



Investigator Manual

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Chapter 1 General Information	5
1.1 Purpose of this manual	5
1.2 What is Human Research	5
1.3 What is the Human Research Protection Program	7
1.4 PI Eligibility Requirements	7
Chapter 2 Training and Disclosure Requirements	9
2.1 Training Requirements for Investigators and Research Staff	9
2.2 Financial Relationship Disclosure and Training Requirements	12
Chapter 3 Submitting to the IRB	15
3.1 New Human Subject Research	15
3.2 Modifications	12
3.3 Continuing Review Reports	16
3.4 Closing a Study	18
3.5 PI Departure from the University of Miami	18
3.6 Writing an Investigator Protocol	19
3.7 Ancillary Review Requirements	20
3.8 Finding Determination Letters and Approved Documents	21

Chapter 4 Reliance and Cooperative Agreements for IRB Oversight	22
4.1 Requesting an External IRB	22
4.2 Obligations of Investigators When Relying on an External IRB	25
4.3 Requesting UM IRB to serve as the IRB for an External Site	26
4.4 Obligations of a Lead PI for a Multi-Site study reviewed by UM IRB	28
Chapter 5 IRB Review of Human Subject Research	29
5.1 Levels of IRB review (Exempt, Expedited Review, Committee Review)	29
5.2 Criteria for Approval	30
5.3 IRB Determinations	31
Chapter 6 Recruiting and Screening Study Subjects	34
6.1 Basic Principles of Recruitment	34
6.2 Identifying Potential Subjects	36
6.3 Recruitment Plan and Materials	39
6.4 Screening Subjects	40
6.5 Participant Payment	41
Chapter 7 Obtaining and Documenting Informed Consent and Assent	42
7.1 Categories of Consent/Assent Processes and Documents	43
7.2 Consent Templates	45
7.3 Elements of Consent	46
7.4 Making a consent Document Readable	46
7.5 Translation Requirements for Consent Documents	49
7.6 Documenting Consent Using a Full Consent Document	50
7.7 Documenting Consent with the Short Form	50

7.8	<u>Obtaining Consent Remotely</u>	52
7.9	<u>Obtaining Parental Permission</u>	55
7.10	<u>Obtaining and Documenting Assent</u>	56
7.11	<u>Deception or Incomplete Disclosure</u>	58
7.12	<u>Re-Consent or Notification of Subjects About Significant New Findings after study approval</u>	60
Chapter 8 Required IRB Reports		62
8.1	<u>Reports of New or Increased Risk (Submit within ten business days)</u>	62
8.2	<u>Reports of External Serious Adverse Events/IND Safety Letters</u>	63
8.3	<u>Reports of Non-Compliance (Submit within ten business days of knowledge)</u>	64
8.4	<u>Protocol Deviations/ Violations</u>	64
8.5	<u>Other Required Reports (Submit within ten (10) business days of knowledge)</u>	65
Chapter 9 Investigator Responsibilities		67
9.1	<u>General Responsibilities</u>	67
9.2	<u>Additional Responsibilities for FDA-Regulated Studies</u>	68
9.3	<u>ICH Guideline for Good Clinical Practice E6(R2)</u>	71
9.4	<u>Issues to Consider when a subject Withdraws from a Study</u>	72
9.5	<u>Maintaining Research Records</u>	73
9.6	<u>Conducting Research Outside of the United States</u>	74
9.7	<u>NIH Genomic Data Sharing Policy Requirements</u>	75
Chapter 10 Privacy and Confidentiality		77
10.1	<u>HIPAA Privacy and Security Rules</u>	79
10.2	<u>Federal Educational Records Privacy Act (FERPA)</u>	81

10.3	Certificates of Confidentiality (CoC)	82
10.4	General Data Privacy Rule (GDPR)	83
10.5	Florida Protecting DNA Privacy Act." (760.40, F.S.) and Research	84
10.6	Secondary Subjects in Research	86
Chapter 11	Emergency/Treatment Use of an Unapproved Drug, Biologic, or Device	87
11.1	Emergency Use of an Investigational Drug, Biologic or Device	87
11.2	Exception to Informed Consent Requirement for Emergency Use	88
11.3	Treatment (Compassionate) Use	89
11.4	Right to Try	89
11.5	Humanitarian Use Device (HUD)	90
Chapter 12	Requirements for Federally Funded Research	91
12.1	Department of Defense (DOD)	91
12.2	Department of Energy (DOE)	92
12.3	Department of Justice (DOJ) and Bureau of Prisons	92
12.4	Department of Education	95
12.5	Environmental Protection Agency (EPA)	95
Chapter 13	HSRO Resources and Contact Information	97
Chapter 14	Obtaining Additional Information	98

Please note: Guidance and regulations are subject to change.

Chapter 1: General Information

1.1 Purpose of this manual

This document, “INVESTIGATOR MANUAL (HRP-103),” will help you work with the IRB and the Human Subject Research Office (HSRO) and collaborative offices that provide oversight to Human Subjects Research within the Office of the Vice Provost for Research + Scholarship (OVPRS). It will also guide you through policies and procedures related to the conduct of Human Research that are specific to this institution.

University of Miami Investigators must read and understand the information in this manual before conducting human subject research.

1.2 What is Human Research?

The definition of “human subject research” depends upon whether and how the research is regulated. For federally funded research, and research overseen by the University of Miami’s IRB, the meaning comes from the Common Rule.

When conducting a clinical investigation under Food and Drug Administration (FDA) jurisdiction, the definition comes from the FDA regulations. FDA defines a test article as any drug (including a biological product) for human use, medical device for human use, human food additive, color, adaptive, electronic product, or any other article subject to regulation under the jurisdiction of the FDA.

FDA Definition of Human Subject
“The recipient of the test article or the control.”

A “living individual” means that human subjects research involving decedents is not covered under the Common Rule. Decedents are still covered by HIPAA's Privacy Rule. Research that includes both decedents and living subjects must be reviewed by the IRB. If the research only pertains to decedents, then the investigator does not need IRB approval but must submit a HIPAA attestation to the IRB prior to conducting the research.

Here are two tools you can use to see if your project is Human Subject Research.

1. Complete “[WORKSHEET: Human Research \(HRP-310\)](#)” on the HSRO website; or
2. Complete an [online survey](#) to determine whether an activity meets either the DHHS or FDA definition of Human Research.

In questionable cases, the IRB ultimately determines whether an activity is Human Research requiring IRB oversight. If your project is determined to be Not Human Subjects Research, you may print the report from the online survey as documentation of this determination. If you plan to publish the results of your project or prefer official documentation from the IRB, you can submit the online survey report

along with a description of the project (abstract) to the Human Subject Research Office. The HSRO will provide you a written documented opinion. You must not conduct Human Subject Research without obtaining IRB review and approval or a confirmation of exemption of Human Research. If a determination has been made that a project is Not Human Subjects Research through the two tools above, without consultation from the IRB, publications must not claim the project was IRB approved.

- Class projects (individual or group) that are designed for **pedagogical** purposes only. That is, the primary purpose of the activity is skill development. The audience for the results of the activity is the other students and the instructor. IRB review is **not** required.
- Class projects (individual or group) that undertaken as both an educational experience AND as research. IRB review **is** required.
- A student-led classroom project that the instructor may use in his or her own research. IRB review **is** required.

Do Case Reports need to be submitted to the IRB?

A case report is a detailed report of the diagnosis, treatment, response to treatment, and follow-up after treatment of an individual patient. A case series is group of case reports involving patients who were given similar treatment. Case reports and case series usually contain demographic information about the patient(s), for example, age, gender, ethnic origin.

When information on more than **three** patients is included, the case series is a systematic investigation designed to contribute to generalizable knowledge (i.e., research), and therefore submission is required to the IRB.

Under HIPAA, a case report is an activity to develop information to be shared for medical/educational purposes. Although the use of protected health information to prepare the paper does not require IRB review, the author of a case report must comply with HIPAA. Ideally, the author of the article will obtain the signed authorization of the subject, or the subject's legally authorized representative if the subject is deceased, to use the subject's information in the article. If it is not possible to obtain authorization, the author should be aware that one of the identifiers described by HIPAA as requiring written authorization is, "Any other unique identifying number, characteristic, or code...." Moreover, HIPAA requires that, at the time of publication, "[t]he covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information."

For further guidance regarding this topic, please contact the HSRO.

The University of Miami HSRO requires investigators to obtain IRB approval before conducting human subject research.

1.3 What is the Human Research Protection Program

The document “HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)” describes this institution’s overall plan to protect subjects in Human Research. The components of this document include:

- The mission of the Human Research Protection Program;
- The ethical principles that the institution follows when conducting Human Research;
- The applicable laws that govern Human Research;
- When the institution becomes “engaged in Human Research” and when someone is acting as an agent of the institution when conducting Human Research;
- The types of Human Research that the University of Miami does not permit; and
- The roles and responsibilities of individuals within the institution.

Protecting human research subjects is the responsibility of everyone involved in the research. The principal investigator (PI) is ultimately responsible for protecting subjects’ rights and safety. This statement is true, even though the IRB oversees the research.

1.4 Who is eligible to be a Principal Investigator

Every research study requires a Principal Investigator (PI). This person takes full responsibility for the conduct of the study.

**Only one individual can serve as Principal Investigator
for a human subject research project**

The PI has ultimate responsibility for the conduct of the research, including compliance with the research project’s activities, administration, fiscal, and scientific requirements. The PI is also responsible for reading and understanding all IRB letters and HSRO acknowledgment notices, when applicable.

The HSRO will address all official IRB correspondence to the Principal Investigator through the HSRO’s electronic system.

Jackson Health System (JHS) employees who obtain approval from the JHS Clinical Research Review Committee (CRRC) may also serve as Principal Investigators on studies.

Registered Nurses with a BSN may serve as a PI if they comply with the following conditions:

1. The Evidence-Based Practice Council has reviewed and approved the research and follow the study until completion;
2. The PI has completed an HSRO-led training on the Institutional Requirements in addition to the training requirements outlined below;
3. The research proposal includes an experienced researcher as a sub-investigator who will mentor the nurse researcher throughout the research.

Nurses should access [Resources for Nurse Researchers](#) for more information. Below is a comprehensive list of who may and may not serve as PI.

