FSU RESEARCH Advancing Creativity and Innovation
Human Subjects Research Office

SOP: Pre-review				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-021	12/6/18	T. Bechert	G. Ostrander	1 of 2

1 PURPOSE

1.1 This procedure establishes the process to pre-review a request for approval (approval of new research, continuing review of research, or modification to previously approved research) or a determination whether an activity is exempt Human Research or is not Human Research.

1.2 The process begins when the IRB receives a request for local IRB approval, including requests from other institutions when this institution is the IRB of record, e.g., for a Collaborative Study or Multi-Site Study.

1.3 The process ends when the information has been placed on the agenda for an IRB meeting or will be handled by Non-Committee Review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 The addition of a previously approved protocol at a new site or sites that will be overseen by a principal investigator who will take separate and full responsibility for that site or those sites is considered a modification to previously approved research.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 If the submission is a response to modifications required to secure approval received within 30 days of the IRB review date:

- 5.1.1 Evaluate whether the investigator made the required modifications.
- 5.1.2 If the investigator made the required modifications, follow “SOP: Post-Review (HRP-052)” to issue an approval.
- 5.1.3 If the investigator did not make the required modifications or made unrequested modifications, execute the “Request Pre-Review Clarification” activity from the investigator. Offer the investigator the opportunity to correct the submission.
  - 5.1.3.1 If the investigator will correct the submission, have the investigator make changes then execute the “Submit Changes” activity and stop processing the current submission until changes are received.
  - 5.1.3.2 If the investigator will not correct the submission, have the investigator execute the “Submit Changes” activity to resubmit and continue processing.

5.2 For all other submissions, complete Pre-Review Activity or review the previously completed Pre-Review Activity and revise as needed, considering the items on ”WORKSHEET: Pre-Review (HRP-308)” and note all remaining contingencies in the “Final Contingencies” section.

5.3 If the information is not complete, contact the investigator by selecting the “Request Pre-Review Clarifications” Activity. Offer the investigator the opportunity to provide additional information.

- 5.3.1 Continue processing once the investigator responds to the request for additional information.

5.4 If the request is for an initial approval and principal investigator is Restricted, contact the investigator. Explain that the investigator is Restricted, give the reasons, and indicate that if a new protocol goes to the IRB, the IRB policy is to disapprove the research. Offer the investigator the opportunity to withdraw the submission pending removal of the Restricted status.

- 5.4.1 If the investigator withdraws the submission, stop processing the current submission.
- 5.4.2 If the investigator will not withdraw the submission, discuss whether you may continue to process the submission with the IRB Manager.

5.5 Evaluate the most likely level of review using “WORKSHEET: Human Research Determination (HRP-310)”, “WORKSHEET: Engagement Determination (HRP-311)”,

"WORKSHEET: Exemption Determination (HRP-312)", "WORKSHEET: Expedited Review (HRP-313)", and/or "WORKSHEET: Criteria for Approval for HUD (HRP-323)" as references:

5.5.1 If the request can be handled as a Non-Committee Review and the principal investigator is not Restricted, Follow "SOP: Non-Committee Review Preparation (HRP-031)."

5.5.2 If the request cannot be handled as a Non-Committee Review, place the protocol on the agenda for a convened IRB meeting in an IRB with appropriate scope.

5.5.3 If the request is a non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested, follow "SOP: Non-Committee Review Preparation (HRP-031)" and "SOP: All Emergency Use, and Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Review (HRP-023)."

6 MATERIALS

6.1 WORKSHEET: Pre-Review (HRP-308)
6.2 HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)
6.3 SOP: All Emergency Use, and Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Review (HRP-023)
6.4 SOP: New Information (HRP-024)
6.5 SOP: Non-Committee Review Preparation (HRP-031)
6.6 SOP: IRB Meeting Preparation (HRP-040)
6.7 SOP: Post-Review (HRP-052)
6.8 WORKSHEET: Human Research Determination (HRP-310)
6.9 WORKSHEET: Engagement Determination (HRP-311)
6.10 WORKSHEET: Exemption Determination (HRP-312)
6.11 WORKSHEET: Expedited Review (HRP-313)
6.12 WORKSHEET: Criteria for Approval for HUD (HRP-323)

7 REFERENCES

7.1 None