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 finalized 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 through IRB minutes, accessible to the Institutional Official.

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 When a modification is reviewed to lift a suspension for a previous Suspension of IRB Approval, the state of the study will change from “Suspended” to “Approved” when the modification is approved.

3.6 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.

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

3.6.1.1 Is HHS-supported or conducted;

3.6.1.2 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

3.6.1.3 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.

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

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

3.7 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.

3.8 For Veterans Affairs (VA) research that involves:

3.8.1 An Unanticipated Problem Involving Risks to Subjects or Others that is a local research death, notification to the VA facility Director, the Research Compliance Officer (RCO) and the Associate Chief of Staff/R&D must occur within 5 business days of the convened IRB's determination(s).

3.8.2 Information determined by the IRB to constitute an Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance or Continuing Non-Compliance, notification to the VA facility Director, the Research Compliance Officer (RCO) and the Associate Chief of Staff/R&D must occur within 5 business days of the convened IRB's determination(s).

3.8.3 If the IRB is unable to make a determination on the apparent Unanticipated Problem Involving Risks to Subjects or Others within 30 calendar days of the convened IRB's initial review due to insufficient information or due to a lack of sufficient time to complete its review, the IRB must notify the VA medical facility Director, the Research Compliance Officer (RCO), and the ACOS/R&D in writing no later than five (5) business days after the determination was due.

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 For initial reviews, continuing reviews, or modifications:

5.2.1 If the communication is an IRB determination of Approved:

5.2.1.1 For DHHS-regulated research involving prisoners, refer to HRP-303 – WORKSHEET – Communication of Review Results to send applicable letters.

5.2.1.1.1 If HRP-415 - PI WORKSHEET – Prisoners reflects prisoners as a class or prisoners as controls, await OHRP approval before proceeding.

5.2.1.2 Execute the "Finalize Documents" to stamp and accept all changes for attached documents.

5.2.1.3 Execute the "Prepare Letter" activity and modify the letter as needed.

5.2.1.4 Execute the "Send Letter" activity.

5.2.2 If the communication is an IRB determination other than Approved:

5.2.2.1 Execute the "Prepare Letter" activity and modify the letter as needed.

5.2.2.2 Execute the "Send Letter" activity.

5.3 Refer to HRP-303 - WORKSHEET - Communication of Review Results to determine if any paper-based letters need to be sent and send all applicable letters within 30 business days.

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

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

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

5.4 For continuing reviews or modifications to studies where enrollment is suspended and the submission does not change the enrollment suspension status, execute the "Suspend" activity in the study workspace, and document that the enrollment to the study remains suspended.

5.5 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:

5.5.1 If the determination was Serious Non-Compliance; Continuing Non-Compliance; or Unanticipated Problem Involving Risks to Subjects or Others:

5.5.1.1 Execute the "Prepare Letter" activity and modify the appropriate letter as needed.

5.5.1.2 Execute the "Send Letter" activity.

5.5.2 If the determination was Suspension of IRB Approval:

5.5.2.1 Execute the “Suspend” activity in the study workspace.

5.5.2.2 Execute the “Prepare Letter” activity in the study workspace and modify the letter as needed.

5.5.2.3 Execute the “Send Letter” activity.

5.5.3 If the determination was Termination of IRB Approval:

5.5.3.1 Execute the “Terminate” activity in the study workspace.

5.5.3.2 Execute the “Prepare Letter” activity in the study workspace and modify the letter as needed.

5.5.3.3 Execute the “Send Letter” activity.

5.5.4 When reporting to OHRP only, complete the *OHRP Incident Report Form*[i] within 30 business days from the determination of a reportable problem.

5.5.5 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.

5.5.6 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-303 - WORKSHEET - Communication of Review Results

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

6.4 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 VHA Directive 1058.01 October 22, 2020

[i] https://oash.force.com/ohrpwebforms/s/incident-web-form