PI Eligible	Case-by-Case Decisions	Not PI Eligible
<ul style="list-style-type: none"> • Tenure-track faculty (full, associate, and assistant professors); and • Non-tenure-track research and clinical faculty (lecturers, full, associate, and assistant professors); • Senior research investigators (Faculty with emeritus status or who are tenured and retired but wish to continue as PI) • The University of Miami BSN or above-prepared Nurses (see specific requirements above) • Jackson employees who are conducting research at Jackson. 	<ul style="list-style-type: none"> • Adjunct faculty • Visiting faculty • Visiting scholars. <p><i>Contact a manager for the Vice Provost for Research + Scholarship or the Associate Vice Provost, Regulatory Affairs and Assessment via email to request permission for such non-PI eligible UM affiliates to conduct research. Please include a letter of support from your Department Chair/Division Chief and, if applicable, IRB Chair decisions/ opinions. Upon approval, upload the confirmation email into the "Other Attachments" section in your electronic submission.</i></p>	<ul style="list-style-type: none"> • Postdoctoral fellows and research assistants (graduate students); • Research associates; and • Graduate and Undergraduate students

Chapter 2

Training and Disclosure Requirements

2.1 Training requirements for investigators and research staff

This section describes the training requirements imposed by the HSRO. You may have additional training required by other federal, state, or institutional policies. A comprehensive table of training requirements is located at the end of this chapter. Personnel who should be listed on the protocol are personnel **engaged** in human subjects research conducting:

- Actively pre-screening (reviewing medical records, obtaining data)
- Consenting participants
- Obtaining data through intervention or interaction (unless it is a commercial agent under certain circumstances)
- Working with Private Identifiable Information

More Information on engagement can be found at [Engagement in Human Subject Research and HRP-101: Human Research Protection Program Plan](#).

Investigators are responsible for ensuring all study team members have completed training *before* submitting an application to the IRB.

University of Miami Training Requirements

The HSRO uses an electronic platform, IBISResearch, for IRB submissions and maintains access the site, Please visit ibis-research.miami.edu/IRB.

- UM Employees and Student Workers are automatically granted access to the Research Suite and can login via Single Sign On (SSO).
- If you are a Vendor, Student, or other Non-UM Employee and have not been given access to our systems previously, please register for a CaneID and then complete the Research Suite Account Access Request form.
- The Research Suite Account Access Request form includes a ‘Submit to OVPRS Help Desk’ button that will automatically draft a new email addressed to OVPRShelpdesk@miami.edu with the completed form attached. Please make sure you hit Send.

More information and FAQs can be found on the HSRO website at:
<https://hsro.uresearch.miami.edu/researchers/irb-system-upgrade/index.html>

You will need to complete training courses on IBISResearch based on your user role. Note: Completing Collaborative Institutional Training Initiative (CITI) Program certification (see below) does not equate to having an IBISResearch account; these are two separate databases.

The HSRO is not reviewing for completed CITI certification courses. By submitting an application in IBISResearch, the PI is attesting to the following:

- *The PI will ensure that all personnel engaged in human subject research for this study completes the required training per HRP-103 – Investigator Manual and that his/ her annual UDisclose System disclosure has been completed and all conflict of interest (COI) concerns are cleared prior personnel initiating human subject research activities (more information on COI requirements can be found in Section 2.2).*
- *The PI will keep a delegation of tasks log (when applicable) that will include the applicable training records and disclosure status of all personnel. This log must be kept up to date and available for inspection purposes by any entity overseeing the research.*
- *The PI will immediately report confirmed COIs, per the University’s Conflict of Interest, Conflict of Commitment, Foreign Influence, and Institutional Conflict of Interest Policy (more information on COI can be found in Section 2.2), to the IRB and await approval before the conflicted individual continues to or initiates human subject research activities.*

Basic Courses in Human Subject Research Training

All personnel involved in human subject research must complete human subject research training before engaging in human subject research activities. The HSRO refers to this requirement as becoming “CITI-Certified” because most courses are on the [CITI](#) website.

Research team members listed in the IBISResearch application must complete the required training **before** applying for a new study to the IRB for review. New research team members must complete the training before engaging in research activities, including accessing and analyzing private identifiable data. For most of the training, researchers must recertify every three years for by taking the CITI Program refresher courses for the Groups discussed above. Failure to maintain certification is noncompliance with institutional requirements for conducting human subject research.

CITI offers the following basic courses:

Group 1

Human Subjects Research (HSR)
Series for Biomedical Researchers -
Required for all personnel involved
primarily in biomedical research or
conducting both biomedical and
social/behavioral research.

Group 2

HSR Series for Social-Behavioral-
Educational Researchers Basic Course
- Required for all personnel involved
primarily in social and behavioral
research.

Trainees should select the courses most applicable to the types of human subject research conducted at their site.

Community Involvement in Research Training Program - Basic Training for Community Partners

In some instances, the research team partners with community health workers or other community members who cannot access the CITI training programs or who require a different kind of training. The HSRO offers research training through the [Community Involvement in Research Training Program](#).

Community Involvement in Research Training Program

Introduces learners to the basics of research, including terminology, people, and methods. It also reviews the history of research abuses that led to our current ethical principles, guidelines, and regulations.

Training for Clinical Trials

In addition to the above courses, investigators and research team members conducting a clinical trial must complete Good Clinical Practice (GCP) training, which is a regulatory requirement for all investigators and research team members conducting clinical trials, regardless of funding. This training requirement also applies to funded *social-behavioral clinical trials as well*.

CLINICAL TRIAL DEFINITION:

A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. (HRP-001: SOP: Definitions)

GCP training

The NIH requires GCP training for biomedical and social-behavioral NIH-funded clinical trials. The CITI training listed below meets the University's and NIH's requirements. GCP training consists of basic and refresher courses provided by CITI tailored to different types of research, including:

GCP for Clinical Trials

Focuses on FDA requirement for clinical trials involving investigational drugs, biologics *and* medical devices.

GCP for Clinical Trials with Investigational Drugs and Biologics

This training does not include requirements for device studies and includes information about the requirements for ICH-GCP.

GCP for Clinical Trials involving Medical Devices

Focuses on FDA requirements for clinical trials involving medical devices.

GCP for Social and Behavioral Research

Focuses on issues investigators face when conducting Social and Behavioral Research.

Trainees should select the courses most applicable to the categories of human subject research conducted at their site.

Technical Issues

For help with technical concerns about your CITI training and account, including transferring completion reports from other sites, contact [CITI](#) or the CITI Help Desk at 888.529.5929. For further questions or concerns regarding the University of Miami policies about proper certification, please contact the Human Subjects Research Office at 305-243-3195 or email our Help desk at hsro@miami.edu.

Training on Conflicts of Interest

Investigators and research team members, including external members who rely on the UM Disclosures & Scholarly Activities Management (DSAM)/ COI Committee (COIC) to review their disclosures, must complete conflict of interest training when joining the UM and prior to engaging in scholarly and/or educational activities. The training focuses on UM's policy and the federal policies that apply to research and externally funded scholarly activities performed at UM.

Training is required:

- Annually;
- Within thirty (30) days of when the University revises its COI policies or procedures in any manner that affects the requirements of University Investigators;
- An investigator is new to the University;
- As required by the University including when an investigator is found non-compliant with conflict policies and procedures or their COI Management Plan.

The HSRO is not reviewing COI training certifications. As part of the IBISResearch submission application, the PI is attesting that COI training certifications of all staff are complete.

For UM personnel, training is administered on the Instructions and Policies page of the team member's Disclosure Profile (DP) in the UDisclose System (<https://UDisclose.miami.edu/>). More information on the step-by-step process may be found at [UDisclose Training Resources](#) (UM single sign-on required). Submission of their DP indicates that the team member has completed the training.

Investigators are responsible for ensuring all study team members have submitted financial disclosure information and completed training before applying to the IRB.

Training on Bio-Safety

Before conducting research involving biological materials, investigators and research team members must complete the University's Environmental Health and Safety Office's training. Review the [Bio-Safety Training Page](#) to learn about the training requirements. The training is available on [ULearn](#) and [Blackboard](#).

2.2 Financial Disclosure

Investigators and key personnel ("Covered Persons"), including external research who rely on the DSAM/COIC to review their financial disclosures, must comply with the Conflict of Interest, Conflict

of Commitment, Foreign Influence, and Institutional Conflict of Interest Policy. This policy was approved by the UM Faculty Senate and Board of Trustees that addresses institutional vulnerabilities with attention to Conflict of Interest and Foreign Influence. You can find additional information on the Disclosures & Scholarly Activities Management (DSAM) website pages.

UM's policy requires that all investigators who participate on human subject research will disclose to participants any relationship he/she/they have to the study (e.g., any relationship with a non-University entity involved in the study, consulting for the sponsor or for the manufacturer of a drug/device used in a study, intellectual property related to the study), *irrespective of receipt of compensation*. The method of disclosure of the interest to study participants is at the purview of the IRB.

If the UM COI Committee determines that a team member's interest is a COI, DSAM and the Committee work with the investigator to develop a COI Management Plan. DSAM shares information about the interest and the COI Management Plan with the IRB. The IRB will then review the research and the information provided by DSAM to determine whether risks to subjects continue to be minimized and are reasonable when compared to anticipated benefits to the participants or others.

For non-UM personnel, the training is administered via email when the team member completes an Interest Disclosure Form (IDF). The IDF must be returned, reviewed, and cleared prior to the non-UM team member participating in the research.

Investigators can check the disclosure (and thus training) status of team members on the "COI" tab in the IBISResearch protocol workspace. Additional information can be found the IRB Researcher Quick Reference Guide.

PIs must ensure that their COI Management Plan is adhered and any supporting documents that require disclosure (i.e. protocol, consent forms and/ or other materials in the management plan highlighted) are updated.

For any ***technical issues*** with the UDisclose System, please contact the Office of the Vice Provost for Research + Scholarship (OVPRS): 305-243-2314 or OVPRShelpdesk@miami.edu.

For questions about the ***policy and what needs to be disclosed***, please contact the UDisclose helpline: 305-243-0877 or DSAM@miami.edu.

Comprehensive Table of Training Requirements for Researchers

Training &	Description	Who Must Complete It
Group 1 CITI Training (Every 3 years)	HSR Series for Biomedical Researchers	Researchers involved primarily in biomedical research or conduct both biomedical <i>and</i> social/behavioral research
Group 2 CITI Training (Every 3 years)	HSR Series for Social-Behavioral-Educational Researchers Basic Course	Researchers involved primarily in social and behavioral research

Community Involvement in Research Training Program (Every 3 years)	Covers the research basics, including terminology, people, and methods, the history of research abuses that led to our current ethical principles, guidelines, and regulations	Community Partners such as Community Health Workers who partner with University Investigators
CITI GCP for Clinical Trials (Every 3 years)	Focuses on FDA requirements for clinical trials involving investigational drugs, biologics, vaccines and medical devices	Researchers who participate in research involving all forms of FDA-regulated products.
CITI GCP for Clinical Trials with Investigational Drugs and Biologics (Every 3 years)	Focuses on FDA regulations and ICH-GCP for studies on investigational drugs, biologics and vaccines – but does not cover the requirements for medical devices	Researchers who participate in studies involving drugs, biologics and vaccines but not medical devices
CITI GCP for Clinical Trials involving Medical Devices (Every 3 years)	Focuses on FDA requirements for clinical trials involving medical devices	Researchers who participate on medical device studies but not drug studies
CITI GCP for Social and Behavioral Research (Every 3 years)	Focuses on issues investigators face when conducting Social and Behavioral Research	Researchers who conduct clinical trials but do not conduct trials involving FDA-regulated products.
Conflict of Interest Training in the UDisclose System (Annually)	Focuses on UM's policy and federal policies that apply to research and externally funded scholarly activities performed at UM * <u>Disclosure</u> (not training) is required at least annually or updated, as applicable.	Investigators and research team members, including external members who rely on the UM DSAM /COIC
Bio-Safety Training	University of Miami's Environmental Health and Safety Office's training. Review the Bio-Safety Training Page to learn about the training requirements. The training is available on ULearn and Blackboard .	All researchers conducting research involving biological materials

Chapter 3

Submitting to the IRB

3.1 Submitting New Human Subject Research

A condensed summary of how to submit research to the HSRO can be found at on the [HSRO Website](#). Guides and videos on the application process may be found on the [IBISResearch Library link](#). Before submitting a research protocol for review, PIs must:

- Ensure all research team members have completed required human subject research applicable trainings.
- Ensure each staff member disclose financial interests, even if not applicable, and enter the information in the [UDisclose](#) system.
- Train research team members on the protocol and the procedures you will delegate to them.

