UNIVERSITY OF MIAMI

SOP: Post-Review				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-052	12/10/2021	F. Conte	K. Viamonte	1 of 6

1 PURPOSE

1.1 This procedure establishes the process for communications after completing submission review.

1.2 The process begins when:

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

1.2.2 An IRB meeting has adjourned; an; OR

1.2.3 An HSRO 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, as applicable, additional tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

2.2 Minor clarifications, remove the expiration dates from the consentwatermark.

2.3 Added requirement to watermark protocol.

2.4 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 GUIDING PRINCIPLES

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 5 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.

4 RESPONSIBILITIES

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

5.3 If approved, execute the “Finalize Documents” to watermark and accept all changes for relevant documents.

5.4 Execute the “Prepare Letter” activity and modify the letter as needed.

5.4.1 .

5.4.2 Execute the “Send Letter” activity.

5.5 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.

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

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

5.5.1.2 Approved documents will be identified in the letter.

5.5.2 For determinations of Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, Termination of IRB Approval, or Unanticipated Problems Involving

Risks to Subjects or Other, use HRP-520 - LETTER - External Report NOT Including OHRP or HRP-526 - External Report to DOD, or equivalent, to send notifications to outside agencies within 30 business days from the determination of a reportable problem.

5.5.2.1 When sending to DHHS only, complete the OHRP Incident Report Online Form[1].

5.5.2.2 If reporting to both DHHS and any other outside agency concurrently, use the OHRP Incident Report Form and HRP-520a, or equivalent.

5.5.2.3 If reporting to other outside agencies NOT including DHHS, complete HRP-520 or HRP-526, or equivalent, as appropriate.

5.6 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.

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-526 - External Report to DOD

7 REFERENCES

7.1 45 CFR §46.103(b)(4)(i), 45 CFR §46.207, 45 CFR §46.306(2)(C), 45 CFR §46.306(2)(D), 45 CFR §46.407, 45 CFR §46 Waiver of Informed Consent Requirements in Certain Emergency Research (November 1, 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

[1] See: https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html