SOP 901: Quality improvement Program

1. POLICY

The Human Research Participant Protection (HRPP) Quality Improvement (QI) Program monitors the effectiveness of the HRPP program. Effectiveness of the Program is measured through routine, for-cause, internal, and self-assessment evaluations, plus observation of the informed consent process for compliance with University policies and procedures, applicable federal regulations, and Oklahoma law. The primary tools used for conducting investigator evaluations, as well as the tool for investigator self-assessment, are the regulations and Good Clinical Practice.

The goals of the Quality Improvement Program are to:

- Determine if the rights and welfare of research participants are being properly protected in accordance with the Belmont Report University policy, IRB policy, applicable federal law/regulations, and Oklahoma state law.
- Determine if research protocols are being implemented as approved by the IRB.
- Monitor the informed consent process to determine outcome and areas of needed improvement.
- Confirm all research team members have completed required HRPP training.
- Promote open communication between the IRB and the research team.
- Provide additional education to the research team.

The evaluations under the QI program are different from the IRB site inspection, as outlined in SOP 903: Non-Compliance/Scholarly Misconduct.

Specific Policies

1.1 Routine Evaluations

Routine QI evaluations of research sites are periodically performed through selection of protocols by the HRPP or at the request of the investigator.

Investigator-initiated studies, in which the investigator holds an IND/IDE are given priority for routine evaluation. In these circumstances, the investigator is evaluated to ensure compliance with the additional regulatory requirements. These requirements are outlined in SOP 802: Sponsor Responsibilities. During routine evaluation of investigator-initiated studies in which the investigator assumes the role of the sponsor the QI Coordinator evaluates whether the investigator is knowledgeable about the regulatory requirements of sponsors and is complying with those requirements.

For VA research projects:

The IRB may also consider the routine Veterans Affairs’ Research Compliance Officer’s triennial compliance and quality improvement study evaluations and informed consent reviews, as applicable.

The IRB may require more frequent evaluations by the research compliance officer or by other means. The IRB also may require the research compliance officer to conduct more focused evaluations of one or more aspects of the study.
The requirement to increase the frequency of evaluations or to evaluate specific aspects of the study might be based on considerations including, but not limited to:

- Involvement of vulnerable populations.
- Level of risk.
- Phase I or Phase II studies.
- Involvement of FDA approved drugs for which there has been a new safety warning issued, or change in the labeling that indicates increased risks.
- Issues of noncompliance.
- Data confidentiality or security concerns.

1.2 For-Cause Evaluations

For-Cause Evaluations of research sites occur as a result of known or suspected problems in the conduct of human participant research. Results of For-Cause Evaluations will be promptly reported to the HRPP Director and to the IRB that requested the evaluation for review and determination.

1.3 IRB Internal Evaluations

Routine QI evaluations of IRB operations are conducted to review and assess the IRB records that include submissions, actions of the convened IRB or IRB Chair or IRB designee, membership rosters, and minutes.

Routine assessment of IRB SOPs is a function of the HRPP Director and/or Director of Compliance to determine if SOPs are in compliance with applicable federal and state law/regulations and University policy.

The HRPP shall measure and improve the program’s effectiveness; quality; and compliance with University policies and procedures and applicable federal, state, and local laws.

Improvements to the HRPP program shall be implemented based upon measures identified through routine evaluations of the program. These improvements include providing education programs, IRB member and staff training, revising policies and procedures, and any making necessary changes to the IRB’s electronic information system.

The improvements shall be monitored and measured by the HRPP program to determine the effectiveness. If necessary, additional improvements shall be implemented.

1.4 Investigator Self-Assessment Evaluations

Investigators may choose to evaluate effectiveness and improve quality of their research through a self-assessment, which allows investigators to identify areas needing improvement. Investigators may obtain the Self-Assessment Evaluation checklist from the IRB website. The checklist helps investigators identify areas of needed improvement by following an algorithmic approach. This model is offered as a resource for Investigators to promote their own quality improvement at their research sites.
1.5 Observing the Consent Process

The IRB has the authority to observe, or have a third party observe, the informed consent process of research it has approved and to verify that the research project is being conducted as required by the IRB and within the University policies and procedures and site-specific procedures, as appropriate. Before the IRB or third party observes the consent process, verbal consent of the participant must be sought. Mechanisms by which observation of the consent process might be implemented, utilizing the “Consent Form Observation Checklist” include, but are not limited to, the following situations:

A. The HRPP Director or the IRB may choose to have the consent process observed as part of the QI Program for routine evaluation, for-cause evaluation, or education.