You must submit new research modifications to approved research and reportable events to the IRB through the HSRO's electronic system, [IBISResearch](#).

As you complete the IBISResearch form, you will need to upload documents (protocol, consent document, etc.) in the indicated sections throughout the IBISResearch form, as applicable for your study. IBISResearch is a Smart Form that will only open sections based on a branching system from applicable responses. When you complete these tasks, the PI must review the submission and **click the "Submit" button** after ensuring it is correct. **If your study appears in a "Pre-Submission" state in the system, it has not been submitted to the HSRO and cannot be processed.** It is recommended that you maintain a folder of electronic copies of all information submitted to the IRB so you can use the original versions to document modifications.

3.2 Submitting Changes/ Modifications after a study is approved

Complete the Modification Smart Form in IBISResearch and attach all requested documents. **When revising previously approved documents, use the Track Changes feature in Microsoft Word** to highlight the revisions. When submitting a modified protocol, complete the following steps:

- Document the study status to help the IRB note if the study is open to enrollment and if participants are enrolled. See Section 7.12 for recommendations on reporting new information.
- Provide a summary of all changes and reasons for the changes on the electronic Smart Form (Modification Information Q#3). This allows the IRB to identify the change(s) and the reasons for the revision(s).
- Include a WORD tracked changes version of the protocol. This word track changes version of the protocol **replaces** the old version of the protocol. Do not delete the old version and add a new version.
- The PI must consider whether the modification impacts updating the Informed Consent Form. If the consent document is revised, include a WORD tracked changes version of the consent document. Do not delete the old version and add a new version.

Revising Research Documents

- **Save the last changes** of the revised documents before you add any new changes. This allows **only new changes** appear as "tracked."
- Ensure consistency of the revisions to the Modification Smart Form in IBISResearch.
- It is unnecessary to provide a clean version of the revised documents AND a WORD track changes version.

The PI must review the submission and click the “Submit” button after ensuring it is correct. A “how to” create and submit a modification, may be found on the [IRB Researchers Quick Reference](#).

If the modification includes an update to study personnel, you must ensure that all new personnel are CITI-certified and have made the appropriate disclosures in the [UDisclose system before submitting the modification](#).

Please note that research must continue to be conducted without inclusion of the modification until IRB approval is received unless a subject safety is pertinent.

Reconsenting (more information can be found in Section 7.12):

The PI has the responsibility to ensure participants (whether active or off-treatment) in human subjects research are informed about new information. Subjects must be informed of the changes, asked if they wish to continue to participate, and signify their willingness as indicated by the IRB. Changes can also be documented in an addendum to the informed consent document should the study team choose to not amend the previous consent. If you have a question regarding whether subjects should re consent, contact the HSRO.

3.3 Submitting Continuing Review Reports

The IRB is required to review and approve most research projects at intervals appropriate to the degree of risk. This is called “continuing review.” The 2018 Common Rule revised the requirements for Continuing Review, eliminating it for some studies unless the IRB reviewer or IRB determined the study does require continuing review. If your study requires continuing review, your initial and any subsequent modification approval letter(s) will include an expiration date. The IBISResearch system will also send you reminders at intervals before the end of the approval period.

Based on the regulatory changes, the following types of studies still require continuing review:

- FDA regulated research;
- Greater than minimal risk research (including research reviewed under Expedited category 8(b)); (no subjects enrolled)
- Research reviewed under the pre-2018 Common Rule; or
- Research where the IRB has determined that Continuing Review is required (i.e. any study with an expiration date).

It is up to the IRB to determine the appropriate review cycle based on the inherent risks of the research, past experience with the investigator(s), as well as the nature of the study's funding (if any). The IRB may require a more frequent review cycle for some studies. See WORKSHEET: Approval Intervals (HRP-302) for more information.

To submit a continuing review application, complete the appropriate Smart Form in IBISResearch, and attach all requested documents. **You must submit this form at least 45 days before the expiration date of the study.** The PI must review the submission and click the “Submit” button after ensuring it

is correct. The PI is responsible for submission of the complete continuing review application regardless of receipt of IBISResearch notifications.

A “how to” create and submit a continuing review/ closure, may be found on the [IRB Researchers Quick Reference](#).

Two different Smart Forms are available for continuing review submissions:

- Continuing Review Smart Form
- Combined Continuing Review and Modification Smart Form

If you need to modify the research simultaneously with the continuing review, submit a combined Continuing Review and Modification Smart Form.

Do not new attach reportable information to the continuing report application. Any Reportable New Information (RNI) (see Chapter 8) must be submitted via the Reportable New Information function.

Effective 2/2023, the University of Miami is keeping enrollment totals under Enrollment Tracking Using REDCap. REDCap (Research Electronic Data Capture) will track the enrollment and status of research participants in clinical research studies (e.g., interventional non-treatment and non-interventional) that fall outside the scope of the existing Clinical Trial Management (CTM) and Participant Enrollment and Tracking Policy (VELOS). More information can be found in Section 7.1.

If Approval Expires

If your IRB approval expires, you will receive a notification of expiration and all Human Research procedures related to the protocol must stop.

The expiration date indicates the end of the approval period for studies that require continuing review. Once a study is expired, it is considered “lapsed.”

Allowing IRB approval of a study to lapse is considered non-compliance. Continuing human research procedures after approval has lapsed violates institutional policy and may also violate the terms of your grant and federal regulations.

If subjects may be harmed by stopping one or more research procedures, provide the following information to the HSRO as soon as possible via an RNI:

- A list of the required procedures;
- The number of subjects who need the procedure(s); and
- A description of the harm that could occur without the procedure.

You should contact the HSRO or an IRB Chair if approval of ongoing activities is needed urgently.

If you submit a continuing review report after approval has lapsed, you must include a summary of any study activities conducted between the time approval lapsed and the continuing review report submission.

You must also **submit a separate Reportable New Information (RNI)** explaining why approval was allowed to lapse and the actions you have taken to prevent lapses in the future.

The HSRO will not render determinations applications for new human subject research when the investigator has a human subject study for which IRB approval has lapsed. Rendering of determinations of the new research may be completed once the IRB receives an application for continuing review or closure to the existing expired study.

3.4 Closing a Study

Investigators may close a study when:

- The study is permanently closed to enrollment or was never open for enrollment;
- They have completed all interactions and interventions with subjects, including long-term follow-up; and
- The study is no longer collecting or analyzing private, identifiable information about the participants.

To close a study, complete the Continuing Review Smart Form in IBISResearch, attach all requested supplements, and have the Smart Form submitted by the PI by clicking the “Submit” activity. If the appropriate research milestones are complete, the study will be closed to discontinue IRB oversight. The “how to” create and submit a continuing review/ closure, may be found on the [IRB Researchers Quick Reference](#).

3.5 PI Departure from the University of Miami

The PI has ultimate responsibility for the conduct of the research, including compliance with the research project’s activities, administration, fiscal, and scientific requirements. If a PI is leaving the University of Miami, the IRB must be notified. Study activities must not be conducted without a PI overseeing the study.

The following must be considered:

- May the study be closed (see above)?
- Will the study stay open at the University of Miami? If so, the Department Chair/ ancillary must indicate a new PI, a modification must be submitted and approved by the IRB and appropriate documents updated, including, if applicable, the consideration of notifying participants (past and currently active, depending on the study).
- Will the study be transferred to another site? Prior to entering into any agreement to transfer a study to another IRB, the study Investigator must contact an HSRO reliance analyst to discuss the proposed transfer. (See Chapter 4).

If you have any questions about the PI departure process and options available, please contact the HSRO.

3.6 Writing an Investigator Protocol

A research protocol provides the scientific basis for the proposed research; it defines the study objectives, the population to be studied, the procedures to be followed, the evaluations to be performed and the plan for analysis; and lastly, it discusses the administrative aspects of the study such as safety management and regulatory issues. When writing an Investigator Protocol, always keep an electronic copy.

The IRB and HSRO recommend that the study's PI keep the following points in mind as best practices when submitting investigator-initiated protocols. Doing so will help reduce your protocol's time for the IRB to render a determination:

- The PI is responsible for the research design, protocol write-up and supporting documents attached to IBISResearch application. Though the **study coordinator(s)** may help with uploading and submitting the protocol, the ultimate responsibility lies with the PI, not with the coordinators or any other study staff.
- If you have any questions **prior** to submitting your application to IBISResearch, contact HSRO staff, applicable ancillaries, or advisors, depending on your concerns. HSRO staff contact can be found [here](#).
- Incomplete IBIS Research applications must not be submitted as place markers (i.e. do not submit and set the study into a Pre-Review state in IBISResearch until complete thoroughly). Incomplete or poorly written applications will be returned to the PI and take longer for a determination to be rendered. The job of editing poorly formulated application is not an HSRO function.
- PIs should use one of several protocol templates, consent templates, and supporting documents on the [HSRO website](#) to create their application. By using a template protocol, the PI ensures that they have included all required information for the application to be reviewed and, eventually, come to a proper and efficient rendering of a determination. HSRO templates are not a requirement but a recommendation. The job of editing poorly formulated proposals is not an IRB function. Again, responsibility for a quality submission lies with the PI.
- Please do not submit unrevised versions of previously IRB-approved protocols, consent(s) and recruitment material(s) or other supporting documents for a new study. Too often, those versions are inconsistent with the new study's aims and goals or omit/ retain irrelevant information as well as human subjects safeguards applicable to the new study.
- **Read thoroughly all documents before submitting the final application (consider peer review and/ or Department advisement). The job of submitting a quality finalized application is not an IRB function.**
- In your research protocol and supporting documents, ensure to distinguish what is standard of care from the research in your application.
- Protocols and supporting documents must acknowledge risks & ways to mitigate those risks such as alternative procedures, precautions, and safeguards. For example, if you are interviewing participants and the questions could indicate a participant is exhibiting

suicidal ideation, a protocol for the PI and staff to adhere must be in place prior to IRB submission to ensure subject safety.

