UNLV Office of RESEARCH INTEGRITY RESEARCH PROTECTIONS

SOP 3.10 - Collaborative Research

1. Objective

The purpose of this SOP is to describe common collaborative or cooperative relationships including the basic considerations and review requirements associated with those relationships

2. General Description

UNLV may become engaged in research with outside researchers, institutions, or groups in a variety of capacities and circumstances. In accordance with 45 CFR 46.114, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. Federally-funded cooperative research is required to rely on a single IRB for review unless there is a law requiring additional review, or the use of a single IRB for review is not appropriate for a particular context. UNLV is a SMART IRB participating Institution.

In the conduct of cooperative research projects, each institution or entity is responsible for safeguarding the rights and welfare of human subjects. Appropriate written agreements with collaborating entities or investigators are to be obtained where appropriate and to help ensure that all human research is conducted in support of the established level of review and oversight.

UNLV reviews reliance requests on a case-by-case basis. Whether UNLV is to be the reviewing institution or will cede review to another trusted institution is determined by ORI-RP staff based on research engagement. Generally, UNLV does not enter into reliance agreements with foreign institutions, nor enter into reliance agreements for exempt-classified research. It is likely UNLV would cede IRB review when a funding agency requires a single IRB, industry-funded studies request a commercial IRB, federal regulations, state laws, or local policies require use of a specific IRB, a research consortium is mandating the use of a single IRB, use of another IRB that has expertise required for reviewing the research, due to resources, legal, organization conflict of interest, or other consider when conducing

Definitions

Collaborative study – A study where the components of the research project may be distributed across more than one institution

IRB Authorization Agreement (IAA) –An agreement that documents the respective authorities, roles, responsibilities, and communication between the reviewing IRB and the relying IRB

Individual Investigator Agreement (IIA) – an agreement between UNLV and an individual collaborator who is unaffiliated with UNLV and is not covered under an institution with an FWA. This agreement allows research which requires coverage under an FWA to be conducted if the individual agrees to conduct research under the direction and supervision of UNLV.

Multi-site study – A study where some or all of the research procedures may occur at two or more locations

Relying IRB – The IRB, who after entering into an IAA, is deferring the review to the reviewing IRB.

Reviewing IRB – The IRB, who after entering into an IAA, is responsible for the IRB review of a study proposal.

3. NIH Single IRB Policy

The NIH single IRB policy applies to NIH-funded, non-exempt, multi-site or cooperative human subjects research studies. This may include grants, cooperative agreements, contracts or an NIH Intramural Research program; however, it does not apply to career development, research training or fellowship awards. An NIH-funded study that is conducted at more than one site in the United States must us a single IRB to conduct IRB review of research. Any exceptions to the policy must be approved by NIH.

When UNLV is the single IRB, the Lead Principal Investigator is responsible for IRB submissions, implementing the communication plan, obtaining auxiliary reviews (e.g., IBC, radiation safety, export controls, conflict of interest), obtaining certificates of confidentiality or certification for the Genomic Data Sharing, the conduct of the study at all sites, obtaining certification and regulatory compliance at all sites as described in the reliance agreements. The awardee organization will ensure all authorization agreements are in place before research begins and that documentation is maintained.

Exceptions to single IRB review for multi-site research include research where a federal, tribal or state law requires local review, non-exempt studies approved before January 20, 2020, international sites, or specific, justified cases approved by the funding agency. For additional information about single IRB for a multi-site study, contact IRBReliance@unlv.edu.

4. IRB Reliance Agreements

MOU, Memorandum of Understanding is required when the relying institution does not have an IRB or FWA.

Master Reliance Agreement –Master Reliance Agreement is used for when multiple studies, or all studies of an institution either rely on UNLV IRB review or UNLV cedes review of multiple studies.

SMART IRB - UNLV is a signatory to the SMART IRB agreement

IAA, IRB Authorization Agreement is used when the relying institution is not a signatory to the SMART IRB agreement

5. Roles & Responsibilities

Execution of SOP: Principal Investigator (PI)/Study Personnel (SP), Office of Research Integrity – Research Protections (ORI-RP) Staff, IRB Members

It is the responsibility of the UNLV researcher to consult with the ORI-RP about the need for possible agreements and/or reviews prior to beginning any research related activities. The Principal Investigator (PI) of the study is responsible for assuring that this has been completed.

