University of Central Florida	**SOP:** Pre-review			
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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 approval.

1.3 The process ends when the information has been placed on the queue for an IRB meeting or has been provided to a Designated Reviewer.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Minor revisions since AAHRPP accreditation; replaces version dated 08/08/2013.

3 POLICY

3.1 None.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Use the "WORKSHEET: Submission Materials" to review the application materials.

5.2 If the information is not complete, the Designated Reviewer returns the submission to the investigator with stipulations to address. The review process cannot continue until the investigator responds to stipulations and provides additional or revised documents, as needed.

5.3 If the investigator or research staff member is Restricted, contact the investigator. Explain that the investigator or research staff member is Restricted, give the reasons, and indicate that if the protocol goes to the IRB and the activity is Human Research, the IRB policy is to not approve the research except where necessary to maintain protection of current participants.

5.3.1 If the investigator will take steps to remove the Restricted status before further review, wait for submission of the materials to remove the Restricted status.

5.3.2 If the investigator will not take actions, continue processing.

5.4 If the research will be conducted outside of Florida, consult with UCF legal counsel to determine whether there are any applicable laws related to the research in the localities where the research will occur.

5.4.1 Have legal counsel document any determinations related to applicable laws in the localities outside of Florida where the research will be conducted for review and consideration by IRB members as part of the administrative review preparation (HRP-062 - SOP - Administrative Review Preparation) or IRB meeting preparation (HRP-030 - SOP - IRB Meeting Preparation) process.

5.5 Evaluate the most likely level of review:

5.5.1 If the request can be handled as an Administrative Review and the investigators and research staff are not Restricted, Follow the "SOP: Administrative Review Preparation."

5.5.2 Otherwise put in the queue for a convened IRB meeting in an IRB with appropriate scope.

6 MATERIALS

6.1 SOP: Administrative Review Preparation.

6.2 WORKSHEET: Submission Material.

7 REFERENCES

7.1 None.