

Single IRB and Reliances

Introduction

Using UM IRB as a Reviewing IRB for a Multi-Site Study

Using an External IRB for Research Conducted at the UM

- Required Language for Consent Documents
- UM Local Context Information
- Institutional information
- Research Oversight
- Translation Requirements
- Ancillary Review Requirements
- State and Local Law

Introduction

Research sites and personnel who are not part of the University of Miami (UM) are not covered by the UM's IRB review unless the review is coordinated through the UM Human Subject Research Office (HSRO).

Likewise, if you are collaborating on a study that will involve an external central IRB, the UM HSRO must be involved in the coordination of the central IRB review.

In each instance:

- An agreement must be in place between the reviewing IRB and the relying institution that describes the roles and responsibilities of each organization; and
- The relying institution must cede the review to the reviewing IRB, in writing.

Obtaining reliance agreements can result in delays in IRB approval. During the initial collaboration discussions, investigators should find out if agreements are already in place or if institutions need to obtain a reliance agreement with the IRB chosen to oversee the study. Many academic institutions use the [Smart IRB](#) reliance agreement to meet this requirement. The UM HSRO has signed this agreement which allows the UM to review for or rely on any of the institutions that have also signed the agreement. When planning the collaboration, it is important to ask the collaborating sites if their institution is part of the Smart IRB agreement.

Most domestic, NIH funded multi-site human subject research must comply with the requirement for single IRB (sIRB) review of all participating sites. Starting in 2020, almost all domestic, multi-site, federally funded research will be required to comply with the requirement for sIRB review. The UM IRB may choose to serve as the reviewing IRB for the collaborating research sites (or single investigators) or may choose to rely on another IRB for such review.

Using UM IRB as a Reviewing IRB for a Multi-Site Study

It is the policy of the University of Miami that researchers submit studies for review by the UM IRBs whenever possible. Should sponsors require centralized review, study teams are asked to provide documentation to this effect and studies will be considered on a case-by-case basis.

When considering whether to use the UM IRB as the reviewing IRB, investigators should be aware that they will incur additional responsibilities. For example, the UM investigator or an established coordinating center will be responsible for coordinating the submissions from each site and submitting information into the UM HSRO's electronic system, ePROST. In addition, the UM investigator will be responsible for ensuring that participating sites receive IRB communications such as approval letters and approval documents and documents, unless another mechanism is used.

If you are interested in using the UM IRB to review a multi-site study or reviewing the research activities of a collaborating independent external investigator, you will need to complete an online [Reliance Questionnaire for Internal IRB Review \(HRP - 217\)](#). HSRO staff will review the completed form and determine whether the research qualifies for a reliance. Once this determination is made, the HSRO staff will contact you with a decision and provide instructions on how to proceed.

If the research qualifies for a reliance, the following actions will happen:

- HSRO staff will determine whether the UM HSRO has a reliance agreement in place with each of the relying sites and will follow-up with the sites if an agreement is needed.
- The UM site must submit the study through the UM HSRO's electronic system, ePROST
- The UM site or a coordinating center must complete a submission eProst.
- Each site must complete a [Relying Information Questionnaire \(HRP - 218\)](#).
- A Responsible Party from each site must sign a Cede Review Letter for the specific study and the letter must be uploaded into the site's submission in the eProst system.

Using an External IRB for Research Conducted at UM

If you are interested in obtaining review from an external IRB for research that will be conducted by a UM site, you will need to complete an online [Reliance Application for External IRB Review \(HRP - 216\)](#). HSRO staff will review the form and determine whether the research qualifies for a reliance. Once this determination is made, the HSRO staff will contact you with a response and provide further directions.

Please note: When an independent, commercial IRB completes the review, the HSRO charges a one-time \$1000 administrative fee for processing submissions for external review.

If the research qualifies for a reliance, the following actions must happen:

- HSRO staff will determine whether the UM HSRO has a reliance agreement in place and will follow-up with the reviewing institution if an agreement is needed.