The ORI-RP/IRBs are responsible for reviewing all research when UNLV researchers are engaged in research. UNLV follows the Office of Human Research Protections (OHRP) guidance on engagement titled: "Guidance on Engagement of Institutions in Human Subjects Research."

6. Procedures

UNLV researchers conducting research at a non-UNLV location

When UNLV researchers conduct research in whole or in part at a location that is not affiliated with UNLV, then a

Facility Authorization Form must be submitted with the research proposal under review. The template is completed by the researcher with research specific information and then is to be printed on the letterhead of the facility prior to being signed by the authorized official at the location. If a researcher is just advertising at a location, a facility authorization does not need to be submitted for review.

UNLV researchers working with another institution that is engaged in research

When UNLV researchers conduct research with another institution that is engaged in research, multiple options for review may occur. The best course of action is to consult with ORI-RP staff to decide which situation best suits the research. The following are the most common options available, though other arrangements may be made:

- Institution has an FWA and an IRB
    - Protocol reviewed by both IRBs during concurrent review – This would occur when an agreement can't be reached about who should be the reviewing IRB. This scenario should be avoided if possible, in order to reduce duplication and effort.

    - IRB Authorization Agreement (IAA)- In this situation, one institution would take the lead as the reviewing IRB and the other would be the relying IRB. The reviewing IRB is responsible for the review and approval of the research study prior to beginning at the research site(s).

- Institution has NO FWA and NO IRB
    - A Memorandum of Understanding (MOU) would need to be completed between UNLV and the institution. This will delineate the roles and responsibilities between the institutions. All MOUs must have General Counsel review after it is submitted for IRB review.

- UNLV as lead in multi-site study
    - When the UNLV IRB is serving as the IRB of record for a PI or site who is serving as the lead investigator or lead/coordinating center of a multi-site or collaborative research project, the PI must describe within the protocol and IRB application how the research will be overseen and how issues relevant to the protection of human subjects (e.g., IRB initial and continuing approvals, study modifications, reports of unanticipated problems, interim results, data-safety monitoring, etc.) will be coordinated and communicated among participating sites and investigators. For FDA-regulated clinical trials, the plan is to address a plan for study monitoring and for the reporting and evaluation of adverse events, significant new risk information, and any other reports mandated by regulation or policy
    - The lead PI or lead/coordinating center is responsible for serving as the liaison with other participating sites and investigators and for ensuring that all participating investigators obtain IRB review and approval prior to initiating the research, maintain approval, and obtain IRB approval for modifications to the research. To add additional, investigative sites to an existing, approved protocol, submit a modification in Cayuse Human Ethics. If there are no other modifications, and no increase in risks to subjects, modifications will be considered minor and receive an administrative review. The ORI-RP staff will evaluate whether the plan for research oversight and management of information that is relevant to the protection of human subjects is adequate.

Duties and Responsibilities of the Reviewing Institution to be Included in Written agreements

a. 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
b. Ensure IRB approval criteria ae satisfied by all participating sites, including local context information provided by relying institutions Bullet example
c. Make HIPAA Privacy Board determinations when applicable
d. Consider conflict of interest determinations, management plans and consider within IRB review as is applicable.
e. For studies involving DHHS, will obtain additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners.
f. Obtain and review local context information from relying sites. This information includes whether they relying organization applies its FWA to some or all research ensuring IRB review is consistent with the relying institution's FWA
g. 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.
h. Provide prompt reporting to the Relying Institution's IRB and appropriate regulatory agencies of any unanticipated events or problems involving risk to subjects or others, serious or continuing non-compliance, or suspension/termination of IRB approval
i. The reviewing IRB will conduct scientific reviews within their scope, investigate potential noncompliance, including complaints, protocol deviations, and results of actions. The reviewing IRB will determine incidence of noncompliance is serious or continuing.