- Name the application documents the naming convention (i.e., the *IBISResearch document “File to attach” name*) that you would want it to appear on a determination letter.
- Please read all determination decisions, requested changes, and documents, if applicable, thoroughly ***before*** contacting the HSRO or the IRB. When a notice is sent by IBISResearch, you will receive an email indicating comments have been added; open the application and review all documents and their respective comments. If requested changes are unclear, contact the HSRO analyst and set up an appointment to discuss your questions.
- Unless directed by the HSRO, do not modify, or add documents while the submission is under “Committee Review” (once made editable by staff) or “Clarifications Requested” state.
- Unless the IRB has specifically requested document changes as part of modifications required to secure approval, uploading additional documents (for example, Investigator Brochure, updates, protocol amendments, etc.) during the “Modifications Required” state may necessitate re-review by the convened IRB; thus, delaying the protocol having a final determination rendered.

If the approvability requirements are met (Criteria for Approval HRP-314), the IRB will approve the protocol.

Unless a revision to the protocol is required to protect subjects from imminent harm, investigators and research staff must comply with the protocol, as written, when conducting human subject research.

The HSRO recommends that PIs use tools, such as checklists, pre-written orders, and calendars to avoid protocol deviations.

If a study is sponsored, routinely sponsors provide the protocol for industry-sponsored research. Investigators must write and submit a “Local Addendum” to describe how they will perform the study at their site. The Local Addendum will describe local issues such as recruitment, confidentiality of the data and any other UM-specific procedures or alterations from the sponsor’s protocol.

3.7 Ancillary Review Requirements

Ancillary review assists the University of Miami with research feasibility, risk, regulatory requirements, and research compliance. In some instances, the HSRO cannot release the IRB approval until you receive ancillary committee approval. Not all studies require ancillary review. You can find the University’s Ancillary Review requirements on the [HSRO Website](#).

3.8 Finding your Protocol landing page, Determination Letters and Approved Documents

The IRB notifies investigators in writing of its determinations. IRB notifications are generated and issued through the electronic IBISResearch system via electronic mail to the investigator and other study personnel designated by the investigator to receive the notifications. You are responsible for reading the final IRB approval letter and HSRO acknowledgment notice, when applicable.

You may want to go to a specific submission workspace (webpage) to view or update its contents, submit it for review, review it, or take other actions. Note that your access to a submission is personalized based on your role in the system and the role you play in relation to the particular submission. In addition, the actions you can take on a submission are personalized.

1. Log into <https://ibis-research.miami.edu/IRB> (the upper right corner, click on Login)
2. Click on 'IRB' tab.
3. Your list of active/ongoing submissions will appear.
4. Click on the particular study that requires action or documentation.

Important! A watermark stamp (with effective date) will only appear on the following documents:

- Protocol
- Consent Materials
- Recruitment Materials/Scripts
- Data Collection Sheets for retrospective chart reviews
- Debriefing Materials, for deception studies.

The IRB does not stamp any other documents with approval dates; however, all documents that are IRB approved are acknowledged in the appropriate activity in which it was submitted in the final determination letter regardless of stamping.

Chapter 4

Reliances and Cooperative Research for IRB Oversight

You must coordinate IRB review when you plan to:

1. Rely on an external IRB to oversee your **non-exempt** human subject research; or
2. Rely on the UM's IRB to oversee external sites participating in a **non-exempt** human subject study you are conducting.

These cooperative research review plans are called “reliances” and are set in place via Reliance Agreements (also called Institutional Authorization Agreement, or IAA). An IAA is an agreement signed by two or more institutions engaged in the same human subject research project. The Agreement permits one or more institutions to cede review to another central, or single IRB.

Types of Reliance Agreements:

Master Agreements: A Master Reliance Agreement is used when multiple studies cede review to a specific IRB. These types of agreements may be for a single protocol or a number of protocols that are negotiated on a case-by-case basis. UM has executed master reliance agreements with NCI CIRB, Advarra and WCG IRB and consortium groups such as NMDP.

SMART IRB: SMART IRB is a platform designed to facilitate the authorization agreement process between participating institutions. UM is a signatory to the SMART IRB master reliance agreement. The SMART IRB agreement may be used as the basis of reliance for studies where UM relies on an external IRB or serve as the CentralIRB/sIRB. For a list of participating sites, click [here](#).

Institutional Authorization Agreement template: In cases where an external institution does not meet the eligibility criteria to sign onto the SMART IRB agreement, they may use an IRB Authorization Agreement to establish a reliance relationship with the UM Central IRB/sIRB.

Individual Investigator Agreement (IIA): An agreement between UM and an individual collaborator who is not affiliated with an institution with an FWA.

4.1 Requesting an external IRB

You may use an external IRB to review and oversee your research when this oversight plan is:

- PHS-funded and external review is required per single IRB mandate
- Industry-funded multi-site study and sponsor is requiring single IRB review as a condition of participation (a statement from sponsor requiring external single IRB review must be provided with your submission)
- Investigator initiated study where UM is a site (justification for using an external IRB must be provided with your submission)

- Study is not exempt from the federal regulations.

If you are interested in obtaining a review from an external IRB for your research, you will need to complete the [FORM: Reliance Application \(HRP 216\)](#). You must submit this form through IBISResearch.

HSRO staff will review the form and determine whether the research qualifies for a reliance on an external IRB (Refer to HRP-832- Considerations for ceding IRB review). Once the HSRO renders this determination, we will contact you with a response and provide further directions.

When an independent, commercial IRB completes the review, the HSRO charges a one-time \$1500 administrative fee for completing UM's administrative 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 with the external IRB and will follow up with the reviewing institution if an agreement is needed.
- The HSRO staff will provide a signed HRP-216 or a Cede Review Letter to the reviewing IRB.
- Before conducting the review, the reviewing IRB may require information about the University of Miami's requirements and local context. Click [Here](#) to find information about:
 - The UM template language that you must include in the consent documents,
 - The local research context (applicable law, Miami's racial and ethnic composition, and local attitudes about human subject research.
- The UM site must:
 - Submit the study through IBISResearch;
 - Obtain all required [ancillary reviews and approvals](#). **Refer to Section 3.6 above.**
 - Submit documents to the reviewing IRB per that IRB's policy;
 - Ensure the consent document includes [language required by the UM HSRO](#);
 - Submit the following approved documents to the HSRO via IBISResearch after the reviewing IRB has completed the review:
 - Protocol
 - Consent Document(s)
 - Recruitment Materials
 - Subject-facing documents

The study may start after:

- The sponsor and the reviewing IRB approve the start-up, **AND**
- You receive an acknowledgment notice from the UM HSRO.

Responsibilities after Starting the Study

Study teams are responsible for submitting updated study documents that are approved by the external IRB of record through Study Updates and Site Modifications for local IRB acknowledgement. The study team must also report new information to the UM IRB after it is reported to the external IRB of record.

Study Updates and Site Modifications

Key points to help PIs decide which documents must be uploaded via **Study Update** vs a **Site Modification**:

- 1) Is the document Study-Wide or Site-Specific (document will be used at UM only)?
- 2) Is this a patient facing document that needs to be finalized for Velos?

Study-Wide documents are documents that are provided to all participating sites and are usually templates. Site-Specific documents are documents that are specific to the UM site.

Study-Wide documents are uploaded through a **Study Update**. Examples are:

- Study Protocols
- Investigator Brochures
- Study-wide documents not specific to the UM site
- Template versions of documents not yet localized

Site-Specific documents must be uploaded through a **Site Modification**. Examples are:

- Localized consent/assent documents
- Localized recruitment materials

The HSRO *does not* review documents that are uploaded after the local site has been activated. The HSRO will only administratively check that the patient facing documents are still meeting UM institutional local requirements as they were at the time of initial approval to provide a local acknowledgement. Corresponding approval letters must always be provided with any documents uploaded to IBIS. If the document has not been approved by the external IRB, the HSRO cannot acknowledge it.

Localized consent documents and localized recruitment materials are the most common example of patient facing documents that must be finalized as part of a Site Modification to transfer them into Velos. Do *not* submit redline versions of these IRB approved documents in place of final versions that are approved by the external IRB of record.

Continuing Review

The University of Miami does not require reporting of continuing review and CR approval letters for externally reviewed studies. Any notification that you may have received was automated by the IBISResearch system because the approval expiration date was recorded on the IBISResearch site.

If approval of this site has been renewed and you would like to record the new expiration date for record keeping purposes, you may submit the **Continuing Review approval letter** as an attachment using the **"Report Continuing Review Data"** function. The HSRO will then create a Study Update to record the new expiration date.

RNI Submissions

It is recommended to reach out to the HSRO Reliance Team to determine if an RNI will need to be submitted to the UM IRB before the external IRB of record reviews and renders their determination.

Study teams are responsible for submitting reports of new information to the external IRB of record. The external IRB of record's determination should be submitted for local UM IRB acknowledgment via IBISResearch.. Not all reportable events need to be submitted to the UM IRB for local acknowledgement, but there are some determinations that must be reported to the UM IRB.

The UM IRB must acknowledge:

- Reports of non-compliance that could meet the UM's definitions of [serious or continuing non-compliance](#);
- IRB suspensions or terminations of study approval;
- IRB determinations of:
 - Serious non-compliance;
 - Continuing non-compliance;
 - Unanticipated problems involving risks to subjects or others;

Though the UM will not render an IRB determination, events that are likely to fall into the above categories must be reported to the UM IRB immediately after submission to the external IRB of record.

For any HIPAA violations, study teams must contact the UM IRB, and the UM or JHS Privacy Offices as applicable.

Study closures:

Submit confirmation of closure and conclusion of external IRB oversight via the Report Continuing Review Data activity in IBISResearch by providing the closure letter/certificate from the external IRB of record.

4.2 Obligations of investigators when relying on an external IRB

When relying on an external IRB, investigators must:

- Obtain administrative sign-off (signed HRP-216 "External IRB Reliance application" from the University of Miami HSRO and appropriate approvals from required ancillary committees before seeking review by an external IRB of record. Not all ancillary committees must provide

their approval before a study is released for external review. **Refer to Section 3.6 “Ancillary Review Requirements” above.**

- Comply with the determinations and requirements of the reviewing IRB.
- Provide the reviewing IRB with the requested information about local requirements or local research context.
- Report the following to the reviewing IRB:
 - Changes in local policies that impact IRB review;
 - Conflicts of interest along with the COIC Management Plan;
 - Changes in research. You must obtain IRB approval before implementing any change except where the change is necessary to eliminate apparent immediate hazards to the participants;
 - Any [unanticipated problems](#) involving risks to participants or others according to the requirements specified in the reliance agreement;
 - Non-compliance, unresolved participant complaints, protocol deviations, or other events according to the requirements specified in the reviewing IRB’s SOPs or the reliance agreement;
 - Data safety monitoring reports as required by the external IRB’s reporting policy.
- Cooperate with all other reporting requirements of the reviewing IRB.
- When enrolling participants, obtain consent from subjects or the subject’s legally authorized representative (LAR) in compliance with applicable regulations, the reviewing IRB’s requirements, the protocol, and the University of Miami requirements [\[SOP: INFORMED CONSENT PROCESS FOR RESEARCH \(HRP-90\)\]](#);
- Maintain records of documentation of consent for each participant, as required by applicable regulations, the protocol, the reviewing IRB and the University of Miami requirements;
- Provide the name and contact information for an individual the IRB can contact for questions and instructions.

