SOP: Post-Review

1 PURPOSE

1.1 This procedure establishes the process for communications after a protocol is reviewed.

1.2 The process begins when:

1.2.1 A Designated Reviewer has completed a Non-Committee Review and provided completed materials to the IRB staff; OR

1.2.2 An IRB meeting has adjourned, and the IRB chair or IRB manager has approved the minutes; OR

1.2.3 An IRB staff member has verified that modifications required to secure approval have been made.

1.3 The process ends when all correspondence related to IRB determinations and actions have been sent and additional tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The IRB reports its findings and actions to the investigator.

3.2 The IRB reports its findings and actions to the institution.

3.3 When the IRB disapproves research, it provides the investigator with a statement of the reasons for the decision and gives the investigator an opportunity to respond in person or in writing.

3.4 Communication of review results to investigators are to be completed within 10 business days of the IRB meeting or receipt of the completed Non-Committee Review materials.

3.5 Reporting of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; and Unanticipated Problem Involving Risks to Subjects or Others to outside agencies is to take place within 30 business days from the determination of a reportable problem.

3.5.1 Reporting to OHRP only occurs for non-exempt Human Research that:

3.5.1.1 Is HHS-supported or conducted;

3.5.1.2 Is conducted or supported by a Federal Agency that has adopted the Common Rule and has not approved a separate assurance, other than the FWA, for the research; OR

3.5.1.3 The institution has chosen to apply the Common Rule on its FWA to all its non-exempt Human Research regardless of the source of support.

3.5.2 Reporting to the FDA only occurs for FDA-regulated Human Research.

3.5.3 Reporting to OHRP or the FDA should not occur if any of the above criteria are not met.

3.6 If the report is determined to be an unanticipated problem involving risk to subjects or others for a multi-site study AND did not occur locally (meaning at any site under this IRB's purview) (e.g. the sponsor submits a protocol modification that includes a newly identified risk), reporting to OHRP and the FDA is not required.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 If the Non-Committee Review indicated a Conflicting Interest or a lack of expertise, follow HRP-031 - SOP - Non-Committee Review Preparation.

5.2 If the title, principal investigator, or research staff for a protocol changed, update the list of protocols.

5.3 For initial reviews, continuing reviews or modifications:

5.3.1 Refer to HRP-302 - WORKSHEET - Approval Intervals to calculate approval intervals (if applicable).

5.3.2 For approvals, stamp all approved long form consent documents with the approval date on the first and last page.

5.3.3 Refer to HRP-303 - WORKSHEET - Communication of Review Results and send all applicable letters within 30 business days.

5.3.3.1 Have letter signed by the signatory in the template letter.

5.3.3.2 Send the letter to the inside addresses and cc list as directed by the letter.

5.3.3.2.1 Attach stamped consent documents to the letter.

5.3.4 For continuing reviews or modifications to studies where enrollment is suspended and the submission does not change the enrollment suspension status, document in the study record that enrollment to the study remains suspended.

5.4 For determinations of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others:

5.4.1 Refer to HRP-303 - WORKSHEET - Communication of Review Results and send all applicable letters to the Principal Investigator within 5 business days.

5.4.1.1 Have letter signed by the signatory in the template letter.

5.4.1.2 Send the letter to the inside addresses and cc list as directed by the letter.

5.5 If reporting to an external agency is required:

5.5.1 When reporting to OHRP only, complete the OHRP Incident Report Form within 30 business days from the determination of a reportable problem.

5.5.2 If reporting to both OHRP and any other outside agency concurrently, utilize the OHRP Incident Report Form email confirmation and HRP-520a - LETTER - External Report - OHRP and Other Agencies and send within 30 business days from the determination of a reportable problem.

5.5.3 If reporting to other outside agencies NOT including OHRP, complete HRP-520 – LETTER – External Report NOT Including OHRP and send within 30 business days from the determination of a reportable problem.

6 MATERIALS

6.1 HRP-031 - SOP - Non-Committee Review Preparation

6.2 HRP-302 - WORKSHEET - Approval Intervals

6.3 HRP-303 - WORKSHEET - Communication of Review Results

6.4 HRP-520 - LETTER - External Report NOT Including OHRP

6.5 HRP-520a - LETTER - External Report OHRP and Other Agencies

7 REFERENCES

7.1 45 CFR §46.103(b)(4)(i), 45 CFR §46.207, 45 CFR §46.305(c), 45 CFR §46.306(a)(1), 45 CFR §46.407, Informed Consent Requirements in Emergency Research (OPRR Letter, 1996)

7.2 21 CFR §56.108(a)(1), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66

7.3 AAHRPP elements I.1.A, I.5.D, I-9, II.1.D, II.1.E, II.2.A, II.2.G, II.2.H, II.2.E-II.2.E.2, II.2.F-II.2.F.3, III.2.D