UNIVERSITY OF MIAMI

SOP: External IRB Review					
NUMBER	DATE	VERSION #	AUTHOR	APPROVED BY	PAGE
095	06/01/2021	2	J. Casanova	C. Gates	1 of 6
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1 PURPOSE

1.1 This policy establishes the process for External IRB review and provides the procedures that will be used to screen studies for local review requirements. The Vice Provost for Research +Scholarship and the Executive Director of the Human Subject Research Office explicitly reserve the right to determine on an individual bases whether to allow external IRB review.

1.2 The use of an external IRB may be warranted when it will:

1.2.1 Enhance the protection of study participants by providing consistent expert IRB review at the national level.

1.2.2 Improve access to clinical trials for potential study participants by enabling UM to use an external IRB

1.2.3 Satisfy regulatory or funding-source requirements for single IRB review.

1.2.4 Provide administrative efficiencies as determined by the Vice Provost for Research + Scholarship or the Executive Director of the HSRO.

1.3 The process begins when the researcher decides to seek UM Human Subject Research Office (HSRO) authorization to use an external IRB for single IRB review of a given study.

1.4 The process ends when the study is closed with the external IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Updated titles of decision makers.

3 GUIDING PRINCIPLES

3.1 Studies meeting one or more of the following criteria qualify for external IRB review:

3.1.1 Multi-site or cooperative research where all sites agree to use an external IRB.

3.1.2 Industry-funded and/or supported when using an external IRB is a participation requirement.

3.1.3 Federally funded research.

3.1.4 Research does not fall under an exempt category.

3.2 Studies that do not meet the above criteria may be reviewed externally if:

3.2.1 Exception 1 – Study has been authorized to use an external IRB with the express written approval of the Vice Provost for Research + Scholarship, the Executive Director of the HSRO, designee.

3.2.2 Exception 2 – The NCI- CIRB reviews and oversees all its member cooperative group sponsored pediatric and adult research.

3.2.3 Exception 3 –Research studies are eligible for review by the Florida Department of Health (DOH) IRB when:

3.2.3.1 The research will take place at a DOH facility, including, but not limited to: County Health Departments (CHDs) or State laboratories

3.2.3.2 The research will involve DOH clients (except when community-based research only incidentally involves a DOH client(s), and

3.2.3.3 The research will involve the use of non-public information maintained by DOH.

3.3 If the reviewing IRB is not accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) or a similar body, the IRB must provide its plan to ensure compliance with ethical standards and regulatory requirements.

3.4 Verification of eligibility and/or written authorization must be obtained via HSRO **FORM: External IRB Reliance Application & Cover Sheet (HRP-216)** before submitting the study to an external IRB.

3.5 If a research study has already been reviewed and approved by the UM IRB, it may not be transferred to an external IRB without the express written approval of the Vice Provost for Research + Scholarship or the Executive Director, HSRO.

3.6 The HSRO reserves the right to assess a one-time fee for administrative review of industry-sponsored studies being sent for external review. The administrative review fee will be in addition to any fees charged by the external IRB. Any applicable fees are described at http://hsro.med.miami.edu.

4 RESPONSIBILITIES

4.1 Principal Investigators and their study teams (hereinafter referred to as "researchers") are responsible for the following:

4.1.1 Complying with applicable laws, regulations and UM policies.

4.1.2 Adhering to all determinations and requirements of the reviewing IRB.

4.1.3 Ensuring that the consent form (typically the Costs, Payment and Compensation for Injury sections) is consistent with the executed clinical trial agreement, once available.

4.1.4 Ensuring that each team member has completed their Conflict of Interest disclosures and, if required, that the review by the Office of Disclosures and Conflict of Interest Management has been completed.

4.1.5 Ensuring that each team member has completed required applicable CITI training requirements.

4.1.6 Obtaining all applicable institution/compliance reviews and approvals (e.g. department/division, SCCC Cancer Protocol Review Committee, Pathology Protocol Review Committee, Human Use Radiation Safety Committee, Institutional Biosafety Committee, Embryonic Stem Cell Research Oversight Committee, Office of Environmental Health and Safety, Clinical Trials Disclosure Committee, Research Operations and Regulatory Support, Clinical and Translational Research Site, Jackson Health System Clinical Research Review Committee, and/or University of Miami Hospital) prior to starting any human subject research activities.