Duties and Responsibilities of UNLV IRB and Relying Institution to be Included in Written Agreements

a. 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.
b. 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.
c. 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
d. 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 updated policies, relevant documentation and records as needed. Each institution must identify and establish at least one individual who will serve as the institution's point of contact who is responsible for communicating on behalf of the institution with respect to the day-to-day implementation of the reliance agreement.
e. Promptly inform the reciprocal institution, the Overall PI, Site Investigator(s), and the Relying Institution(s) of applicable review decisions, findings and actions (including any suspension or termination of IRB approval of Research and required corrective actions) with respect to (i) serious and/or continuing noncompliance or apparent serious and/or continuing noncompliance with the Federal Policy, other applicable federal human

subjects protection regulations or policies, and/or the FDA Clinical Investigation Regulations, as applicable, or with the requirements or determinations of the Reviewing IRB, by the Relying Institution or its Personnel; and (ii) such serious and/or continuing noncompliance or apparent serious and/or continuing noncompliance at any other Relying Institution if such noncompliance relates to or may affect the conduct of the Research or the safety, rights, or welfare of Research participants at the notified Relying Institution(s). With respect to Research that is the subject of an Exemption Determination, such notifications will be limited to decisions, findings and actions regarding serious and/or continuing noncompliance or apparent serious and/or continuing noncompliance with the Federal Policy or with the terms of the Exemption Determination that disqualifies the Research from the relevant exemption. All such notifications may be made through the Reviewing IRB/Reviewing IRB Institution's designee

f. Each institution will ensure that its personnel, and, the reviewing IRB, will ensure its IRB members have adequate education, training, qualifications, and resources to perform their roles to safeguard the rights and welfare of research participants

Duties and Responsibilities of the Relying Institution to be Included in Written Agreements

a. 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.
b. 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. Management plans will be reviewed by the IRB or designated member.
c. 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. The local context questionnaire includes AAHRPP accreditation status. UNLV will only consider ceding to a non-accredited agency with a current registered IRB and FWA.
e. Maintain oversight for local unanticipated problems involving risk to participants or others and local non-compliance.

Termination of Reliance Agreements

The Terminating Institution, will work with the remaining institution (s) to determine the effect of such termination on any ongoing Research and covered activities being conducted under the Agreement at the time of termination, with the goals of ensuring the continued protection of research participants and of limiting the potential disruption to the research. Without limiting the foregoing, the Reviewing IRB/Reviewing IRB Institution will, when possible and appropriate, provide continued oversight for such ongoing Research for the reasonable time necessary to appropriately transfer oversight of the Research to another IRB or for the affected Participating Institutions to transition to another IRB authorization or reliance agreement.

UNLV Researchers conduct Research with Community members who are not affiliated with any institution

UNLV researchers may conduct research with community members who are not otherwise affiliated with any institution. These are considered volunteers and as such would need to complete the "Volunteer Agreement

for Researchers" form. Community researchers must also satisfy CITIProgram.org education courses as required by ORI-RP

Community Based Research (CBR)

Community based research (CBR) is research that is based in a community and conducted in collaboration with members of that community. Community is often self-defined, but general categories of community include geographic community, a community of individuals with a common problem or issue, or a community of individuals with a common interest or goal.

Where research is being conducted in communities, investigators are encouraged to involve members of the community in the research process, including the design and implementation of research and the dissemination of results when appropriate. The most significant community involvement is in a subset of CBR called Community Based Participatory Research (CBPR) where there is an equal partnership between the academic investigators and members of a community, with the latter actively participating in all phases of the research process including the design and implementation of research and the dissemination of results where appropriate

Questions to be considered as CBR studies are developed, and issues that the IRB will consider when reviewing CBR, are as follows:

- How was the community involved or consulted in defining the need for the proposed research (i.e., getting the community's agreement to conduct the research)?
- How was the community involved or consulted in generating the study research plan?
- How will the research procedures, including recruitment strategies and consent processes be assessed to ensure sensitivity and appropriateness to various communities (e.g., literacy issues, language barriers, cultural sensitivities, etc.)?
- How will the community be involved in the conduct of the proposed research?
- How will community members who participate in the implementation of the research be trained and supervised?
- How have "power" relationships between investigators and community members on the research team, and in subject recruitment strategies been considered to minimize coercion and undue influence?
- What are the risks and benefits of the research for the community as a whole?
- How will boundaries between multiple roles (e.g., investigator, counselor, peer) be maintained, i.e., what happens when the investigator/ research staff is the friend, peer, service provider, doctor, nurse, social worker, educator, funder, etc.)
- How will the research outcomes be disseminated to the community?
- Is there a partnership agreement or memorandum of understanding to be signed by the investigator and community partners that describes how they will work together?

7. References

OHRP document, "Guidance on Engagement of Institutions in Human Subjects Research" dated October of 2008 - https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

OHRP document, "Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement" dated Jan 1, 2005 -

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