SOP: External IRB Updates

1 PURPOSE

1.1 The purpose of this process is to ensure that the relying institution is made aware of updates approved by the external IRB or when the local investigator makes changes at the site level.

1.2 This process begins when the local site investigator submits newly approved materials from the external IRB or when the local investigator submits local site changes.

1.3 This process ends when an external IRB submission has been updated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 An investigator relying on an external IRB must update the site record with changes approved by the external IRB, including providing notification of Continuing Review approval, by the external IRB, using the "Update Study Details" activity.

3.2 If changes are made at the local site that affect institutional requirements (including changes to personnel, conflicts of interest, funding, HIPAA, or changes to institutionally required consent language) on an external IRB study, the investigator must update the site record using the "Create Site Modification" activity.

3.3 Any reportable new information (RNI) that is determined to be Serious Non-Compliance or Continuing Non-Compliance should be reported by using the "Reportable New Information" activity.

4 RESPONSIBILITIES

4.1 The Reliance Coordinator or IRB staff generally carry out these procedures.

5 PROCEDURE

5.1 If the item includes updates to the local site information (Site Modification for study team members or other parts of the site), review the updates using HRP-830 - WORKSHEET - Communication and Responsibilities.

5.1.1 If the item is a personnel change, ensure the personnel are qualified and have required training.

5.1.2 If the item is a change to a conflict of interest management plan, follow HRP-055 – SOP - IRB Review of Financial Conflicts of Interest.

5.1.3 If the item is a change to HIPAA authorization waivers or alterations and the local site is serving as the Privacy Board, review and document the appropriate waivers using HRP-441-WORKSHEET for HIPAA Waiver of Authorization.

5.1.4 If the item is a change triggering an ancillary review, execute the Manage Ancillary Review activity and assign the appropriate ancillary review organization or individual as outlined in HRP-309 - WORKSHEET - Ancillary Review Matrix.

5.2 If the item was determined to be Serious Non-Compliance or Continuing Non-Compliance or an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) that occurred locally:

5.2.1 If the external IRB has not notified the local IRB of the event, contact the external IRB, request additional information and documentation as needed, and confirm reporting requirements as described in the reliance agreement terms.

5.2.2 Consult with the HRPP Director or designee to determine whether any additional actions are needed, including local review of the event.

5.2.2.1 Follow HRP-024 - SOP - New Information to review the event.

5.2.2.2 In coordination with the HRPP Director or designee, notify the IO/OO and other local departmental offices as appropriate (i.e., department leadership, deans, privacy, quality, or risk management).

5.2.3 Respond to the external IRB with any edits requested to any applicable reporting requirement letter(s) or file the report with any appropriate agency(ies) in accordance with oversight requirements outlined in the Authorization Agreement terms.

5.3 If the item is an update to the overall study (Update to Study Details for funding, study scope, or study related documents and template), review the updates in accordance with the roles and responsibilities of your institution as outlined in the Authorization Agreement or HRP-830 - WORKSHEET - Communication and Responsibilities.

5.3.1 The institutional policy requires that the IRB Reliance Coordinator or IRB staff execute the "Finalize Updates" activity in the system:

5.3.1.1 Review the updates and if they are satisfactory, determine if the changes require an update to the sIRB Decision:

5.3.1.1.1 If yes, execute the "Edit sIRB Decision" activity and complete the SmartForm, indicating whether documents need to be finalized or a letter needs to be sent.

5.3.1.1.2 If applicable, execute the "Finalize Documents" activity and then the "Send Letter" activity to send HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update.

5.3.1.1.3 If no, no further action is necessary.

5.3.1.2 If the item includes other updates and are not satisfactory:

5.3.1.2.1 Contact the investigator by posting a comment in the submission workspace with requested changes. Instruct the investigator to edit the submission.

5.3.1.2.2 When the investigator edits the submission, confirm that the requested changes were made.

5.3.1.3 Review the updates and if they are satisfactory, determine if the changes require an update to the sIRB Decision:

5.3.1.3.1 If yes, execute the "Edit sIRB Decision" activity and complete the SmartForm, indicating whether documents need to be finalized or a letter needs to be sent.

5.3.1.3.2 If applicable, execute the "Finalize Documents" activity and then the "Send Letter" activity to send HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update.

5.3.1.3.3 If no, no further action is necessary.

6 MATERIALS

6.1 HRP- 024 - SOP - New Information

6.2 HRP-055 - SOP - IRB Review of Financial Conflicts of Interest

6.3 HRP-309 - WORKSHEET - Ancillary Review Matrix

6.4 HRP-441- WORKSHEET - HIPAA Waiver of Authorization

6.5 HRP-830 - WORKSHEET - Communication and Responsibilities

6.6 HRP-859 - LETTER - Acknowledge External IRB Update

7 REFERENCES

7.1 None.