B. The IRB may determine it is necessary to observe the informed consent process in order to provide additional protections and may conduct informed consent observations in the following situations:
   1. Non-compliance per SOP 903: Non-Compliance/Scholarly Misconduct;
   2. Unanticipated problems involving risks to participants or others per SOP 407: Protocol Deviations and Unanticipated Problems;
   4. Participant complaints, or
   5. Any other situation the IRB deems appropriate where additional protections are necessary.

Additionally, Investigators may be asked to submit copies of signed informed consent documents or other documents to ensure their compliance with IRB requirements. The IRB may conduct interviews with screened and/or enrolled research participants as deemed necessary.

Results from the Observation of the Informed Consent Process will be reported as outlined in Section 1.6 of this policy.

1.6 Reporting of QI Outcomes

All QI findings are confidential and are not disclosed to entities outside the University, unless otherwise required by applicable state or federal law. All QI evaluations are conducted for quality improvement purposes and should not be viewed as punitive. Findings/results from the evaluations are reviewed at least annually during IRB Executive Meetings, with emphasis on evaluation of the overall effectiveness of the HRPP program and suggestions for educational improvement. Any concerns about the QI program should be directed to the HRPP Director.

2. SCOPE

This SOP applies to all research being conducted under the University’s FWA.
3. RESPONSIBILITY

3.1 The HRPP Director and/or a QI Coordinator are responsible for identifying protocols for routine evaluations, including identifying those studies that are investigator-initiated in which the investigator holds the IND/IDE, and for identifying internal evaluation needs.

3.2 A QI Coordinator is responsible for conducting routine and for-cause evaluations to monitor and measure the effectiveness of HRPP.

3.3 A QI Coordinator is responsible for providing feedback of the evaluation to the investigator, HRPP Director, IRB Chair or IRB designee, and IRB Education Coordinator.

3.4 The IRB Chair or IRB designee is responsible for notifying the HRPP Director and the QI Coordinator of any for-cause evaluations requested by the IRB or as required under SOP 903: Non-Compliance/Scholarly Misconduct.

3.5 Investigators are responsible for conducting ethical and lawful research. They are also required to grant access to research materials so that an evaluation can occur and to cooperate in such an evaluation.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56
38 CFR 16
45 CFR 46

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 303C: Meeting Minutes
SOP 407: Protocol Deviations and Unanticipated Problems
SOP 701: Consent Process and Documentation
SOP 801: Investigator Qualifications and Responsibilities
SOP 802: Sponsor Responsibilities
SOP 903: Non-Compliance/Scholarly Misconduct

6. ATTACHMENTS

901-A Quality Improvement Evaluation
901-B Quality Improvement Self Assessment
901-C Consent Observation Checklist
901-D Informed Consent Compliance Tool
901-E Evaluation Form

7. PROCESS OVERVIEW

7.1 Procedures for Routine Evaluation

7.1.1 A QI Coordinator, with input from the HRPP Director, will query the IRB’s electronic information system to determine those studies that are investigator-initiated studies using FDA regulated items (particularly those
in which the investigator holds the IND/IDE) or sponsored/non-sponsored studies considered to be high-risk to participants and/or the University.

7.1.2 From those identified, the QI Coordinator will select the study(ies) to be evaluated. Once a research project has been identified, a notification is sent from the QI Coordinator to the investigator, and a mutually acceptable time is scheduled for the evaluation.

7.1.3 The evaluation of the study is conducted using an Evaluation tool (attachment 901-A) and may also include evaluating the consent process.

7.1.4 A formal letter is drafted by the QI Coordinator at the conclusion of the evaluation and is reviewed with the HRPP Director and/or IRB Chair prior to distributing to the investigator. The investigator is also provided with a summary of the evaluation findings.

7.1.5 The formal letter addresses positive findings and identified areas for improvement. If investigator misconduct or non-compliance is identified during the evaluation, SOP 903, Noncompliance/Scholarly Misconduct, shall be implemented.

7.1.6 A copy of the formal letter is also distributed to HRPP Director, IRB Chair, and IRB Education Coordinator. The Department Chair and applicable federal entities may also be copied, depending on the findings of the evaluation.

7.1.7 Results of routine evaluations are reviewed at least yearly during an IRB Executive Committee meeting to evaluate the overall effectiveness of the HRPP program.

7.1.8 The QI Coordinator or HRPP Director maintains documentation of correspondence concerning the evaluation.

7.2 Procedures of a For-Cause Evaluation

7.2.1 The HRPP Director, IRB, or Director of Compliance may request a for-cause evaluation of any study. Justification for the evaluation shall be documented in writing and must include all of the relevant issues to support the need for the evaluation.