4.3 Requesting the UM IRB to serve as the IRB of Record (Reviewing IRB)

Generally, UM agrees to serve as the Central IRB/sIRB for a relying institution participating in a multi-site non-exempt human research when:

- UM PI receives an award through a grant, contract, or cooperative agreement directly from a federal agency for non-exempt Human Research (federally funded study)
- UM is engaged in the research (Refer to HRP-311- Engagement Determination and HRP-833- Considerations for serving as the Central IRB/sIRB).
 - UM’s employees or agents, for the purposes of a research project, obtain: data about the subjects of the research through intervention or interaction with them; identifiable private information about the subjects of the research or informed consent of human subjects.

Other extenuating circumstances are considered on a case-by-case basis. The complexity of the protocol and the number of sites will factor into this decision.

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, IBISResearch. The UM investigator must also ensure that participating sites receive IRB communications, such as approval letters and approval documents.

A pre-submission consultation with the reliance team is highly advisable to identify whether a study is eligible for reliance, provide you with guidance on how to submit to the IRB and how to initiate reliance agreements, which will ensure a smooth onboarding of sites and review process. During this consultation, you can be expected to provide a brief description of the study, describe the involvement of UM and the relying sites, funding sources and status, name of the UM PI, number of sites expected to rely on the UM CIRB, etc...

In addition, please ensure that the following questions on the Smart Form indicate that the study is a multi-site or collaborative research study and that the question "Will the UM IRB act as the single IRB of record for other participating sites?" is marked as Yes.

The study-wide and the UM (parent study) submission will always be reviewed and approved first. This parent page will serve as an umbrella project where all study-wide documents that apply to all sites (main study protocol and template documents), as well as the UM specific documents (UM-site documents) will reside. For this purpose, at the time of initial review, in addition to uploading UM specific documents, the coordinating center/liaison should upload template consent documents under the study related documents section for sites to use as models when submitting their site-specific consent documents for IRB review. It is important for sites to follow the approved template consent document as this will ensure faster onboarding, review and approval of sites.

After the UM (parent study) has been reviewed and approved by the UM CIRB, the coordinating center/liaison must complete and upload [FORM: HRP-217 External Site application for UM IRB Review in IBISResearch](#) if interested in adding other relying sites for UM CIRB review. The HSRO reliance analyst will review the completed form and determine whether the research qualifies for a reliance.

The following are some circumstances in which the UM IRB may not serve as the Central IRB/sIRB for a multisite study as the study does not qualify for reliance:

- The relying institution is not engaged in the research activities
- The study is determined to be Exempt. If this is the case, please submit to the UM IRB for internal review of the UM site.
- The study is determined to not involve human subjects research
- The external sites are international

Once the HSRO renders the determination that the study qualifies for reliance, HRP-217 will be signed by the reliance analyst, you will be contacted with a decision and provided 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 UM PI or coordinating center if an agreement is needed.
- Each site must complete, [FORM: HRP-218 Relying Site Information Questionnaire, which serves as a local context document for the relying site to document any required state or local laws, institutional policies and community expectations at the site.](#)
- The reliance analyst will provide the signed HRP-217 or a Cede Review Letter to the local team/coordinating center to indicate a decision to serve as the IRB of record for the site.
- The reliance analyst will create a site page for the relying site under the UM Parent study page and instruct the coordinating center/liason to upload all site specific documents into IBISResearch. Site specific documents will include: signed HRP-217, completed HRP-218, executed reliance agreement, site specific consent documents (modeled after approved study-wide ICF template document submitted at approval of the parent study), local protocol (if applicable), locally required consent language* and all other site specific materials that will be used at the relying site.

*Consent language that deviates from the previously approved template language, (other than addition of relying site PI's name and contact information specific to site), must be justified by the site by uploading a site's local consent required language document.

4.4 Obligations of a Lead PI for a Multi-Site study reviewed by UM IRB

When you are the Lead PI for a Multi-Site study reviewed by the UM IRB, you will have the following additional responsibilities:

- 1) Coordinating with HRSO personnel to determine whether the University of Miami's IRB can act as the single IRB for all or some institutions participating in the study or if a different, external IRB will assume oversight.
- 2) Providing information about all sites that will be [engaged in the human research](#) and requiring review and oversight by the University of Miami IRB.
- 3) Provide to the reviewing IRB a description of the roles and responsibilities of key stakeholders and the plan for communicating and coordinating key information to and from study teams at relying sites and the UM IRB or HRSO.
- 4) Unless other arrangements are in place:
 - a. Provide relying site investigators with the [policies of the UM HSRO](#);
 - b. Establish a process for obtaining and collating information from all sites and submitting this information to the reviewing IRB; (This information includes site-specific variations in study conduct, such as the local consent process and language, subject identification and recruitment processes and local variations in study conduct);
 - c. Prepare and submit IRB applications on behalf of all sites. Submissions include initial review, modifications, personnel updates, reportable new information and continuing review reports;
 - d. Report the absence of continuing review information from relying sites if they do not provide the required information before you submit the continuing review materials to the HSRO;

- e. Notify the relying site of their lapse in approval and obtain a preventive action plan outlining how the site will submit timely information;
- f. Submit reportable new information from relying sites to the HSRO;
- g. Provide relying site investigators with the IRB-approved versions of all study documents;
- h. Provide investigators with all determinations and communications from the reviewing IRB;
- i. Provide approval documents and communications to the relying institutions;
- j. Ensure that relying sites use the consent template the UM IRB approved for that site;
- k. Respond to questions or information requests from study teams or the IRB or HRPP staff at relying sites; and
- l. Ensure that all relying sites receive UM IRB approval before starting their research.

Chapter 5

IRB Review of Human Subject Research

The IRB follows policies and procedures to conduct research. These policies are included in Standard Operating Procedures (SOPs) located on the [HSRO Website](#). This chapter describes what investigators should expect from IRB review.

5.1 Levels of IRB Review

When the HSRO receives a submission, the first task is to determine whether the proposed project is, indeed, human subject research. If the IRB determines that it meets the definition of a human subject and research, the next task is to determine the level of review. The following are descriptions of the various levels of review available:

Not Human Subject Research (HSR)

Activities that do not meet the definition of “research” and/or do not include “human subjects,” as defined by regulations, are not subject to IRB oversight or review. **This determination is not the same as “exempt” (see below) nor does this mean you are “IRB approved.”** If you believe your activity may not be human subjects research, contact may contact the HSRO prior to developing your Investigator Protocol and submitting an application in IBISResearch. If you believe your research meets this description, click [SURVEY](#) to complete a survey that will to help determine if the project is HSR. If your project is determined to be Not Human Subjects Research, you may print the report from the online survey as documentation of this determination. If you plan to publish the results of your project, you can submit the survey result along with a description of the project (abstract) to HSROletterrequest@miami.edu for a written opinion on official letterhead.

Grant/ Just-In-Time (JIT) Request

Administrative review by the IRB is required for certain types of grants that:

1. have been submitted with the knowledge that human subjects may be involved within the support period, but definite plans were not included in the application/proposal;
2. involve research undertaken without the intention of involving human subjects but it is later proposed to involve human subjects; or
3. support more than one human subject research protocol.

To ensure that the NIH's timelines are met, the IRB encourages investigators to start working on the study submission in IBISResearch as soon as a fundable score is received. Investigators should alert the IRB as soon as possible when a just-in-time review will be needed. The Investigator will receive a letter within the IBISResearch system. **This is not an authorization to begin research involving human subjects.** Once the JIT letter is documented in IBISResearch, the study is “withdrawn” to allow the PI to complete the research protocol for review and approval prior to the initiation of human subjects' research. It is the PI's responsibility to keep the IRB informed of any changes in the research.

Exempt Research

The research is still considered human subjects research and requires IRB review. The University of Miami does not permit the investigator to make the determination that their research qualifies for exemption. The Investigator must complete and apply in IBISResearch for the IRB to render a determination. You do not need to request an “exempt review.” For certain exempt categories, a limited IRB review is required to determine that adequate provisions are in place to protect the privacy of subjects and the confidentiality of data. Exempt studies do not go to the full committee. Instead, a single reviewer will review the submission and render the appropriate determination. See WORKSHEET: Exemption (HRP-312) to see the requirements.

Expedited Review

The regulations identify several categories of minimal risk HSR that do not need to go for full committee review. A designated IRB reviewer will review these studies and may request modifications and approve the research but cannot disapprove the research. You do not need to request an “expedited review.” See WORKSHEET: Expedited Review (HRP-313) to see the requirements.

Full Committee Review

The full IRB Committee will review HSR that involves greater than minimal risk and minimal risk HSR that does not fit within an category guidance designates as an [expedited category](#).

5.2 Criteria for Approval

The [Belmont Report](#) is a document that describes the basic ethical principles that should underlie the conduct of research involving HSR. The Federal regulations incorporate the ethical principles found in the Belmont. Included in the regulations are the criteria below that must be met before an IRB can approve a regulated non-exempt research study that includes human subjects. The criteria for approval can be found on [HRP-314](#). [HRP 314](#) references other checklists that might be relevant. These

worksheets and checklists are available on the [HSRO Website](#). The IRB uses the checklists and worksheets for initial review, continuing review, review of modifications and review of new information.

See [Section 46.111](#) of the Common Rule and [21 CFR 56.111](#) (FDA regulations). [Here](#) is a worksheet you can use to apply the criteria for approval to your **non-exempt** human subject research. [Here](#) is a worksheet you can apply to your exempt human subject research. The IRB must also ensure that additional criteria are met before approving regulated research that will include children, prisoners, pregnant women, cognitively impaired subjects and neonates.