- The HSRO staff will provide a signed Cede Review Letter to the reviewing IRB.
- Prior to conducting the review, the reviewing IRB may require information about the University of Miami's local context. [See below](#) for this information.
- The UM site must:
 - Submit the study through the HSRO's electronic system, eProst
 - Obtain all required ancillary reviews
 - Ensure documents are submitted to the reviewing IRB
 - Ensure the consent document includes language required by the UM HSRO ([see below](#))
 - Submit the following approved documents into eProst after the reviewing IRB has completed the review:
 - Protocol
 - Consent Document(s)
 - Recruitment Materials
 - Subject-facing documents
 - Refrain from starting the research until you receive acknowledgement from the UM HSRO
 - Refrain from starting the research until each step above is completed

During the course of the research, you need to submit to the following as a modification into UM HSRO's electronic system, eProst:

- Any document that needs to be uploaded into Velos
- Reports of non-compliance that could meet the UM's definition of serious or continuing non-compliance
- IRB suspensions or terminations of a study
- IRB determinations of unanticipated problems involving risks to subjects or other
- Study closures

Required Language for Consent Documents

The external IRB will probably approve one or more consent template documents for the study. You are responsible for adding language required by the University of Miami to the consent template. The IRB should then approve a consent document that includes the required language.

The following language must be included in the consent document, when appropriate:

If subjects are being compensated:

If you receive \$600 or more during a calendar year from the University for participating in research, you may receive a 1099 for tax reporting purposes. Reimbursements for travel and other expenses are not included in this amount.

If the research collects specimens:

The University of Miami may retain, preserve, or dispose of these specimens and may use these specimens for research, which may result in commercial applications. You will not receive money for donating blood, urine or tissue samples nor will you receive money from any future proceeds as a result of this research project.

Compensation for Injury Language:

[Non-Sponsored studies that involve greater than minimal risks:]

If you are hurt or get sick as a result of being in this study, treatment will be available in most cases. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages, and other damages caused by injury are not available. This policy does not prevent you from trying to obtain compensation through the legal system.

[Sponsored studies that involve greater than minimal risks:]

If you are hurt or get sick as a result of being in this study, treatment will in most cases be available. If you experience an injury as a result of the study drug or procedures, the Sponsor will cover the cost of treatment of these injuries. Funds to compensate for pain, expenses, lost wages, and other damages caused by injury are not available. This policy does not prevent you from trying to obtain compensation through the legal system.

[To be used if your study involves the use of a drug or device.] If you are hurt or get sick due to being in this study, treatment will be available in most cases. If you are hurt because of [Chose one: a correctly done study procedure or because you took the study medicine as you were instructed, OR. the device you received or because of a correctly done study procedure,] the Sponsor will pay for the cost of treating the injury. The University of Miami and the sponsor are not planning to pay for pain, lost wages, and other costs you incur because you were hurt. You do not give up any of your legal rights to obtain payment for an injury if you sign this consent document.

[Include the following, if applicable, otherwise delete.] If the Sponsor pays any of your medical expenses, we may be required to give the Sponsor your name, date of birth, and Medicare ID or Social Security number.

If one or more members of the research team has a reportable financial relationship:

[Study doctor] has disclosed that he/she has a personal interest related to this study. Please ask any questions to assure yourself that this relationship has not overly influenced the conduct of this research study. If you require further information, please contact the study doctor or the University of Miami Human Subject Research Office at 305-243-3195 to ask questions or discuss concerns.

Note: The language above is an example. If the Conflict of Interest Committee requires language that is different, that required language must be substituted for the above language.

If research information will be added to University of Miami Medical Record:

If you are, or have been, a patient at a University of Miami facility, you will have a University of Miami medical record. We use an electronic medical record system known as UChart, which improves access to information important to your medical care. UChart will show that you are in a research study and a copy of this signed consent form will be included. Some or all of your research information may be placed in UChart to provide as complete a record as possible. Included in this information are information about investigational drugs, devices, biologics, or anything else that may interfere with our clinical treatment or place you at greater risk of harm if used separately or together with other substances or activities. Including this information in the electronic medical record system is intended only to give information to caregivers providing treatment for you while you are on this study.

This information will be available to University of Miami doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you medical care, or who are otherwise allowed to access your information. The confidentiality of the results and other documents in UChart will be governed by laws, such as HIPAA, that concern medical records. We suggest that you tell any non-University of Miami doctors that you are in a research study and that more information may be made available to them at your request. The research team may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

If the study involves HIV, hepatitis B, or hepatitis C testing with subjects who have not already been diagnosed with those conditions:

As part of the study you will be tested for_____. Florida regulations require health care providers/laboratories to report new cases of HIV, AIDS, hepatitis infection, and some STDs to the county health department. If you test positive for _____, by law we have to report your personal identifiers such as name, sex, date of birth, address and phone number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be kept confidential to the extent permissible under the law. The health department may contact you with resources for counseling and medical care, if you need them and want them.

