

Memorandum of Understanding
Between the Human Research Protection Programs at University
of Nevada, Reno (FWA00002306)
and
University of Nevada, Las Vegas (FWA00002305)

- 1) Agreement — This Memorandum of Understanding (MOU) sets forth an express agreement between and among the Human Research Protection Programs at the University of Nevada, Reno (UNR) and the University of Nevada, Las Vegas (UNLV) campuses. This MOU concerns reliance by these Nevada System of Higher Education (NSHE) Human Research Protection Programs (HRPP) on the review and approval by the other NSHE HRPP of human subjects research as defined by federal regulation and state law that is deemed exempt from Institutional Review Board (IRB) review, eligible for expedited IRB review, or requires review of the convened IRB under federal regulations.
- 2) Types of Research covered by this Agreement —
This MOU applies to collaborative human subjects research efforts between campuses as defined by federal regulation and state law that are determined to be exempt, that are eligible for expedited review, or require review of the convened IRB and that:
 - a) Involve obtaining personally identifiable data or samples from one or both the campuses, and one or both of the campuses will conduct analyses of the data/samples; or
 - b) Involve obtaining samples that are not identifiable for which the U.S. Food and Drug Administration (FDA) is providing oversight of the research.
- 3) Compliance with Agency Guidance — This MOU meets the federal requirements for designation of another institution's IRB as the reviewing IRB, as set forth in Office for Human Research Protections' (OHRP) guidance, Terms of the Federalwide Assurance.
- 4) Definitions
 - a) Human Subjects Research — The definition of human subjects research is that set forth in 45 Code of Federal Regulations (CFR) 546.102 and 21 CFR 50.3(g), 50.3(e), 50.3(b) and 50.3(p).
 - b) Exempt Human Subject Research — The definition of exempt human subject research is that set forth in 45 Code of Federal Regulations 546.101 (b).
 - c) Expedited Human Subject Research — The definition of expedited human subject research is that set forth in 45 CFR 546.110 and 21 CFR 556.110 and OHRP guidance, Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure, dated November 9, 1998 and Guidance on the Use of Expedited Review Procedures, dated August 11, 2003.
 - d) Institutional Official — The Institutional Official is the Signatory Official on the Federalwide Assurance (FWA) filed with the OHRP to assure compliance with regulations governing protection of human subjects. The OHRP requires the Institutional Official to be a high-level official who has the authority to represent the institution named in the FWA.

- 5) Reliance on the IRB Review and Approval of Another Organization — The Institutional Officials signing below agree that the HRPP at his or her campus may accept and rely on the determination of exemption or review and approval by another NSHE HRPP named in this MOU of research involving human subjects meeting the definitions in paragraph #4 above.
- 6) Compliance with Federal and State Law — A determination of exemption or review of human subject research under this agreement shall be conducted in accordance with all relevant federal and state statutes and regulations governing the protection of human subjects, and with all relevant NSHE, UNR and UNLV policies and procedures pertaining to the protection of human subjects participating in research conducted at or by employees of those organizations or their affiliated organizations.
- 7) Informed Consent Form — Research subject to this agreement shall employ a consent process set forth in 45 CFR 546.1 16 and 546.1 17, including documentation of informed consent, a waiver of documentation of informed consent, and a waiver or alteration of informed consent that meets all federal and state requirements and is approved by the IRB of the reviewing campus.
- 8) Reviewing IRB — The reviewing IRB shall be at either
 - a) The NSHE campus that is the prime recipient of the research award (or, in studies where the research is not funded by an external award, the campus with which the PI is primarily affiliated) or
 - b) The NSHE campus where subject contact, recruitment, and/or interactions/interventions, shall entirely or substantially take place.
 - c) Exceptions to this provision shall be determined by the HRPP Director at the NSHE campus that is the prime recipient of the research award (or, in studies where the research is not funded by an external award, the campus with which the PI is primarily affiliated).
- 9) Duties and Responsibilities of the Principal Investigators —
 - a) From the Relying Campus
 - i) The PI will sign the Notice of Intent to Rely on Another NSHE IRB and forward it to the Reviewing Campus PI and HRPP Director for each initial review.
 - ii) The PI will follow the standards and guidelines of the Reviewing IRB for the reporting of any post approval events. These include unanticipated problems involving risks to subjects and others, adverse events, other safety information, and/or protocol violations or incidents.
 - iii) The PI will complete and will ensure that all personnel on the project complete human subject protection training as required by the relying campus.
 - iv) The PI will ensure that all significant financial interests are appropriately disclosed on the Notice of Intent to Rely on Another NSHE IRB form.
 - b) From the Reviewing Campus —
 - i) The PI will submit his or her IRB Application and include the completed Notice of Intent to Rely on Another NSHE IRB
 - ii) The PI will actively communicate with the PIs at the relying NSHE campus to make sure that the necessary and required coordination of

any research activities occurs. iii) The PI will complete and will ensure that all personnel on the project complete human subject protection training as required by the reviewing campus.

iv) The PI will ensure that all significant financial interests are appropriately disclosed on the Notice of Intent to Rely on Another NSHE IRB form.