5.3 IRB Determinations

According to federal regulations, the IRB may approve research, require modifications to the research before it can be approved, or disapprove research (convened IRB only). The regulations require the IRB to render additional determinations in certain circumstances. The following is list of determinations the IRB may make:

- **Approval:** When all criteria and other requirements are met, the IRB renders this determination. You will receive an approval letter explaining the requirements you must follow during the conduct of the research.
- **Modifications Required to Secure Approval:** The IRB renders this determination when the IRB requires specific modifications to the research before granting final approval. You will receive a letter explaining the modifications that are required and should follow the directions in the letter to submit the modifications.
- **Tabled:** The IRB renders this determination when the convened IRB cannot approve the research at a meeting because of issues with the IRB, such as loss of quorum. When taking this action, the IRB automatically schedules the research for review at the next meeting. Investigators do not need to take further actions when a tabling occurs.
- **Deferred:** The IRB renders this determination when the convened IRB determines that they cannot approve the research and suggests significant modifications that might make the research approvable. You will receive a letter explaining the reasons for the decision and recommended revisions to the research to make it approvable. You should revise the research as recommended or respond to the IRB in person or in writing if you disagree with the IRB's determination.
- **Disapproval:** The IRB renders this determination when the convened IRB agrees that it is unable to approve research and cannot describe/ recommend modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the Investigator an opportunity to respond to the IRB in person or in writing.
- **Serious Non-Compliance:** The IRB will determine it serious non-compliance when an investigator or research team member failed to comply with regulations, university policies, or the requirements/determinations of the IRB, when, in the judgment of the institution, such failure substantially increases risks to subject welfare/safety, subject rights, or data integrity.
- **Continuing Non-Compliance:** The IRB will determine continuing non-compliance when there is a recurring pattern of behavior or noncompliance during the conduct of the research; that, if not remediated, may compromise subject welfare/safety, subject rights, or data integrity.

- Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO): The Investigator must report to the IRB incidents that are initially determined by the PI to be (1) unanticipated, (2) related to the research, and (3) indicates that subjects or others are at increased risk of harm. For more information on reporting requirements, review Chapter 8 Reporting Requirements.
- Waiver of Consent Process: Consent from subjects is required before involving the subjects in research procedures for non-exempt research, in most instances. However, regulations allow the IRB to waive the requirement for consent in limited circumstances. See “[CHECKLIST: Waiver or Alteration of the Consent Process \(HRP-410\)](#)” to see the requirements for approval of this waiver.
- Waiver of Documentation of Consent: Regulations allow the IRB to waive the requirement for the signature when the study involves only minimal risk and additional criteria are satisfied for non-exempt research. The investigator must obtain consent following the same requirements as written consent, but the subject does not sign a consent form. It may still be appropriate to document that the consent process took place. See “[CHECKLIST: Waiver of Written Documentation of the Consent Process \(HRP-411\)](#)” to see the requirements for approval of this waiver.
- Waiver of the requirement for a HIPAA Authorization: Investigators cannot look at a patient’s medical record for research purposes without a signed authorization from the subject, in most instances. However, the IRB can waive the requirement for a signed authorization when specific regulatory requirements are met. The conditions to waive HIPAA are more stringent than for waiver of consent under the Common Rule (research regulations). It is vital to provide a compelling argument for not being able to practicably carry out the research without the waiver. If the subject is physically present, it is usually **practicable** to obtain written HIPAA Authorization. **Practicable means possible; it does not mean convenient.** See [CHECKLIST Wavier of HIPAA Authorization \(HRP 441\)](#) to see the requirements for approval of this waiver.
- Waiver/Alteration of requirements for HIPAA Authorization: Investigators cannot look at a patient’s medical record for research purposes without a signed authorization from the subject, in most instances. However, the IRB can alter the requirement for a signature and date due to current pandemic or other reasons. See [CHECKLIST Wavier of HIPAA Authorization \(HRP 441-A\)](#) to see the requirements for approval of this waiver
- Non-Significant Risk Device Determination: FDA regulations allow investigators to study “Non-Significant Risk” (NSR) devices without an Investigational Device Exemption (IDE). The convened IRB must determine as to whether the investigational device involves significant risk or NSR. See [CHECKLIST: Devices \(HRP 418\)](#) to see the requirements for this determination and other determinations relating to devices.
- Exemption Determination with Limited Review: For certain exempt categories, a limited IRB review is required to determine that adequate provisions are in place to protect the privacy of subjects and the confidentiality of data. See [CHECKLIST: Exemption Determination with Limited Review \(HRP 403\)](#) to see the requirements for this determination.

- Inclusion of Cognitively Impaired Subjects: The International Conference on E-6(R2), is an international guidance document that describes the requirements for the conduct of clinical research of investigational drugs. This guidance includes requirements for including adults who are cognitively impaired in clinical trials. The UM IRB applies these requirements for **all** human subject research. See [CHECKLIST: Cognitively Impaired Adults \(HRP 417\)](#) to see the requirements for this determination.
- Inclusion of Prisoners in Research: Investigators cannot include prisoners as subjects in some federally-funded human subject research unless specific requirements are met. The UM IRB applies some of these requirements to research that is not federally funded. See [CHECKLIST: Prisoners \(HRP-415\)](#) to see the requirements for this determination.
- Inclusion of Pregnant Women in Research - Investigators cannot **purposefully** include pregnant women or fetuses as subjects in some federally-funded human subject research unless specific requirements are met. See [CHECKLIST: Pregnant Women \(HRP-412\)](#) to see the requirements for this determination.
- Including Neonates in Research - Investigators cannot include non-viable neonates and neonates of uncertain viability as subjects in some federally-funded human subject research unless specific requirements are met. See [CHECKLIST: Non-Viable Neonates \(HRP-413\)](#) and [CHECKLIST: Neonates of Uncertain Viability \(HRP-414\)](#) to see the requirements for these determinations.
- Including Children in Research - Investigators cannot include children in FDA-regulated research and some federally-funded human subject research unless specific requirements are met. The HSRO extends the requirements to most human subject research. There are three different checklists based on the risks and benefits involved in the research. See [CHECKLIST: Children \(HRP-416\)](#) to see the three different checklists and choose the checklist that best fits the proposed research.
- Waiver of Consent Process for Emergency Research: This waiver is for IRB approved research that is done in emergency situations when there is no time to obtain informed consent. See [CHECKLIST: Waiver of Consent for Emergency Research \(HRP-419\)](#) to see the requirements for these determinations.
- Department of Defense: Investigators and the IRB must consider additional determinations involved in the research when HSR is funded or supported by the Department of Defense (DoD). See [CHECKLIST: Department of Defense Supported Research \(HRP-420\)](#).

The IRB will provide you with a written decision indicating that the IRB has approved the human subjects research, requires substantive or non-substantive modifications to secure approval, or has disapproved the human subjects research. **The PI is required to read the determination letter and any questions on the IRB's determination may be facilitated by HSRO staff.**

- If the IRB has **approved** the human subjects research: The human subjects research may commence once all other institutional approvals have been obtained. Approval letters may

also have special instructions from the IRB. **Do not start human subjects research activities until you have read the final IRB approval letter and received approval from ancillaries that require approval prior to commencing research with their resources.**

- Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
 - Ensure that research staff are qualified (e.g. including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
 - Personally conduct or supervise the human subjects research. Recognize that the PI is accountable for the failures of any study team member.
- **If the IRB requires modifications to secure approval:** All required changes will be outlined in a letter. Make the required modifications and submit them to the IRB. If all requested modifications are made, the IRB will issue a final approval. Research cannot commence until this final approval is received. If you do not agree with the modifications, write up your response with justification as to why the modifications cannot/should not be made and submit it to the IRB. If you do not agree with the modifications, the convened IRB must re-review the response, which may impact the final rendering of a determination.
 - **If the IRB defers the human subjects research:** The IRB will provide a statement of the reasons for deferral and suggestions to make the study approvable, and give you an opportunity to respond in writing. In most cases, if the IRB's reasons for the deferral are addressed, the human subjects research can be approved; however, the convened IRB must re-review the modification (take this into consideration when you are thinking of timelines).
 - **If the IRB disapproves the human subjects research:** The IRB will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.
 - The Investigator may appeal the decision of the IRB in writing. Appeals must be addressed to the IRB Chairperson or Chair Designee and include the reasons the Investigator believes the proposed research or issue at hand follows IRB policies and procedures, state and local laws, and federal regulations. The IRB will consider the appeal(s) based upon new information provided. The Investigator may request to attend the IRB meeting(s) where his/her research and appeal are reviewed to address issues raised by the convened IRB.

Chapter 6

Recruiting and Screening Research Subjects

6.1 Basic Principles of Recruitment

Recruitment material must comply with the [University of Miami's Visual Identity Guidelines](#).

Recruiting a potential research participant is the **first step of the consent process**. The research team should consider the following ethical questions when evaluating recruitment strategies. The table below discusses issues to consider and questions to ask before using a recruitment strategy.

PRINCIPLE	QUESTIONS TO ASK
Justice - Equitable selection of participants:	<ul style="list-style-type: none"> • Participants should be included and excluded for scientific reasons only. • Does the recruitment strategy help ensure that selection of research participants is equitable and appropriate for the study? Will subjects be excluded from the study because they do not understand English? Is appropriate and possible to enroll subjects whose main language is not English. • Studies that offer a prospect for direct benefit, especially Phase 3 confirmatory trials targeting serious or life-threatening diseases, should generally make the greatest effort to enroll all eligible subjects.
Respect for privacy:	<ul style="list-style-type: none"> • Does the recruitment strategy respect an individual's reasonable expectations for privacy? • If you ask questions for screening, will the questions be asked in a private setting where others will not overhear the answers? • If you recruit patients from a recruitment database in the clinic, have those patients given their permission beforehand for this use of their medical information?
Reduce undue influence and coercion:	<ul style="list-style-type: none"> • Do the recruitment materials and/or consent document present information about the study in an unbiased manner without emphasizing possible benefits or underemphasizing possible risks? • Will the potential subject have sufficient time to comprehend the study and to discuss the study with their family before they are asked to agree to participate? • Will someone who has authority over the participant conduct the recruitment/consent process (for example, employer/ employee, teacher/ student)? If yes, how will the study minimize the risk of coercion or undue influence? • Are inducements such as compensation emphasized or are they of such value that potential subjects may not consider the risks associated with participation? • If the study is FDA-regulated, avoid representing the investigational product as safe or effective for the purposes for which it is under investigation. (see federal regulation 21 CFR 312.7)

6.2 Identifying Potential Subjects and Recruitment Methods

You will be asked to explain your method(s) of recruiting subjects in your protocol. Individuals initiating contact (in person or by phone) with potential subjects must have basic knowledge about the study (so they can answer questions) and training in the voluntary nature of research participation.

The IRB will review the recruiting plan to make sure that it complies with HIPAA and institutional requirements. Under HIPAA, in general, the use of a person's protected health information (PHI) for research is not permitted without authorization from the subject or an IRB waiver of authorization. Therefore, HIPAA requires either authorization from the subject or a full or partial IRB waiver of HIPAA authorization for screening and/or recruitment. If you have any questions about recruitment strategies, contact HSRO staff, applicable ancillaries, or advisors, depending on your concerns. For additional information on resources for recruiting clinical trial participants, link to the [CTSI's website](#).

