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 and the Executive Director, Human Subject Research Office (HSRO Director), explicitly reserve the right to determine on an individual basis whether to allow external IRB review of human subject research to be conducted by employees, faculty and students of the University of Miami.

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 or the HSRO Director.

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 None.

3 GUIDING PRINCIPLES

3.1 Studies meeting the following criteria qualify for external IRB review:

3.1.1 Non-exempt multi-site or cooperative human subject research in which UM employees, faculty members or students are engaged.

3.1.2 For research that is minimal risk, the reviewing IRB must agree to comply with applicable ethical standards and regulations.

3.1.3 For research that is greater than minimal risk, the reviewing IRB must be accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) or have completed an acceptable internal quality review process.

3.1.4 An executed IRB Authorization Agreement applicable to the proposed research, which meets the requirements outlined in must be in place.

3.2 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 or the HSRO Director.

3.3 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.
5 PROCEDURE

5.1 Researchers must create a "shadow initial review submission" in eProst for record-keeping purposes. The eProst submission number assigned at the time of creation will be provided to the HSRO concerning the study.

5.1.1 The person completing the eProst form must indicate "Yes" when asked if the study will be reviewed IRB and must be referenced in all future correspondence from the study team with the HSRO, who will assist in resolving this.

5.1.2 In addition to other pertinent documents, a completed copy of HRP-216 must be uploaded to the Supporting Documents section (External IRB page) of the eProst New Study SmartForm. At this point, the HSRO staff members authorized by the Associate Vice Provost for Human Subject Research to manage the external IRB process are responsible for the following:

4.2.1 Verifying eligibility of a study to go to an external IRB by completing WORKSHEET: Reliance on External IRB;

4.2.2 Ensuring an IAA covering the proposed research has been executed;

4.2.3 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);

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

5.1.3 Authorized HSRO staff members will review HRP 216 to ensure that the study meets all of the eligibility criteria outlined in item 3.1.

5.1.3.1 If the eligibility criteria outlined in Section 3.1 above are not satisfied, the HSRO staff member will refer the submission to the HSRO Director for review.

5.1.3.2 If the HSRO Director determines the study is not eligible for external review but qualifies for review by a UM IRB, the eProst submission must be reassigned for internal review (Study Information page, question 6).
5.4.4 Once the HSRO determines that all requirements for external IRB review 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).

5.2 Researchers or their study teams are encouraged to submit the study to the external IRB upon receipt of the confirmation of eligibility.

5.3 When the external IRB has completed the review, the researcher must submit the approval letter and all approved documents to the HSRO through eProst.

5.4 Authorized HSRO staff members will complete WORKSHEET: External IRB Review of UM Human Subject Research to ensure the submission is complete and execute the Confirm External IRB activity 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 appropriate question in eProst and the approval and expiration dates (if applicable) listed in questions 4 and 5 of the External IRB page of the SmartForm are consistent with the letter.

5.4.3 The “Update Study Information” activity has been completed, applicable questions have been answered and any required documents (including Sponsor Protocol 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 Researchers are not responsible for submitting documents relating to changes in research or continuing review.

5.6 Researchers must close the study with the HSRO within 30 days of closure with the external IRB.

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

Key:
- Investigator Responsibilities
- HSRO Responsibilities
- Ancillary Committee Responsibilities

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 to external IRB

PI modifies submission in eProst for local IRB review

Clarifications requested

Yes

Study eligible for external IRB?

No

PI Submits study in eProst

HRP-216 FORM & IAA/other returned via comment in eProst

Clarifications requested

Yes

PI/Proxy Submits Response

HSRO confirms external IRB oversight

No

All required changes addressed?

Yes

Provide Approval Letter to study team

No

PI Submits study in eProst

Approved by External IRB?

Yes

PI/Proxy Submits Response

No

Ancillary Committees approve study (if applicable)

Automated Notification from eProst

Ancillary Committees notified of item pending review (if applicable)