FSU RESEARCH Advancing Creativity and Innovation
Human Subjects Research Office

SOP: Post-Review				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-052	12/6/18	T. Bechert	G. Ostrander	1 of 1

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.

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

5.2 Refer to "WORKSHEET: Approval Intervals (HRP-302)" to calculated approval intervals (if applicable).

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

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

5.3.2 Execute the "Send Letter" activity.

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 Use "LETTER TEMPLATE: External Report (HRP-520)" to send to outside agencies within 30 business days from the determination of a reportable problem.

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