4.1.6.1 Notifying the HSRO of any Determination of continuing non-compliance;

4.1.6.2 Determination of unanticipated problem involving risk to subjects or others;

4.1.7 Comply with protocol, amendments, and recruitment procedures as applicable and approved by reviewing IRB.

4.1.8 The researcher (or sponsor on behalf of the researcher) is responsible for submitting subsequent submissions, retaining all approved documents and consent forms pursuant to good clinical practice and/or confidentiality and security standards.

4.2 Reviewing IRB: If the study is approved for submission to an external IRB, the reviewing IRB becomes the IRB of Record for the study and is responsible for the following:

4.2.1 Conducting review of research according to all applicable regulations and laws.

4.2.2 Ensure that any UM requirements identified on **FORM: External IRB Reliance Application & Cover Sheet (HRP-216)** are reflected in the approved informed consent documents. If the reviewing IRB is not able to utilize the UM/JHS-required language, the external IRB is responsible for communicating with the HSRO, who will assist in resolving this issue.

4.2.3 Reviewing modifications, continuing reviews, unanticipated problems involving risks to subjects or others (UPIRTSO) or any serious or continuing noncompliance, and information intended for use by current or prospective study participants.

4.2.4 Notifying UM researchers in writing of any determination including termination or suspension of the study.

4.3 HSRO staff members authorized by the Executive Director, HSRO, to manage the external IRB process are responsible for the following:

4.3.1 Verifying eligibility of a study to go to an external IRB.

4.3.2 Providing a signed confirmation that the study qualifies for submission to an external IRB to the researcher via **FORM: External IRB Reliance Application & Cover Sheet (HRP-216)**.

4.3.3 Perform local context functions in compliance with federal regulations and University policy.

4.4 The Vice Provost for Research + Scholarship or the Executive Director, HSRO, are responsible for the following:

4.4.1 Granting exceptions to the criteria for external IRB review.

4.4.2 Designating HSRO staff members to facilitate the external IRB review process, including giving necessary approvals, as applicable and so authorized.

5 PROCEDURE

5.1 Researchers must create a “shadow submission” in eProst for record-keeping purposes. The eProst submission number assigned at the time of creation will be provided to the reviewing IRB and must be referenced in all future correspondence from the study team with the HSRO concerning the study.

5.1.1 The person completing the eProst form must indicate “Yes” when asked if the study will be submitted to an external IRB on the Basic Information page of the New Study SmartForm .

5.1.2 In addition to other pertinent documents, a completed copy of **FORM: External IRB Reliance Application & Cover Sheet (HRP-216)** must be uploaded to the Supporting Documents section (External IRB page) of the eProst New Study SmartForm.

5.1.2.1 A Study-Level Initial Approval letter must be provided (if available).

5.1.2.2 Applicable UM/JHS required language in the HRP-216 must be reflected in the consent documents.

5.1.3 Authorized HSRO staff members will review the form to ensure that the study meets all of the eligibility criteria outlined in item 3.1.

5.1.3.1 If seeking an exception to the criteria for external IRB review, researchers must provide the rationale as a written attachment at the time of such request.

5.1.3.2 If the study is not eligible for external review but qualifies for review by a UM IRB, the eProst submission must be withdrawn and resubmitted to be reassigned for internal review (Study Information page)).

5.1.3.3 If the study is not eligible for external review and should not be reviewed by a UM IRB, HSRO staff will confirm their understanding of the circumstances with the researchers and request that the study be withdrawn and discarded in eProst.

5.1.4 Once the HSRO determines that all requirements have been met, the HSRO reviewer will return the signed form to the researchers as a comment in the study workspace in eProst. The completed and signed form must be submitted to the reviewing IRB as a cover sheet, describing the institutional requirements for research at UM/JHS (local context).

5.1.5 In the absence of an existing Master Reliance Agreement or similar instrument, an IRB Authorization Agreement may be required. Once the agreement is determined to be acceptable, the Institutional Official or designee will sign the agreement and return it to the HSRO staff member to be uploaded in eProst via a comment.