Include UM and/or JHS Footer if you are enrolling participants at clinical care facilities that are part of either of these systems

UM Local Context Information

Institution Information

The Miami community has a positive attitude toward the conduct of human subject research.

UM's Institutional Official (IO)

Responsible for identifying, managing, and reporting potential unanticipated problems involving risks to subjects or others and/or serious or continuing noncompliance:

John L. Bixby, Ph.D
Vice Provost for Research
Phone number: 305-243-9635
Email address: jbixby@miami.edu

Local Context Representative (Primary Contact)

Evelyne Bitai, MA, CIP
Associate Director
Phone number: (305) 243-9977
Email address: ebital@med.miami.edu

Research Oversight

The Institutional Official (IO) is responsible for the oversight of the conduct of research at University of Miami to ensure the safe and appropriate performance of the research and at all Component and Affiliate Institutions, including:

- Ensuring the initial and ongoing qualifications of investigators and research staff.
- Overseeing the conduct of the research: The IO, supported by the Human Subject Research Office and the Office of Research Compliance and Quality Assurance, is charged with overseeing all research at the University of Miami.
- Monitoring protocol compliance: The Office of Research Compliance and Quality Assurance conducts both routine and for-cause audits. Any study can be selected for auditing, including studies that rely on external IRBs. Note: The Clinical Research Operations and Regulatory Support Office conducts study monitoring of clinical investigations involving an investigator held IND or IDE.
- Serious or Continuing Noncompliance: Under the direction of the IO, the Compliance Review Committee is charged with reviewing any complaints, reports or allegation involving federally regulated research that may rise to the level of serious and/or continuing noncompliance. Refer to HRP-024 SOP: New Information and HRP-027 SOP: Serious or

Continuing Noncompliance for details on how the IO identifies and manages serious or continuing noncompliance.

- Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO): the IRB reviews reports of new information and considers whether the information meets the regulatory criteria for a UPIRTSO. See HRP-024 SOP: new Information for additional information.
- Maintaining compliance with state, local, or institutional requirements related to the protection of human subjects: The University of Miami Investigator Manual incorporates all local and state requirements related to the protection of human subjects. The Human Subject Research Office serves as a liaison between the University research community as well as a resource to answer any questions related to such local requirements.
- Providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research: Anyone who wishes to make an anonymous report — via the web or by telephone — can use 'CaneWatch to report concerns related to violations of policies and procedures, rules and regulations, or other irregularities/improprieties. The Human Subject Research Office also receives and responds to complaints or inquiries received regarding research conducted at or by the University of Miami or Jackson Health System.

Translation Requirements for Informed Consent Document

Informed consent documents should be presented to prospective subjects in a manner and language that they can understand. The same is true for other research related documents such as interviews or surveys. Every effort should be made to express a scientific concept/idea in lay terms at an approximate 8th grade reading and comprehension level.

If a potential subject cannot read English

- **But can read another language** – Written consent should be obtained in the language the subject can read
- **But can fully understand spoken English**
 - Read the English version of the written consent document to the subject
 - Answer the subject's questions
 - Perform "[Teach-Back](#)" to assess the subject's understanding
 - Document the subject's ability to understand English
 - Ensure a witness observes the signatures of the subject and the person who obtains consent
 - Obtain the signature of the witness
- **And cannot read any other language and does not understand spoken English**
 - Ensure a translator reads to the subject a consent form that has been translated into a language the subject understands
 - Use the translator to answer the subject's questions

- Perform “[Teach-Back](#)” to assess the subject’s understanding
- Document the subject’s ability to understand the alternate language
- Ensure a witness observes the signatures of the subject and the person who obtains consent
- Obtain the signature of the witness

Translations Requirements

Due to the diverse culture of the Miami area, the following language translations are routinely provided:

- Spanish
- Haitian Creole
- Portuguese

For studies involving an IND or IDE, translations must be:

- Performed by a certified translator approved to conduct such business at the UM
- Accompanied by a signed translator certification statement that includes the date of translation

For studies that do not involve an IND or IDE translations may be shown to be correct with a “back translation”

Required Ancillary Reviews

Financial Conflicts of Interest

University of Miami gathers and evaluates Principal Investigator and research staff financial interests that are related to proposed or ongoing research. The Conflict of Interest Committee evaluates the reported interest and communicates the results of the review to the HSRO.

