



SOP: External IRB Review					
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HRP-095	07/17/2019	1	J. Casanova	C. Gates	1 of 5
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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 and the Associate Vice Provost for Human Subject Research 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 or Associate Vice Provost for Human Subject Research
- 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 one or more of the following criteria qualify for external IRB review:
  - 3.1.1 Multi-site or cooperative research
  - 3.1.2 Industry-funded and/or supported
  - 3.1.3 Involve an FDA-regulated product (drug, device, or biologic)
  - 3.1.4 The reviewing IRB is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) or similar body.
- 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, the Associate Vice Provost for Human Subject Research or 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 Verification of eligibility and/or written authorization must be obtained via HSRO **FORM: External IRB Reliance Application & Cover Sheet (HRP-216)** prior to submitting to an external IRB.
- 3.4 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 Associate Vice Provost for Human Subject Research.
- 3.5 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>.



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#### 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 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.
    - 4.1.5.1 Notifying the HSRO of any Determination of continuing non-compliance;
    - 4.1.5.2 Determination of unanticipated problem involving risk to subjects or others;
  - 4.1.6 The researcher (or sponsor on behalf of the researcher) is responsible for submitting subsequent 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.
  - 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 Associate Vice Provost for Human Subject Research 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 or Associate Vice Provost for Human Subject Research 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.



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## 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 (question #6).
  - 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. At this point,
  - 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 reassigned for internal review (Study Information page, question 6).
    - 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 Service 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 Researchers or their study teams are encouraged to submit the study to the external IRB upon receipt of the confirmation of eligibility and other documentation from the reviewing IRB, if applicable.
- 5.3 Authorized HSRO staff members will ensure the submission is complete and execute the Confirm External IRB activity if the following criteria are met:
  - 5.3.1 All applicable eProst SmartForm questions are answered.
  - 5.3.2 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 listed in questions 4 and 5 of the External IRB page of the SmartForm are consistent with the letter.
  - 5.3.3 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.
  - 5.3.4 All required Ancillary Committee approvals have been submitted via eProst.
- 5.4 If 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.



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- 5.4.1 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.
- 5.5 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.
  - 5.5.1 Upon approval, the researcher must use the Update Study Information activity to reflect any modifications and to ensure that any documents have been updated.
    - 5.5.1.1 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. Additionally, the researchers should update eProst and attach all applicable IRB forms and watermarked consents. This is done by selecting the “Update Study Information” activity in eProst. The External IRB approval letters should be uploaded in the “Update External IRB Status” activity.
    - 5.5.1.2 If the modification includes revisions to an already-approved document, use the Update button to upload the revised document over the previously approved version, as opposed to deleting the earlier version and adding a new version.
    - 5.5.1.3 If the modification includes new informed consent documents, advertising materials or data collection sheets that require finalization in eProst, use the Add button to upload the revised document and contact the individual listed as the IRB coordinator for that study in eProst for further processing.
- 5.6 Continuing review. The sponsor, investigator and external IRB are responsible for ensuring that continuing review is conducted in accordance with the federal regulations.
  - 5.6.1 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. This is done by selecting the “Update Study Information” activity in eProst. The External IRB approval letters should be uploaded in the “Update External IRB Status” activity.
  - 5.6.2 The PI or PI proxy must ensure that expiration dates are updated when the study is approved for continuation. This is done by selecting the “Update External IRB” activity in eProst.
  - 5.6.3 The PI or PI proxy must ensure study closure is reflected in eProst by selecting the “Update External IRB” activity in eProst and selecting “yes” to the question of whether the external IRB has closed 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

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