- **Medical Record Review** – Reviewing medical records (UChart) and patient logs is one method of identifying potential subjects. However, patients' medical records are private information belonging to the patient. **You must not view a patient's medical record unless you are directly involved in a patient's care.** The following are the different avenues you can use to identify subjects; however, the PI may consider different options.
- **Clinician's Own Patients:** Clinicians may review medical information of their own patients to identify and contact potential study subjects. The method of contact must be specifically outlined in the research protocol to ensure confidentiality and privacy are maintained. Investigators, or nurses or staff working with the investigators approaching patients directly is considered on a case-by-case basis. This approach respects privacy, but also raises ethical concerns because of the difficulty of saying no and the therapeutic misconception.
- **Preparatory to Research Exception:** Investigators may use the exception to the requirement for an HIPAA Authorization for purposes preparatory to research by completing a **Certification for Reviews Preparatory to Research (Form E)** and sending it to HSROletterrequest@miami.edu. This certification allows you to review medical records, but you must not copy, write down or otherwise collect identifiable information from the records, or contact patients about participation without IRB approval. The data obtained must be the minimum necessary for the proposed purpose. This Certification can be used to determine whether a study is feasible.
- **Waiver of Authorization for Recruitment:** Investigators may request a Waiver of Authorization for Recruitment by documenting the request in their protocol or completing the [standalone request form](#) (for studies using an external IRB). This waiver allows you to review information in the medical record, record the minimum necessary information needed to contact a potential subject and to make that contact. If a PI is seeking a waiver, **scientifically justify in the research protocol** why research could NOT practicably be conducted without access to and use of the protected health information (convenience is insufficient).
- **Data Broker Services combined with Consent to Contact:** The University's Data Brokers can provide lists of patients who meet specific are an excellent resource for identifying

potential subjects. Investigators can submit [a request to obtain a list of potential participants](#) and use the [Consent to Contact](#) initiative to contact the patients in the list. You must :

- Include information about using Consent to Contact for recruitment in your protocol;
 - Scientifically justify the use of this initiative as a method of recruitment;
 - Submit the approved [Consent to Contact script](#) edited for your study along with the screening questions you will ask during the phone call; and
 - Provide the information needed to obtain a waiver of authorization from the IRB written confirmation included in your protocol.
- **Referrals:** Participants may be referred from non-investigator healthcare providers, snowball sampling (participants referring other participants). Investigators may provide their colleagues with a “Dear Patient or Potential Participant” letter describing the study or researcher may provide information sheets about the study to colleagues or associates. This Institution prohibits payments to professionals in exchange for referrals of potential subjects (“finder’s fees”) and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”). Only individuals listed as study team members may gather information for the study, including names and contact information. Treating physicians who are not listed on the protocol may not pass patient information to other study teams. Individuals not listed study team members on a protocol may present study information for the subject to self-initiate contact with the other research team, if they are interested in participating.
 - **IRB-approved Screening/Recruitment Database:** You could submit a new protocol to maintain a database of potential research participants who have agreed to be contacted for studies and have signed a consent document and HIPAA authorization for this purpose, when applicable. Consideration on whether the database will only be used for the PI or shared with other UM investigators must be disclosed in the consent form. Investigators contact these potential subjects about studies in accordance with their protocol and the (typically signed) consent. PIs may also consider prospective participants be given the option in an active study (on the consent form) to be contacted for future studies by means of check-off box in a consent form for a previous study.
 - **Department Pools:** There are several ways undergraduates can get involved in research. Students can participate as a research subject in ongoing projects to fulfill course requirements. Course instructors normally do not enroll their own students for their research. For more information and amount of credit fulfillment, you may contact the [Department of Psychology](#) or [School of Communications](#). Note: No HIPAA-regulated PHI is used in this recruitment strategy.
 - **Advertisements, notices and/or media::** Note: No [HIPAA-regulated PHI](#) is used in this recruitment strategy. Advertisements, notices and/or media offers researchers the opportunity to extend the reach of their recruitment efforts. The continuously evolving nature of media, however, generates uncertainty for both researchers and IRBs regarding the management of risk to human subjects. One-way ads that do not involve direct communication with potential subjects (i.e. paid Facebook Ads), are reviewed according to existing IRB review policies See:

WORKSHEET: Advertisements (HRP-315). The IRB **discourages** study teams from establishing a social media account simply for the purposes of recruitment. As an alternative, PIs may consider that University of Miami Departments and Offices routinely have their own social media accounts. Investigators should consult with the University's [News and Media Relations Department](#) for additional information on social media sites.

- **Phone Calls: Individuals who are not providing direct patient care may not contact patients** except through the Consent to Contact process discussed above. Direct care providers may verbally explain the study and, if the subject expresses interest, introduce a study team member to discuss the study in more detail. “Cold calling” is defined as the act of researchers calling potential research participants on the phone without having a prior (clinical) relationship, or information about the study being otherwise previously provided. “Cold Calls” to patients without prior authorization could result in legal issues for any covered entity. **“Cold calling” is not a recommended practice; however, cold calling patients is not allowed.** Contacting potential study subjects must be conducted in a manner that respects the individual’s right to say no to participate in your research. If a contacted individual indicates that they do not want to hear about the research and/or participate (e.g., saying no), they may not be called back again, nor pressured, convinced, or coerced to say yes. If you are using a contracted service to survey or recruit study subjects, you must ensure they are following these IRB guidelines for your protocol.
- **Health Fairs:** A health fair is an educational and interactive event designed for outreach to provide basic preventive medicine and medical screening to people in the community or employees at work in conjunction with workplace wellness. Investigators may use this mechanism to recruit participants with IRB approved scripts or advertisements.
- **University of Miami Health Research Website – UMiamiHealthResearch.org:** The CTSI provides resources to help researchers recruit. A website for UM study teams to feature their health research studies and connect with participants is available. Possible study participants can search the site for active studies and/or they sign up to be part of a registry to be contacted about studies.
- **Participant Transfer:** In a multi-site and/ or collaborative study, if a participant is transferred from another institution to the University of Miami, participants must consent with the IRB approved Informed Consent Form from the University of Miami. Furthermore, the transfer of PHI must be obtained between the Investigators. HIPAA Authorization must also be obtained from the participants. The University of Miami Investigator must ensure this participant is counted to UM enrolled totals.
- **MyChart Research Recruitment Tool:** This is a recruitment tool available to study teams through UChart. The MyChart Research Recruitment tool allows Investigators to send recruitment messages to UHealth patients who agreed to be contacted if they meet the initial study eligibility criteria from the EMR. More information about MyChart Research Recruitment Tool can be located [here](#).
- **Recruiting researchers’ students and staff and recruitment in classrooms:** Researchers should not directly ask their students or staff to be research subjects, as it may be hard to refuse such a request. The IRB prefers that researchers post flyers and allow volunteers to initiate contact

about the study. No pressure should be applied to encourage participation. Potential participation in research must be presented as a voluntary option. Participation cannot be tied to grades or condition of employment. It must be clear that there will be no stigmatization of students or staff who decline to participate. Employees (individuals or groups) or students should not be selected solely on the basis of convenience when they would not otherwise be appropriate for inclusion. In general, potential participants should be solicited from a “broad base” of individuals meeting the conditions for study, rather than from individuals who report directly to the investigator(s). If class time will be taken for research participation, alternative activities should be provided for those who decline (especially in pre-college levels).

- Texts/ Postal Service envelopes and Emails: IRB approved phone scripts, and MyChart messages from the physician are acceptable for contacting potential participants. IRB-approved letters that are mailed in a UM-endorsed sealed envelope are also acceptable methods.

However, normal texting and email for initial contact/recruitment is not recommended unless the investigator has received permission to contact the recipient after receiving information about the risks. Even if permission is received, you must use the University’s email system and type SECURE in the subject line.

Email and texting are subject to the federal CAN SPAM Act that requires permission for the individual or a specific, already established defined relationship with the individual.

Normal email and text messaging are generally not considered secure methods for communicating sensitive information, especially where prior permission has not been obtained for a specific purpose. Email/texting is subject to CAN-SPAM rules which require prior permission from the individual or a specific already-established and defined relationship. Such messaging should always have clear and conspicuous opt-out functionality.

6.3 Recruitment Materials

The IRB must approve the recruitment method and all recruitment materials before the materials are used. You should describe your recruitment process in your protocol and submit recruitment materials with your application. The IRB application should describe how you will use the materials (e.g., newspaper, Internet, radio). You must submit any additions or changes to these documents to the IRB and obtain approval before implementing the changes. More information about the requirements of advertisements and information usually included in recruitment materials can be found in WORKSHEET: Advertisements (HRP-315).

Recruitment materials may include:

- Letters, emails, or information sheets that you will send or give to potential subjects
- Advertisements
- Scripts or guides that will be used for in-person or telephone recruitment interviews- these materials should include consent content and questions, as applicable.

- Printouts of web postings or pages used for direct recruitment

Recruitment materials should NOT usually include coercive language:

- Claims that a device or drug is safe and effective
- The words “new treatment,” “new medication,” or “new drug” if the test article is investigational; promises of “free medical treatment”
- Emphasize payment or use the words “free” in large or bold face type
- Statements or implications indicating a favorable outcome or other benefits beyond what is outlined in the consent document and protocol
- Claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, or device
- Exculpatory language that appears to waive any rights of the prospective participants or indicate that the investigator, sponsor or University cannot be held liable or at fault for any research-related event.

Stock Photos:

Use of a stock photo with an individual’s likeness in recruitment materials must comply with any licensing requirements and/or the terms of use of the website or other entity sourcing the photo. If the advertisement is written as a first-person testimonial (either actual or fictitious), the IRB will require the addition of a disclaimer to the advertisement conveying that the individual in the photo is not an actual patient. This notice may appear in small type at the bottom of the advertisement as follows:

“Person(s) depicted in this photo is not actual patient or study subject.”

6.4 Screening Subjects

Screening includes collecting data directly from prospective subjects through written screening tools or questionnaires or accessing private information such as medical test results for purposes of determining eligibility. Screening activities are reviewed as part of the overall recruitment and consent process.

The protocol should include the following information with respect to screening procedures:

- The screening materials that may be used
- Data, if any, that will be collected during screening
- The location and timing of where and when the screening will take place
- Whether the investigator intends to retain data from subjects who are ineligible upon screening; and if so, why and how the data collected during the screening procedures will be stored.
- The consent process, if applicable, to screen participants.

