 45 CFR 46, including approval of consent forms for all sites, review of amendments to approved protocols, and review of information that requires reporting (i.e. unanticipated problems involving risks to participants or others, non-compliance, protocol deviations, etc.) for all sites.
2. Suspend or terminate approval of research that is not being conducted in accordance with REVIEWING INSTITUTION policies, is not in compliance with Federal Regulations 45 CFR 46, or that has been associated with unexpected increased risk to participants.
3. Provide prompt reporting to the Relying Institution’s IRB of any unanticipated events or problems involving risk to subjects or others, serious or continuing non-compliance, or suspension/termination of IRB approval.

## IV. Duties and Responsibilities of the Relying Institution

1. Ensure that research activities at its site are in compliance with the IRB’s determinations and with the terms of this IAA. This includes retaining authority to conduct audits of the research being done at their location to ensure compliance.
2. Evaluate the potential financial conflicts of interest of its investigators, research staff, and institution in adherence to its institutional conflict of interest policies and procedures. The Relying Institution is responsible for providing the reviewing institution with any applicable conflicts of interest and corresponding management plans related to the study.
3. Ensure principal investigators and other research personnel involved in the research are appropriately qualified, and meet its institutional standards for eligibility to conduct research including, but not limited to, having the proper training in the protection of human subjects.

d.Provide local context review of COI, training/qualifications of local research team members, ancillary reviews and application of local laws and policies and confirm that the local context review is complete to the Reviewing IRB prior to beginning research.

e.Maintain oversight for local unanticipated problems involving risk to participants or others and local non-compliance.

## V. Duties and Responsibilities of both UNLV IRB and [Insert Relying Institution] IRB.

1. Agree to abide by all applicable regulations in the conduct of human subjects research at each facility as dictated by their FWA and 45 CFR 46.
2. Use reasonable efforts to preserve the confidentiality of Protected Health Information (as defined by law) it receives from the other party, and shall be permitted only to use and disclose such information to the extent permitted pursuant to the Health Insurance Portability and Accountability Act of 1996, regulations promulgated under (“HIPAA Regulations”) and applicable state law.
3. Keep this Reliance Agreement on file at their respective institutions and to make it available upon request to OHRP or any U.S. federal department or agency conducting or supporting research to which the FWA applies.
4. Maintain effective communication and cooperation mechanisms sufficient to ensure adequate protections for human research subjects. Both institutions agree to fully cooperate with the reciprocal IRB, including providing relevant documentation and records as needed.
5. Promptly inform the reciprocal institution of reports of serious or continuing noncompliance in the conduct of the study and unanticipated problems involving risks to participants or others, encountered in research as specified in this agreement.

## VI. Notices and Primary Contacts

a. Any correspondence regarding this study should be addressed to:

 University of Nevada, Las Vegas

 Name: Brad Woods

 Title: Executive Director and Research Integrity Officer

 Address: 4505 S. Maryland Pkwy, Las Vegas, NV 89154

 Email: brad.woods@unlv.edu

 Phone: 702-895-5948

 [Insert Relying Institution here]

 Name:

 Title:

 Address:

 Email:

 Phone:

This agreement will become fully executed upon the date of the last signature by the institutional officials below and will remain in effect until the termination of the research study listed in Part II or until such time that either institution provides 30 days written notice of termination to the other institution.

Signature of Institutional Official for [Insert Relying Institution here]:

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Full Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Institutional Official for the University of Nevada, Las Vegas:

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Full Name: Brad R. Woods

Institutional Title: Executive Director and Research Integrity Officer