**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:

Maria L Alcaide, M.D. Vice Provost for Research and Scholarship

Phone number: 305-243-8434

Email address: malcaide@miami.edu

Local Context Representative (Primary Contact)

Evelyne Bital, MA, CIP

Associate Director, Regulatory Affairs and Reliance

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 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 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 that may rise to the level of serious and/or continuing noncompliance. Refer to HRP-024 SOP: New Information and the Investigator manual 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 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”](https://www.ahrq.gov/professionals/quality-patient-safety/patient-family-engagement/pfeprimarycare/interventions/teach-back.html) 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”](https://www.ahrq.gov/professionals/quality-patient-safety/patient-family-engagement/pfeprimarycare/interventions/teach-back.html) 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”

**Consent to Contact as Method of Recruitment**

The University of Miami allows use of the consent to contact process for recruitment.

Investigators can submit a request to obtain a list of potential participants from the University’s Data Brokers and use the Consent to Contact initiative to contact the patients in the list. Investigators must:

• Include information about using Consent to Contact for recruitment in the protocol;

• Scientifically justify the use of this initiative as a method of recruitment;

• Submit the approved Consent to Contact script edited for the study along with the

 screening questions that will be asked during the phone call; and

• Provide the information needed to obtain a waiver of authorization from the IRB written

 confirmation included in the protocol.

**Required Ancillary Reviews**

<https://hsro.uresearch.miami.edu/researchers/how-to-submit-to-the-irb/ancillary-committees/index.html>

**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 before the individual can participate may 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
	+ Individuals who are married or have 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
* (AIDS)- Acquired Immune Deficiency Syndrome
* Chancroid
* Chlamydia
* Gonorrhea
* Granuloma Inguinale
* Hepatitis A
* Hepatitis B
* HIV -Human Immunodeficiency Virus
* Lymphogranuloma Venereum (Venereal Disease)
* Syphilis

HIV Testing – The University of Miami consent template 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 person 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.*