UNIVERSITY OF MIAMI

SOP: Reliance Pre-Review				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-803	12/10/2021	F. Conte	K. Viamonte	1 of 4

1 PURPOSE

1.1 The purpose of this process is to validate that a particular study meets the criteria either for this institution to serve as the IRB of record or for this institution to rely on an external IRB.

1.2 This process begins when a request to rely or cede oversight is submitted for pre-review.

1.3 This process ends when reliance on the external IRB is confirmed or this institution confirms it will assume oversight for external Participating Sites (pSite).

2 REVISIONS FROM PREVIOUS VERSION

2.1 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 POLICY

3.1 Any institution located in the United States that is engaged in federally-funded cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

3.2 An NIH funded study being conducted at more than one U.S. site involving non-exempt human subjects research may be subject to the NIH Single IRB policy and/or the revised Common Rule cooperative research provision (§46.114).

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

3.3.1 Exception 1 – Study has been authorized to use an external IRB by the Associate Director of the HSRO or designee.

3.3.2 Exception 2 –Research studies are eligible for review by the Florida Department of Health (DOH) IRB when required.

1.1.1.1

3.4 Studies utilizing the NCI CIRB may be submitted directly to NCI CIRB without first requesting reliance.

3.5 Before a UM investigator relying on an external IRB as the IRB of record can start a study, the following requirements must be met:

3.5.1 Verification of eligibility must be obtained via HSRO FORM: HRP-216 External IRB Reliance Application. Studies utilizing the NCI CIRB do not need to complete the HRP-216.

3.5.2 An executed authorization agreement covering the proposed research must be in place

3.5.3 The HSRO must review the study materials to ensure that all local requirements are met

3.5.4 Study personnel must comply with training and financial reporting requirements

3.5.5 Documentation for all required ancillary reviews must be submitted and the following ancillary reviews must be completed, when applicable:

3.5.5.1 Cancer Protocol Review Committee

3.5.5.2 Data Security Ancillary Committee

3.5.5.3 Radiation Safety

3.5.5.4 Institutional Biosafety Committee

3.5.5.5 Embryonic Stem Cell Oversight Committee

3.5.5.6 Conflict of Interest Committee Review

3.6 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 Director of the HSRO.

3.7 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 If the site is approved for submission to an external IRB, 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) <u>prior to starting any human subject research activities</u>.

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;

For reporting requirements and timeframes, please consult the HSRO investigator manual and the external IRB policy.

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.

4.1.9 If the site is approved for UM to serve as the reviewing IRB, obtaining all applicable institution/compliance reviews and approvals.

4.1.9.1 Notifying the HSRO of any non-compliance;

4.1.9.2 Notifying the HSRO of unanticipated problem involving risk to subjects or others; For reporting requirements and timeframes, please consult the HSRO investigator manual.

4.1.10 Comply with protocol, amendments, and recruitment procedures as applicable and approved by UM CIRB.

4.1.11 The researcher, coordinating center liaison (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 Coordinating Center Liaison: When a multisite study is submitted for UM to be the single IRB of record, a coordinating center liaison is required to manage submissions and correspondence between external sites and the HSRO / UM central IRB.

4.3 <u>Reviewing IRB:</u> When the study is approved for reliance (external IRB or UM CIRB), the reviewing IRB becomes the IRB of Record for the study and is responsible for the following:

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

4.3.2 Ensure that any site requirements identified on **FORM: External IRB Reliance Application & Cover Sheet (HRP-216)** or **FORM: External Site Application Questionnaire (HRP217 & 218)** are reflected in the approved informed consent documents.

4.3.2.1 Studies submitted for external IRB: 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.

4.3.3 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.

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

4.4 HSRO staff members authorized by the HSRO Director to manage the reliance process are responsible for the following:

If the submission is for external IRB review:

4.4.1 Verifying eligibility of a study to go to an external IRB via WORKSHEET: HRP-832 Consideration for Ceding IRB Review.

4.4.2 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)**.

4.4.3 Providing local context information sheet and ICF required language to external IRB

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

If the submission is for UM to be the reviewing IRB:

4.4.5 Verifying eligibility of a study to be reviewed by the UM Central IRB via WORKSHEET: HRP-833 Consideration for Serving as sIRB

4.4.6 Providing a signed confirmation that the study qualifies for submission to UM CIRB to the researcher via **FORM: External Site Application Questionnaire (HRP-217)**.

4.4.7 Review local context information sheet and ICF required language provided by the external site,

4.5 The Vice Provost for Research + Scholarship or the HSRO Director are responsible for the following:

4.5.1 Granting exceptions to the criteria for external IRB review.

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

5 PROCEDURE

5.1 If the item is a request for UM to rely on an external IRB, eresearchers 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.

If the item is a request for a participating site to rely on the UM IRB, researchers must submit the protocol in eProst for main study approval. Once the main study approved, the participating sites will be added.

5.2 If the item is a request for this IRB to review for another participating site, do the following:

5.2.1 Review FORM: HRP-217 and determine if the site qualifies for reliance on the UM IRB by using HRP-833 (considerations for serving as sIRB). If the site qualifies for reliance, sign the HRP-217 and return it to the UM PI or coordinating center liaison. A signed HRP-217 serves to inform the site that this institution is willing to serve as the IRB of record for the site. If not, inform the requestor that this IRB will not serve as the IRB of record for that site.

5.2.2

5.2.3

5.2.4 Identify the site.

5.2.5 Determine whether the site has an Institutional Profile

5.2.5.1 If not, determine whether or not you will execute an Authorization Agreement.

5.2.5.1.1 If so, follow “SOP: Establishing Authorization Agreements (HRP-801).”

5.2.6 Determine whether the site has an Authorization Agreement that covers the study activities.

5.2.6.1 If so, under the parent study (UM site record), create site by using the “Add participating sites” activity. “Submit invitation decision” andproceed with Pre-Review.

5.2.6.1.1.1 .

5.3 If the item is a request for this institution to rely on another IRB for review, do the following:
- 5.3.1 Identify the IRB.
- 5.3.2 Determine whether an existing Authorization Agreement covers the study activities.
  - 5.3.2.1 If so, proceed with Pre-Review.
  - 5.3.2.2 If not, determine whether or not you will execute an Authorization Agreement.
    - 5.3.2.2.1 If so, follow "SOP: Establishing Authorization Agreements (HRP-801)." Proceed with Pre-Review when the agreement has been executed.
    - 5.3.2.2.2 If not, inform the requestor that this institution will not rely on the other IRB.

6 MATERIALS

6.1 SOP: Establishing Authorization Agreements (HRP-801)
6.2 FORM: HRP-216 External IRB Reliance Application
6.3 FORM: HRP-217 External Site Application for UM IRB
6.4 FORM: HRP-218 Relying Site Information questionnaire
6.5 WORKSHEET: HRP-832 Considerations for Ceding IRB Review
6.6 WORKSHEET: HRP-833 Consideration for Serving as sIRB
6.7 FORM: UM Local Context Information
6.8 FORM: UM Required Consent Language

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