SOP 5.02 - Determination of Activities that Require IRB Review

1. Objective

To describe procedures for determining the types of activities that qualify as human subject research or clinical investigations and therefore require Institutional Review Board (IRB) review and approval prior to initiation of study activities.

2. General Description

In accordance with federal regulation and institutional rules and procedures, and prior to project implementation, the IRB and/or ORI-HS must review and acknowledge/approve any undertaking in which a University of Nevada Las Vegas (UNLV) faculty, staff, or student conducts human subject research. The UNLV IRB Rules and Procedures document outline what types of activities constitute human subjects research and therefore require IRB review and approval.

Definitions

Research - is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge." Research includes, but is not limited to, surveys and interviews, behavioral investigations, retrospective reviews of data, experiments with blood and tissue, demonstration and service programs, and clinical trials.

Human Subject - means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or collects identifiable private information. "Human subject" under FDA regulations includes an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A "subject" may be a healthy human or a patient.

Clinical investigation - means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration (FDA) or where the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

Projects that may fit either definition may be subject to these Rules and Procedures, and researchers must contact the ORI-HS for assistance prior to conducting any project activities.

3. Roles & Responsibilities

Execution of SOP: Principal Investigator (PI)/Research Team Members, Office of Research Integrity –Human Subjects (ORI-HS) Staff, IRB Chairs/Co-Chairs.

4. Procedures

1. It is the responsibility of each PI to seek IRB/ORI-HS review and approval/acknowledgment prior to initiation of any research involving human subjects or before conducting any clinical investigation.

2. The investigator may contact ORI-HS staff and/or the IRB Chair for advice and/or an authoritative decision on the application of the federal regulations, UNLV Rules and Procedures, or other applicable regulations or requirements (e.g. applicable NV state regulations).

3. In cases where it is not clear whether the study constitutes human subjects research or clinical investigation and requires IRB review, such as classroom research, quality improvement, case reports, program evaluations, and surveillance activities, the ORI-HS or the IRB may ask the investigator to send a memorandum to the IRB/ORI-HS by e-mail or hard copy detailing the project proposal. In uncertain cases or if the PI requests official documentation, the ORI-HS or the IRB may direct the investigator to complete and submit an excluded, exempt or protocol proposal form to the ORI-HS/IRB for a decision. The ORI-HS Executive Director, Administrators, IRB Chair or a designated IRB member may make the final determination.

4. If it is clear after the ORI-HS and/or IRB review that the information does not meet the definition of either research or human subject, or clinical investigation, then a formal notice will be sent to the PI.

5. References

45 CFR 46.102
21 CFR 56.101
UNLV IRB Rules and Procedures 2.4