5.2 After an administrative review of the eProst submission is completed, authorized HSRO staff members will confirm reliance on the External IRB. The eProst submission state will then transition to Pending sIRB Review, and the study team will be cleared to proceed with submission to the External IRB.

5.3 Study teams will upload approval documentation and the corresponding IRB approved documents onto eProst.

5.4 Authorized HSRO staff members will ensure the submission is complete and execute the Record sIRB Decision function if the following criteria are met:

5.4.1 All applicable eProst SmartForm questions are answered.

5.4.2 The approval letter from the reviewing IRB adding UM/JHS as a site has been uploaded to the Local Site Documents section in eProst.

5.4.3 All required and IRB approved documents (including Sponsor Protocol, finalized consent forms, and Investigator Brochure or Device Manual as applicable) have been uploaded.

5.4.4 All required Ancillary Committee approvals have been submitted via eProst.

5.5 Once the acknowledgement letter has been provided by the HSRO, all Ancillary Committee approvals are completed, and the clinical trial agreement (CTA) has been executed, researchers may begin study activities. All subsequent submissions must be sent to the reviewing (external) IRB and the eProst submission must be updated by the study team as these submissions get approved.

5.5.1 NOTE: Any discrepancies between the informed consent language and the CTA must be brought to the attention of the HSRO and if changes are required, the informed consent must be modified to become consistent with the CTA.

5.6 Changes in research. The sponsor or researcher is responsible for submitting subsequent changes of all types directly to the external IRB, without HSRO authorization or screening. Use the forms and follow the procedures provided by the reviewing IRB.

5.6.1 After site approval and acknowledgement, the researcher must use the Update Study Details (study-wide)/ Create Site Modification (local site) activities to reflect any study updates and modifications, and to ensure that any documents have been updated.

5.6.1.1 The researcher must maintain current versions of all study documents in eProst and upload revised versions thereof as they are modified and approved by the reviewing IRB.

5.6.1.2 Researchers must submit Study Updates to provide new or revised study-wide documents that are not specific to UM/JHS. This is done by selecting the "Update Study Details" function in eProst.

5.6.1.3 Researchers must submit Study Modifications to provide new or revised UM/JHS specific documents or documents that require finalization (study protocol, consent form, recruitment materials). Corresponding External IRB approval letters must be uploaded to the Local Site Documents section.

5.7 Continuing review. The sponsor, investigator and external IRB are responsible for ensuring that continuing review is conducted in accordance with the federal regulations.

5.7.1 The researcher must maintain current versions of all study documents in eProst and upload revised versions thereof as they are modified and approved by the reviewing IRB. Additionally, the researchers should update eProst and attach all applicable IRB forms and watermarked consents.

5.7.2 The UM does not require Continuing Reports for studies reviewed by an External IRB. Study teams may provide Continuing Reports for record keeping purposes through the Report Continuing Review Data function on eProst. (Note: Only a PI or PI Proxy has access to this function.)

5.7.3 For the purposes of study closures, the PI or PI proxy must provide the External IRB closure letter through a comment attachment on eProst. Authorized HSRO staff will close the study.

