Subject: Procedure for the IRB Optimization Committee Activities

Procedure:
This procedure describes the responsibilities and activities of the HRPPs IRB Optimization Committee (OC).

I. Activities Related to the Mission of the Committee. The IRB OC will review the following:
   A. Unresolved issues identified during an IRB Committee meeting or during the day-to-day operations of the HRPP that relate to its operations;
   B. Unresolved issues identified during an IRB Committee meeting or during the day-to-day operations that are sensitive in nature or complicated;
   C. Complex issues that require additional discussion and an opportunity to gather insight from experienced members, that may be of value to the IRB Committee prior to making final determinations;
   D. Discrepancies between IRB Committees;
   E. Complaints received by the HRPP that involve sensitive issues and
   F. Significant revisions/modifications to HRPP policy or procedures.

II. Meetings.
   A. The full IRB Optimization Committee will meet monthly.
   B. In addition, the HRPP Medical Director and the HRPP Director will meet as necessary for an OC working group meeting. Depending on the agenda, additional committee members or protocol analysts may be requested to attend the working group meeting. Working group discussions will be focused on the review of forms, policies and procedures, and the identification of issues that should be brought to the full OC for discussion.
   C. OC minutes will be taken at both the full OC meetings.

III. Dissemination of the IRB Optimization Committee Determinations.
   A. The minutes from the IRB OC meetings will be provided to each OC member for dissemination to his or her respective Committees or teams.
   B. It is the responsibility of the IRB Committee Chair and Team Leader to disseminate the information to each IRB Committee member and Team member. Generally, the IRB Chair provides an OC update at the next convened IRB Committee meeting.