10) Duties and Responsibilities of the Reviewing IRB —

- a) Review and Oversight — The reviewing IRB shall conduct initial and continuing reviews, and shall review amendments to approve protocols and reports of unanticipated problems and serious and/or continuing noncompliance. The reviewing IRB shall have the authority to suspend or terminate the research. The reviewing HRPP shall notify the relying HRPP of any determinations of unanticipated problems, serious or continuing noncompliance, and suspensions and terminations.
- b) Approval Letter — The reviewing IRB shall send a copy of the IRB Approval Letter to the relying IRB.
- c) Right to Refuse to Be IRB of Record — An NSHE HRPP may refuse, on a case-by-case basis, to be relied upon as the IRB of record for research involving another NSHE campus. If this occurs, the HRPP will notify both the PI and the HRPP of the relying PI.
- d) Record Keeping — The reviewing HRPP will keep records of studies that are subject to this MOU. The records will include at minimum the date the application is submitted, review determinations, dates of approval, location of research activity, as well as oversight actions.

11) Duties and Responsibilities of the Relying HRPP

- a) Acknowledgement Letter — The relying HRPP will issue an Acknowledgement Letter to the PI of the relying campus.
- b) Compliance and Oversight — The relying HRPP shall monitor compliance with the terms and conditions of the reviewing HRPP's approval of research being conducted at the relying NSHE location. The relying HRPPs shall advise the reviewing HRPP of any incidents of noncompliance or unanticipated problems of which it becomes aware, including but not limited to, violations of human research protection regulations and policies.
- c) Right to Refuse to Rely — An NSHE HRPP may refuse, on a case-by-case basis, to rely on the review by another NSHE HRPP. If this occurs, the HRPP shall notify both the PI and the reviewing HRPP in writing and include the reason for the refusal.
- d) Record Keeping — The relying HRPP will keep records of studies that are subject to this MOU. The records will include at minimum when the application is submitted, review determinations, dates of approval, location of research activity, as well as oversight actions.

12) Duties and Responsibilities of Both the Reviewing and the Relying HRPP

- a) Local Institutional Review Committees — Both the reviewing and relying HRPPs will ensure the local institutional review committee reviews and approvals are in place before the research commences at each site. This includes but is not limited to review and management of conflict of interest, institutional biosafety review, radiation safety review and others as locally required.

- b) Reporting Unanticipated Problems and/or any Serious and/or Continuing Noncompliance — The reviewing and relying HRPPs shall immediately report to the reciprocal HRPP any unanticipated problems involving risks to subjects or others or any incidents of serious and/or continuing noncompliance. This reporting duty is in addition to and does not replace the investigator's duty to report unanticipated problems or serious and/or continuing noncompliance as required by regulation and institutional policies and procedures.
- c) Cooperation — The reviewing and relying HRPPs shall cooperate fully with the reciprocal HRPP concerning the operation of this agreement. Relevant documentation to support review, compliance and oversight by the respective HRPPs will be made available to the reciprocal HRPP upon request. Each HRPP will make available records applicable to regulatory and accrediting agency activity if and when the reciprocal HRPP requires such records.
- d) MOU on File — This MOU must be kept on file at the HRPPs of the reviewing and relying HRPPs named in this agreement and must be provided to OHRP upon request.

Execution — The undersigned Institutional Officials of the HRPPs at the University of Nevada, Reno and the University of Nevada, Las Vegas have read and agreed to all of the terms above. This MOU shall remain in effect from the date of execution and implementation thereof until cancelled by either party with 180 days prior written notice.

University of Nevada, Reno
FWA00002306

 8/12/09

Marsha H. Read, Ph.D. Date
Interim Vice President for Research
Institutional Official

University of Nevada, Las Vegas
FWA00002305

 8/18/09

Stanley S. Smith, P D. Date
Associate Vice President for Research
Institutional Official