Title: Monthly HRPP Evaluations

SOP # HRP-061  Revision # 1  Effective Date 12/01/2014

Reviewed/Recommended for Approval: Mark Holdsworth, Pharm.D., Executive Chair HRRC  Date: 11/18/14

Approved: Richard Larson, MD PhD Vice Chancellor for Research  Date: 11/19/14

1 PURPOSE
1.1 This procedure establishes the process to conduct quality improvement of the human research protection program (HRPP).
1.2 The process begins the first business day of each month.
1.3 The process ends when all evaluations have been completed and if needed, acted upon.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Correction of spelling and grammatical errors throughout SOP.
2.2 Replaced all references to "IRB" with "HRRC."
2.3 Section 1.2 – Changed frequency from quarterly to monthly.
2.4 Expanded scope of evaluation to the full HRPP.
2.5 Added Quality Improvement Assessment process for investigators.

3 POLICY
3.1 The goal of the quality improvement plan is to achieve and maintain compliance and to achieve targeted levels of quality, efficiency, and effectiveness of the HRPP.
3.2 Objectives of the quality improvement program are to:
   3.2.1 Improve compliance of investigators with their responsibilities.
   3.2.2 Improve compliance of minutes with regulatory compliance.
   3.2.3 Increase efficiency of recording and finalizing minutes.
3.3 The measures of the quality improvement program are defined in:
   3.3.1 CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)
   3.3.2 CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)

4 RESPONSIBILITIES
4.1 HRPO staff ensure completion of these procedures.

5 PROCEDURE
5.1 Review the results of "CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)" sent out the previous month, track the results and examine for significant trends.
5.2 Complete "CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)" on the minutes of the previous month. Track compliance and the days required to complete minutes and examine for significant trends.
5.3 Send the results to the HRPP Director and Institutional Official or designee.
5.4 If the results of any evaluation demonstrate high variability or are outside performance targets, work with the HRPP Director to implement an intervention.

5.5 Complete "TEMPLATE LETTER: Investigator Quality Improvement Assessment (HRP-534)" and send "CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)" to a minimum of 5 investigators.

6 MATERIALS
6.1 CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)
6.2 CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)
6.3 TEMPLATE LETTER: Investigator Quality Improvement Assessment (HRP-534)

7 REFERENCES
7.1 None