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, under a variety of 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.

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 should be obtained where appropriate and to help ensure that all human research is conducted in support of the established level of review and oversight.

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

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. Roles & Responsibilities

Execution of SOP: Principal Investigators (PI)/Study Personnel (SP), IRB Chair, IRB, Office of Research Integrity – Human Subjects (ORI-HS) Staff.

It is the responsibility of the UNLV researcher to consult with the ORI-HS 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-HS/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."

4. 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. A template is provided in IRBNet that must be used. 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-HS 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 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 an FWA but NO IRB
    - The UNLV IRB would serve as the reviewing IRB and enter into an IAA with the collaborating institution.
- 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 should address the 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. The UNLV IRB will evaluate whether the plan for research oversight and management of information that is relevant to the protection of human subjects is adequate.

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. This is completed in its entirety, a copy submitted to the appropriate Human Resources Office, and then a copy attached to the proposal submission. Community researchers must also satisfy CITI education requirements as required by the ORI-HS.

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 when 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?

5. References

OHRP document, "Guidance on Engagement of Institutions in Human Subjects Research" dated October of 2008 - http://www.hhs.gov/ohrp/policy/engage08.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 - http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.html

UNLV Rules and Procedures for Conducting Human Subjects Research document section 3.1