UNM | *Office of the Institutional Review Board*

Standard Operating Procedures		
SOP #107.2 Revision 2	**TITLE: HRPP Quality Assessment Program**	Effective Date: 2/1/2017
Approved By: OIRB Director	Signature	Date 2/10/2017
Approved By: IRB Chair	Signature	Date 2/10/17

PURPOSE

To define the Human Research Protections Program (HRPP) quality assessment function at the University of New Mexico.

REVISIONS FROM PREVIOUS VERSION

Added a plan for quality assessment of IRB minutes

POLICY

Quality assessment (QA) is an evaluation of whether or not activities meet defined standards. The UNM HRPP QA program as a commitment to strengthen human participant protections and make continuous quality improvements. The goal of the QA program is to identify strengths and weaknesses of protection efforts that can be used to improve the quality, efficiency, and integrity of our research activities and continue UNM's tradition of excellence.

The QA program includes assessing the HRPP at varying levels, increasing institutional awareness of existing processes, operating procedures, educational programs, and acquiring information necessary for enhancing protections. The program allows the HRPP to ensure that our research community adheres to federal, state, and institutional regulations. The program is designed to continually evaluate, provide education, and improve research processes, ultimately providing a higher degree of safety to our research participants.

The QA program allows researchers, OIRB staff, IRB members, and the community the opportunity to provide input to help improve the HRPP. Education, training, and outreach conducted by the OIRB will be tailored based on the responses from the various components of the QA program (described below). Additionally, QA data will be used to make improvements to the IRB review process and increase compliance in human subject research and IRB review.

RESPONSIBILITIES

Execution of SOP: HRPP Director, OIRB Staff, Researchers

PROCEDURE

1. **Post Approval Monitoring**
   1.1. **Voluntary Self-Assessments:** The OIRB provides a guided Self-Assessment tool that researchers may use at their discretion to monitor compliance of their projects. Researchers are not required to submit completed assessments to the OIRB unless requested to do so by the IRB. Researchers are encouraged to conduct a self-assessment when preparing for an audit.
   1.2. **Audits:** Audits help ensure that projects are being conducted in accordance with the IRB approved protocol and applicable policies and regulations. There are two types of audits.
      1.2.1. **Random Audits:** Random audits will be conducted on an ongoing basis according to SOP 406 "Directed and Self-Audits". Circumstances for which a study may be chosen for a random audit may include, but are not limited to:
      - Recruitment of vulnerable populations;
      - Federal funding;
      - Large numbers of participants; and/or
      - More than minimal risk procedures.

      1.2.2. **For Cause Audits:** For Cause audits will be conducted according to SOP 406 "Directed and Self-Audits". Circumstances where for cause audits may occur include, but are not limited to:
      - Concern or compliant from a research participant;
      - Request by the IRB or IRB Chair due to noncompliance issue; and/or
      - Result of an adverse event or unanticipated problem involving risks to subjects or others.
2. **HRPP Quality Improvement**
   2.1. **OIRB Quality Assessment Reviews:** OIRB staff conduct routine QA assessments of internal processes and IRB determinations and records. These are conducted monthly by a random selection of submissions. The purpose of the reviews is to determine adherence of staff and IRB members to standard operating procedures and maintenance of IRB records in accordance with federal regulations, state law, and institutional policies governing human research. Any problems that are identified during a QA review are corrected, noted and discussed in staff meeting and used to identify and rectify training deficiencies.
   2.2. **IRB Review Metrics:** Submission metrics are collected and analyzed monthly for the length of time from submission to approval, detailed by stage of the review process. These monthly stats are combined to create an annual trend of turnaround times, broken out by new projects and amendments and by exempt, expedited, and full board reviews. Annual trends of number of submissions per month is also tracked. This data is used to identify areas of the review process to target for improvement as well as staff planning so that office initiatives and staff leave are not planned during busy times.
   2.3. **Researcher Feedback Survey:** A short online survey is sent to researchers at designated times through the listerv or by email after a submission has received a determination from the IRB. The survey covers a variety of topics including the quality of the submission experience,

adequacy of resources and the IRB review. Responses from this survey are used to identify the areas of excellence as well as potential areas for improvement.

2.4. **Participant Feedback Survey:** A short online survey is available on the OIRB website that collects information regarding participants' experiences being in a research study. The OIRB encourages researchers to promote this survey to their participants. Results of this survey are used to identify areas of improvement for the HRPP as well as areas where researchers may need additional education.

2.5. **Annual Targeted QA:** At the time of annual employee evaluations (beginning of the calendar year), there is a concurrent department evaluation and goal setting process. The HRPP Director with input from OIRB staff and IRB Chairs evaluates the previous year's goal(s) and establishes the current year's goal(s). OIRB initiatives are planned based off of the specified goals.

2.6. **IRB Member and Chair Evaluations:** Evaluation of IRB members is conducted annually according to SOP 102 in order to assure a well-functioning HRPP and IRB. Evaluations serve to validate performance, identify areas for improvement and to make changes in membership and/or training when appropriate.

2.7. **IRB Minutes QA:** A quality assessment of IRB minutes will be conducted quarterly to ensure that minutes include all of the necessary requirements as well as to verify that the appropriate reviews were conducted for requested modifications. The results of the assessment will be shared with the executive committee so that changes can be implemented if necessary.

3. **HRPP Resources Evaluation**

3.1. The Institutional Official, IRB Chairs, and HRPP Director meet annually to review HRPP metrics, resources and staffing to ensure that the program has sufficient resources to protect the right and welfare of research participants.

3.2. This review will include analysis of equipment, budget, space, and personnel. It will also include an evaluation of resources needed for the HRPP including, but not limited to:

3.2.1. HRPP Educational program
3.2.2. Legal counsel
3.2.3. Conflict of Interest
3.2.4. Quality improvement plan
3.2.5. Community outreach
3.2.6. IRB membership and number of IRBs