SOP 15.01 - Assessing the Quality, Effectiveness, and Efficiency of the Human Research Protection Program

1. Objective

UNLV's Quality Improvement Program (QIP) main objectives are to evaluate the quality, efficiency, and effectiveness of the Human Research Protection Plan (HRPP), and also to assess compliance with the HRPP and applicable laws, regulations, and policies.

2. General Description

The QIP monitors a variety of actions and includes goal setting to identify methods and objectives for assessing compliance and marking where improvements can be made. Current practices, procedures, and processes are evaluated using qualitative and quantitative information.

3. Roles & Responsibilities

Execution of SOP: Office of Research Integrity (ORI), Office of Research Integrity – Human Subjects (ORI-HS) Staff.

ORI Responsibilities

The ORI is responsible for the administration of the User Satisfaction survey, analyzing results, and reporting results to the ORI-HS, the IRBs, and the Institutional Official (IO). The ORI is responsible for tracking ORI-HS and IRB performance metrics, such as number of protocols received and approved, and turn-around-time, and reporting results to the IRB administrators, IRB chairs, and to the IO. Reports are made when and where appropriate.

ORI-HS Responsibilities

The ORI-HS is responsible for tracking communication received from the research community, and for accurately inputting data related to study protocol proposal reviews into the current study tracking system. The ORI-HS is responsible for processing and vetting compliance related events.

PI Responsibilities

It is the responsibility of the PI to protect the rights and welfare of individuals enrolled in his/her research project and to ensure that all research team members follow the procedures outlined in the IRB-approved research protocol. When an audit is being conducted, the PI must make available all requested study related documentation and provide access to auditors where needed.

4. Procedures

Turn-around-time for excluded, exempt, expedited, and full board reviews are calculated on a monthly basis and reported to the IO when appropriate. The number of protocols received and approved is also calculated monthly. The main objective is to maintain a turn-around time for review of study proposals at or below the national average as reported by AAHRPP. Additional objectives include using this information to help determine efficiency, workload, and use of available resources. Quarterly reports for IRB metrics are provided to IRB chairs, ORI-HS Director/staff, the IO, the VPR, Associate Deans for Research, the Research Council and other entities upon request.

An anonymous online survey is provided to PIs upon approval of a research protocol. On a quarterly basis, ORI summarizes the results, and communicates results to IRB chairs, ORI-HS Director/staff, the IO, the VPR, Associate Deans for Research, the Research Council. Responses are discussed at length and improvements to the program are implemented as needed or desired. The ORI aims for an 80% satisfaction rate across three dimensions: use of the IRBNet platform, interactions with IRB chairs and the ORI-HS staff, and protocol processing.

Comments, questions, and issues received from UNLV investigators and associated research community are reviewed during staff meetings and otherwise as needed or desired among ORI and ORI-HS staff.

For-cause audits assess compliance with protocol and applicable policies, procedures, laws, regulations, codes, and guidance. For-cause audits are conducted, when applicable, following receipt of an Incident Report and on an as-needed basis.

ORI-HS staff reviews IRB Records as needed and no less than annually to assess compliance and quality/effectiveness/efficiency with the HRPP, policies, laws and applicable regulations. With each review, the staff will define the following: at least one objective to achieve or maintain compliance/effectiveness, at least one measure of compliance/ effectiveness, and the methods used to assess compliance/effectiveness and make improvements.

Review of records may include: review of full board meeting minutes for appropriate determinations and quorum, individual study files and informed consent materials for adequate documentation and informed consent elements, review of the IRB database for completion of all necessary fields, review of IRB and ORI-HS staff workload, and review of other IRB-related activities as appropriate. Review results are shared with the ORI-HS Director and discussed with the IO. A corrective action plan will be drafted as may be needed to address any noted deficiencies. The ORI-HS Director will have the responsibility for implementing and reporting the results of any corrective actions taken, which will be evaluated by the IO.

The ORI-HS Director will also work with offices conducting outreach activities such as the Vice President for Research and Economic Development, Associate Vice President for Economic Development and/or the Office for Community Engagement to discuss and evaluate outreach activities on a yearly basis. This will be done to assess whether improvements should be made to the outreach activities.

With the above, qualitative and quantitative data are reviewed by the ORI-HS Director, the IO, and the VPR to assess resources for maintaining and improving the program as needed and no less than annually. Additional objectives include using evaluating information to help determine efficiency, workload, and

effective use of available resources. If at any time substantive or concerning issues or trends are identified, a corrective action plan will be considered for implementation.

5. References

User Satisfaction survey
Incident Intake Form 11-2