Protocol Review and Monitoring Committee (PRMC)

Required for all cancer related studies

Radiation Materials – Radiation Safety (HRSC)

Required for protocols where radiation/radioactive materials or radiation producing devices are being used for research purposes and not simply as the standard of care.

Recombinant DNA Materials – Institutional BioSafety Committee (IBC)

Studies involving recombinant DNA (rDNA) must be approved by a BioSafety Committee (IBC) prior to receipt of IRB approval.

Embryonic Stem Cell Oversight Committee (ESCRO)

Required for research involving human embryonic stem cells and/or their derivatives prior to receipt of IRB approval.

Office of Environmental Health and Safety (Biosafety Officer)

Required for research involving infectious or potentially infectious biological

agents prior to receipt of IRB approval. Approval must be obtained for studies involving Biosafety Level 2 (BSL2) and higher agents.

Clinical Research Operations and Regulatory Support (CRORS)

Required for new studies involving an investigator-held IND or IDE and for amendments to studies involving an investigator-held IND or IDE.

Clinical Translational Research Site (formerly Clinical Research Center)

Required for research involving the use of aUM Clinical Translational Research Site (CTRS) facilities prior to receipt of IRB approval.

Jackson Health System – Clinical Research Review Committee (CRRC)

Required before any research activities can be conducted at a JHS facility, any JHS resources can be used or JHS patient information can be accessed for research purposes.

University of Miami Hospital (UMH) Research Review Committee

Required before any research activities occurring at or using resources at the University of Miami Hospital.

State and Local Law

Age of majority – 18 years of age. Under Florida law, parental permission must be obtained before individuals under 18 years of age can participate in human subject research. This means the IRB cannot waive the requirement for parental permission unless the child is emancipated. Only the following categories of individuals are considered emancipated and may consent to participate in human subject research when they are under 18 years of age:

- Individuals who have been emancipated by a Circuit Court
- Individuals who are married or have previously been married
- An unwed pregnant woman may consent to research relating to her pregnancy but may not consent to research involving herself or her child after delivery

Foster Children – Parents retain the right to consent to their child's participation in research. Any researchers considering research with this vulnerable population should consult with the Florida Department of Health for more specific guidance.

Research on Fetuses – Florida law prohibits research on any live fetus or premature infant before or after delivery or termination of pregnancy except as necessary to protect the life and health of the fetus or premature infant.

Genetic Testing – Informed consent must always be obtained prior to DNA testing.

Sexually Transmitted Diseases – Positive tests results of the following sexually transmitted diseases must be reported to health authorities:

- HIV
- AIDS
- Chancroid
- Chlamydia
- Gonorrhea
- Granuloma Inguinale
- Hepatitis A
- Hepatitis B
- Lymphogranuloma Venereum (Venereal Disease)
- Syphilis

HIV Testing – Specific consent for HIV testing must be obtained. The University of Miami template consent includes the required language.

When the Adult Subject Cannot Consent - Florida recognizes that the following individuals (in order presented) may consent to the enrollment of an individual in medical research that has been approved by an IRB:

- A competent adult surrogate designated by the research participant in writing to make health care decisions on behalf of the participant
- In the absence of a designated surrogate, a Court Appointed Guardian
- A person holding a valid power of attorney (durable POA) which contains language in which the potential participant gives the surrogate the right to make health care decisions
- In the absence of a surrogate, Court Appointed Guardian or POA, one of the following:
 - Spouse
 - Adult child (or a majority of the adult siblings who are reasonably available for consultation)
 - Parent
 - Adult sibling (or a majority of the adult siblings who are reasonably available for consultation)

The decision must be based on what the proxy reasonably believes the patient would have made under the circumstances. If there is no indication of what the patient would have chosen, the proxy may consider the patient's best interest in deciding that proposed treatments are to be withheld or that treatments currently in effect are to be withdrawn.

Note: That above information is offered for informal guidance purposes only, and should not be considered as legal advice on a particular matter.