6 MATERIALS

6.1 FORM: External IRB Reliance Application & Cover Sheet (HRP-216)

7 REFERENCES

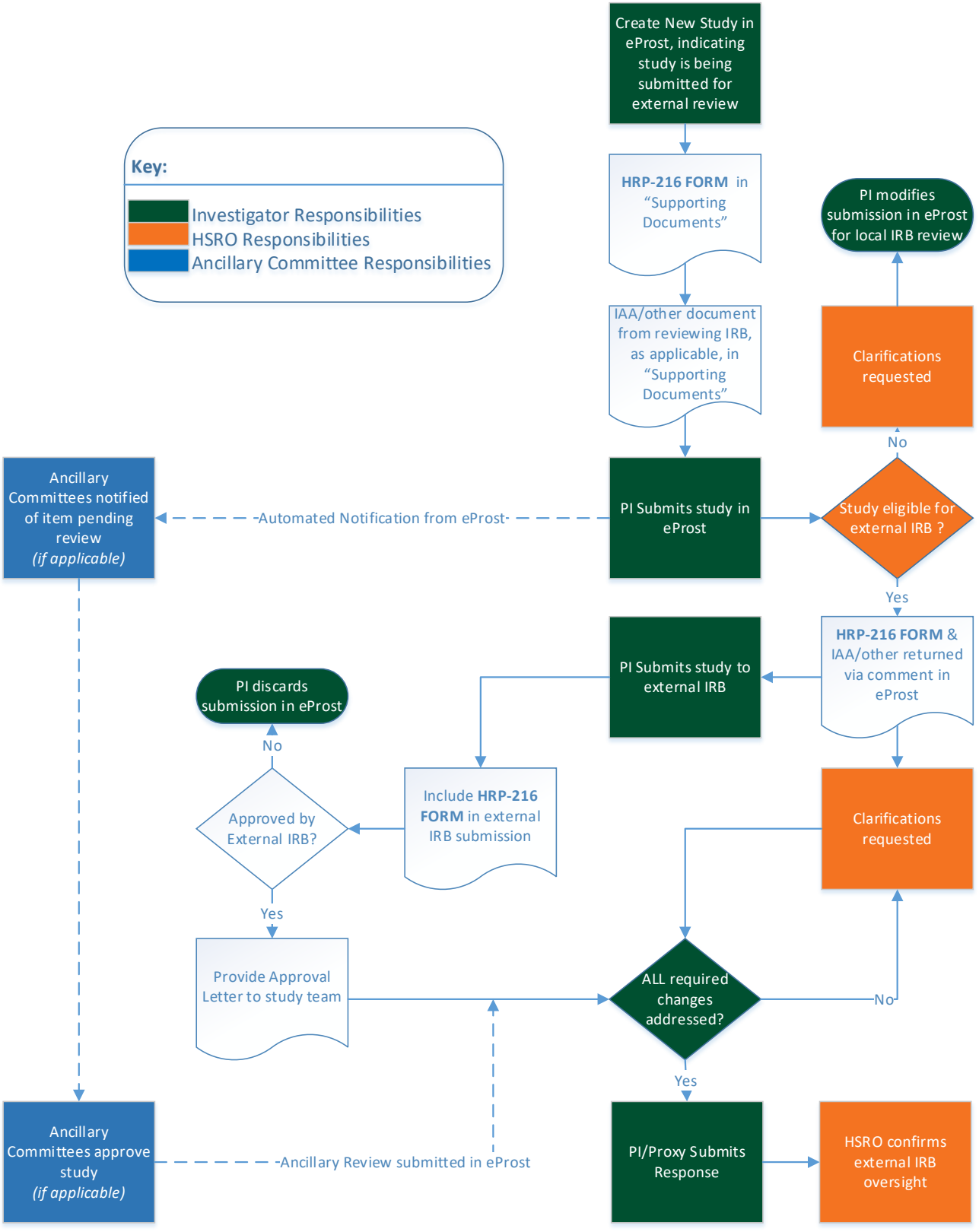
7.1 45 CFR 46.114

7.2 21 CFR 56.114

7.3 Section 381.86, Florida Statutes

7.4 National Cancer Institute Central Institutional Review Board Standard Operating Procedures
7.5 AAHRPP Tip Sheet 24: Relying on an External IRB

8 FLOW CHART


Create New Study in eProst, indicating study is being submitted for external review
HRP-216 FORM in "Supporting Documents"
IAA/other document from reviewing IRB, as applicable, in "Supporting Documents"
PI Submits study in eProst
Study eligible for external IRB ?
No
PI modifies submission in eProst for local IRB review
Clarifications requested
Yes
HRP-216 FORM & IAA/other returned via comment in eProst
PI Submits study to external IRB
Clarifications requested
No
ALL required changes addressed?
Yes
PI/Proxy Submits Response
HSRO confirms external IRB oversight
Automated Notification from eProst
Ancillary Committees notified of item pending review (if applicable)
Ancillary Committees approve study (if applicable)
Ancillary Review submitted in eProst
Provide Approval Letter to study team
Approved by External IRB?
No
PI discards submission in eProst
Yes
Include HRP-216 FORM in external IRB submission
Key:
Investigator Responsibilities
HSRO Responsibilities
Ancillary Committee Responsibilities