7.2.2 The investigator is contacted regarding the for-cause evaluation and a mutually acceptable time is negotiated. However, it may be necessary to schedule a for-cause evaluation without first obtaining the formal agreement of an investigator (for example, where there is or may be increased risk of harm to participants or others).

7.2.3 The evaluation of the study is conducted, which may also include evaluation of the consent process, in accordance with the IRB SOPs.

7.2.4 Results of For-Cause Evaluations will be promptly reported to the HRPP Director and the requesting IRB for determinations.

7.2.5 Sponsors and/or sites may be asked to submit copies of the sponsor’s monitoring reports, or to provide additional information regarding the research project and/or the research site.

7.3 Procedures for Routine Internal HRPP Program Evaluations
7.3.1 Internal HRPP evaluations are ongoing and may include the following activities by the QI Coordinator and/or HRPP Director:

A. Review IRB meeting minutes to measure that all elements outlined in SOP 303C: Meeting Minutes, are included as appropriate. This includes:
   1. Quorum
   2. Recusal
   3. Consultants
   4. Protocol specific findings
   5. Appropriate IRB actions.

B. Review random selection of all research projects to measure the following:
   1. Accuracy of category selection for Exempt and Expedited research projects
   2. Use of checklists (by IRB staff and IRB reviewers)
   3. Accuracy and completeness of correspondence
   4. Actions are appropriately posted to agenda

C. Evaluate pending items to close out and to identify areas of deficiencies.

D. Check file room to ensure the file system is organized and maintained in a functional manner.

E. Check Notice of Study Expiration letters to ensure prompt notification to the investigator of an expiration.

F. Evaluate IRB Member knowledge and application of regulations and policies and procedures:
   1. Monitor use of checklists for areas in need of improvement
   2. Educate IRB staff on areas in need of improvement
   3. Monitor outcomes and provide education as needed

G. Evaluate IRB Staff knowledge and application of regulations and policies and procedures.

H. Monitor and evaluate internal processes of IRB staff and their work product

I. Implement education to focus on areas in need of improvement

J. Monitor outcomes and develop or modify training programs to improve practice

K. Perform other evaluations as determined by HRPP Director

7.3.2 The objectives of internal evaluation exercises are to determine adherence to the Belmont Report, federal regulations, state law, University policy, and IRB policy. Outcomes of the internal evaluations
are used to address educational issues involving IRB Administrators and IRB Chairs and Board members.

7.3.3 The QI Coordinator provides the internal evaluation findings to and discusses with the HRPP Director at the conclusion of an evaluation exercise.

7.3.4 The HRPP Director or designee and/or Director of Compliance periodically review IRB SOPs for quality improvement.

**7.4 Procedures for Investigator Self-Assessment Evaluations**

7.4.1 Investigator self-assessment is not mandatory; it is a voluntary exercise the investigator can go through to determine areas of strength and weakness at the investigator’s research site.

7.4.2 The objectives for investigator self-assessment include, but are not limited to:

- Promote quality improvement at the University.
- Educate investigators on compliance with the Belmont Report, federal regulations, state law, University policy, and IRB policy.
- Foster open communication between the IRB and investigators regarding such law, regulations, and policies.

7.4.3 A QI Coordinator is available to the investigator to answer any questions the investigator may have at the conclusion of a self-assessment evaluation.

7.4.4 A QI Coordinator provides anecdotal feedback to the HRPP Director and/or IRB Education Coordinator as needed.

**7.5 Procedures for Observing the Consent Process**

7.5.1 The IRB shall observe the informed consent process to verify compliance or as part of the QI program. Site visits will be conducted in accordance with this policy.

7.5.2 During an evaluation:

- The consent process shall be reviewed to determine outcome and areas of improvement.
- The consent process shall be reviewed to confirm consent is being conducted in accordance with the Belmont Report, applicable federal regulations, state law, University policy, and IRB policies,
- The informed Consent Documents shall be reviewed to ensure the most current IRB-approved version is being used,
- Any other materials shall be reviewed as necessary.

7.5.3 A third party might be asked by the IRB Chair or IRB designee to conduct the observation.

**7.6 Overall evaluation of the HRPP program**
The HRPP Directors shall conduct an evaluation of the HRPP program annually. The evaluation form shall be completed by the Education and Quality Improvement staff and evaluated by the HRPP Directors. The evaluation and proposed improvements shall be discussed with the Director of Compliance for the NC, the HSC Vice President for Research for HSC, and the IRB Executive Committees. The Education and Quality Improvement staff shall implement changes and improvements under the direction of the HRPP Directors.

APPROVED BY: ___________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016