UNIVERSITY OF MIAMI

SOP: Post-Review				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
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1. PURPOSE

1.1This 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 IRB staff; OR

1.2.2 An IRB meeting has adjourned and the IRB chair or IRB director has reviewed the minutes; 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 additional tasks have been completed.

2. REVISIONS FROM PREVIOUS VERSION

2.1 None

2.1 Minor clarifications, remove the expiration dates from the consent watermark.

2.2 Added requirement to watermark protocol.

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 These reporting procedures are to be completed within four (4) 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 is to take place within 30 days from the determination that the event meets reporting requirements.

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 “SOP: Non-Committee Review Preparation (HRP-031).”

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

5.3 Refer to “WORKSHEET: Approval Intervals (HRP-302)” to calculate approval intervals.

5.4 The protocol and all approved consent documents will be watermarked with the approval dates on all pages.

5.5 Refer to “WORKSHEET: Communication of Review Results (HRP-303)” and send all applicable letters.

5.5.1 Determination letter will be electronically signed by the signatory in the template letter.

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

5.5.3 Approved consent documents will be identified in the letter.

6. MATERIALS

6.1 SOP: Non-Committee Review Preparation (HRP-031)
6.2 WORKSHEET: Communication of Review Results (HRP-303)
6.3 WORKSHEET: Approval Intervals (HRP-302)

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