Points to consider:

- To protect the individual's privacy, ask the eligibility questions **before** asking for the subject identifiers such as name and contact information. If the potential subject is not eligible, do not collect the identifying information.
- Screening questions should be limited to the information needed to determine whether the potential subject should come to the research site for the consent process and screening/study procedures.
- The screening consent form (if one is required) should focus entirely on the procedures for the screening visit and not on the main study. The purpose of screening is to determine if the prospective subject, who has an interest in participating in the main study, is eligible or not. The information about the main study will be in the consent form for the main study.
- Whether HIPAA regulations apply to the screening process. If screening involves review of medical records, investigators must obtain prospective HIPAA authorization, submit a [Form E](#), or apply for a waiver of HIPAA authorization and informed consent.
- Some sites use an Eligibility Log. If the log includes identifiable information about potential subjects who have not signed a consent form or authorization, the monitor cannot see that information. For best practice, the Eligibility Log should include only coded information and a link to the individual's identity can be kept in a separate file if it is needed.

6.5 Participant Payment

There are no hard and fast rules about how much subjects should or should not be paid. Subjects should be paid enough to make up for their time and trouble, but not so much that their decision to volunteer or continue in a study is influenced by the amount being offered. Subjects should not see research participation to make a living or regularly supplement their income. Large payments can suggest this possibility and can be coercive.

Just as the size of payment can put inappropriate pressure on subjects, so can the schedule of payment. Holding payment until the subject has completed every procedure in a long, multi-week, multi-visit study is inappropriate. For studies with more than two or three visits, payment should be prorated, that is, based on the amount of time subjects have spent participating so far.

Compensation Payments:

Payments that compensate for time, effort and inconvenience to parents and child participants are permissible. For tax purposes, flat-rate payments for travel, parking and meals are grouped with compensation payments. The size of payments varies with the demands of each study.

Reimbursement:

Reimbursement for expenses incurred because of research participation, such as taxi fare, other travel expenses, parking, babysitting fees, or meals, should be designed to offset actual anticipated expenses so as not to create an undue inducement. Only payments based on actual expenses can be called reimbursement.

Tokens of Appreciation:

Appreciation gifts for research participation are essentially bonuses to thank the participant for their time. These should be limited to no more than items of token value such as T-shirts, mugs, calendars, books, stuffed animals, etc.

Drawings/ Lotteries/ Raffles:

Investigators must not offer to include participants in a drawing or raffle in exchange for participation. Florida statutes prohibit “an enterprise in which, from the entries submitted by the public to the organization conducting the drawing, one or more entries are selected by chance to win a prize.”

Methods of Payment:

Depending on the needs of the study, the subject payments may be done in the following manner:

- Cash
- Check
- Gift Cards
- Electronic: Venmo, Zelle, Cash App: Electronic methods of compensation are allowed; however, the Investigator must also provide an alternative method as well when using electronic payment.
- Greenphire ClinCard: The Office of Research Administration (ORA) manages the Greenphire ClinCard reloadable debit card. The program is available to all qualifying University of Miami research studies. More information can be found at the Office of Research Administration. The IRB's template consent forms include language to be inserted if Greenphire ClinCard will be used.
- Class Credit

Payments, except for reimbursements for expenses based on actual receipts, are taxable. University of Miami Finance does not track payments to subjects for the purpose of reporting to the IRS unless there is the possibility that an individual could receive \$600 or more over the course of a single year. The IRB's template consent forms include language to be inserted if a subject may earn \$600 or more in a single year.

Chapter 7

Obtaining and Documenting Informed Consent

Informed Consent is a voluntary agreement from a research subject to participate in research. It is not merely a form. Instead, it is a process through which the subject gains an understanding of the research. Unless the IRB waives the requirement for informed consent, obtaining such consent is essential.

Consent is an ongoing process as the subject progresses through the research.

Subjects' participation must be free from undue pressure or coercion. This principle is especially true for vulnerable populations such as children, prisoners and adults with cognitive impairment. These

subjects might not be able to consent on their own behalf, but they should be allowed an opportunity to agree or disagree to participation when they have some capacity to understand the risks and procedures associated with participation.

Federal regulations and [ICH E-6\(R2\)](#) set out the information that must be included in an informed consent document. Investigators and IRB members refer to the requirements as the “elements of consent.” The regulations include a list of elements that are required during every consent process as well as a list of elements that are required under certain circumstances. The University of Miami requires additional elements to be included in consent documents. “[WORKSHEET: INFORMED CONSENT \(HRP 314\)](#)” includes all of the elements and is a helpful tool for use when drafting a consent document.

Signature blocks on the consent document are very important. ***Before submitting the consent template for approval, investigators are encouraged to assess whether the blocks intended for subject signatures are consistent with the research being done.*** For example, if the study will not include subjects who lack capacity to consent for themselves, the signature block should not include a line for a legally authorized representative to sign on the subject’s behalf and vice versa.

7.1 Categories of Consent/Assent Processes and Documents

When drafting a new consent document, investigators are recommended to use an HSRO Consent Templates, which includes language that satisfy all of the required elements including those of UM. Templates for all scenarios below may be found on the HSRO Consent Template site.

Consent – An adult subject, capable of giving permission to participate in a research study, can provide consent. The subject must be 18 years of age and competent to make the decision to participate in research.

Parental Permission – When children/minors are included in research, the parent/guardian must agree to the child being a participant through a parental permission consent document. Some situations require permission from at least one parent, while other situations require permission from both parents. Florida law requires parental permission before a minor can be included in human subject research, unless the minor’s involvement is limited to a record review, such as a medical chart review.

Assent – When an individual is unable to consent for his or herself, the investigator must obtain that individual’s agreement to participate in a study whenever possible. This agreement is referred to as assent. Assent is applicable not only to minors but also persons who are developmentally or cognitively impaired. The IRB cautions Investigators to consider: (1) whether children enrolled in research may become adults during the course of the study (2) if enrolling in a college setting, whether students within the approached cohort may be minors (3) how expressed and/ or informed assent shall be obtained from a cognitively-impaired individual, if possible.

Verbal and Online Consent (e.g., by checking a box or proceeding to online study) (non-clinical)– Generally when the IRB approves a waiver of a signed consent document, verbal consent (often with use of an information sheet) or online consent will still be required. Verbal consent means that the individual obtaining consent reads/explains a verbal version of a consent form and subjects give their verbal consent in place of written consent. For online consent, you may choose to include the information sheet as a recruitment email or at the beginning of the online study. Subjects will consent to the research by clicking "Agree" or "Continue" (or similar) if they wish to participate.

In all cases when a Waiver of Documentation of Consent (see below) is approved by the IRB, subjects should be given the opportunity to ask questions and provided with a copy (or print their own) of the information sheet. The IRB also cautions that if the study is subject to HIPAA, written HIPAA authorization may still be required unless the study also qualifies for alteration of the requirement for written HIPAA Authorization.

Short Form – A “short form” is generally used when there is a language barrier and an English IRB-approved consent is orally translated in the subject’s native language. See 7.7 [Documenting Consent with the Short Form](#).

Waiver of Documentation of Informed Consent – A waiver of documentation of informed consent (waiver of the requirement for a signature on a consent form) can be obtained under certain circumstances by the Investigator:

(1) The study involves only minimal risk and the research does not include any procedures for which written consent is required.

(2) The IRB may also waive the requirement of documentation of consent the only record linking the subject and the research would be the informed consent form AND the principal risk would be potential harm resulting from a breach of confidentiality. A consent form should be available when in case the subject wishes to be linked. The form of documentation could include any of the following:

- Note written in the study subject's record;
- A consent/assent documentation form with a signature page that is left unsigned;
- On a consent form with a page for documentation of verbal consent and when applicable; documentation of verbal assent and HIPAA Authorization.

(3) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Waiver of Informed Consent or Alteration of the Requirements for Informed Consent – An IRB may approve a waiver of informed consent or a waiver of one of the required elements of informed consent, when specific regulatory requirements are met. When the IRB approves a waiver of informed consent, the investigator may involve human subjects in the research without obtaining consent from the subject.

When the IRB approves a waiver of one or more of the elements of consent (this is called alteration), the information provided to the subject does not have to include information related to the waived element during the consent discussion or in the written consent document. This is often found in studies involving Deception or Incomplete Disclosure (See more information in Section 7.11 below).

Remote Consent – The term “Remote Consent” is used to describe the various methods that can be used to obtain consent outside of an in-person meeting. For clinical studies or other studies that require signed consent, you may, on occasion, wish to use an appropriately secure electronic signature. Studies that require FDA oversight, more information can be found [here](#).

The University uses two versions of Research Electronic Data Capture (REDCap). REDCap is accessible to all UM Faculty, Staff, and Students. External users can also access REDCap if they have a CaneID. More information on setting up a REDCap account for your study can be found [here](#). Some studies are required to use REDCap to track accruals at [UM](#). This policy applies to UM faculty and research personnel conducting IRB-approved human subject research studies in any UM or Jackson Health System (JHS) facility, as well as in the community, as defined below:

- All interventional non-treatment studies lacking any services or protocol events that are capable of generating a clinical charge in UChart (including health-related biomedical outcomes and behavioral outcome studies); or
- All non-interventional studies (See PROCEDURE section below)
- This policy does not apply to studies and research participants registered in the Velos Clinical Trial Management System (CTMS).

More information can be found on the Enrollment Tracking Using REDCap page [here](#).

Proxy Consent – When a subject cannot consent (cognitively impaired adults), Florida recognizes that a proxy (a substitute, competent decision maker in the event the patient is incompetent or incapacitated) may consent (where the patient has not executed an advance directive, or designated a Surrogate to make health care decisions) to experimental treatment, provided, the experimental treatment has been approved by and IRB, and the proxy reasonably believes that the patient would have made the decision under the circumstances. SOP:Legally Authorized Representatives, Children, and Guardians (SOP-013).

The “proxy consent” only applies to “an incapacitated or developmentally disabled patient [that] has not executed an advance directive, or designated a surrogate to execute an advance directive, or the designated or alternate surrogate is no longer available to make health care decision.” Further, the statute requires that any proxy decision “must be based on the proxy’s informed consent and on the decision the proxy reasonably believes the patient would have made under the circumstances.

7.2 Consent Templates

The FDA ,federal funding agencies, state laws and/ or UM policies have specific requirements for the information that must be provided to subjects during the consent process.

Consent templates that comply with the requirements are available on the [HSRO Website including Information Sheets when the IRB approves a Waiver of Documentation of Consent](#). For some funded studies, sponsors may provide a sample or draft consent documents. The study team must revise the sponsor’s template to include [UM required language](#).

For significant risk medical devices, the FDA considers the consent document to be a part of the investigational plan in the Application for an Investigational Device Exemption (IDE). FDA always reviews these consent documents. The Agency's review is generally limited to ensuring the presence of the required elements of informed consent and the absence of exculpatory language. Sponsors must submit any substantive changes to the document to the FDA for review and approval. The FDA is usually unaware of studies involving non-significant risk (NSR) device studies and does not review or approve consent documents for these studies.

7.3 Elements of Consent

Consent must be obtained in a manner that provides the subject with sufficient opportunity to discuss and consider whether to participate, while minimizing coercion and undue influence. Subjects must be able to understand the language used in a consent document. Consent must be provided in sufficient detail and the language/format must be organized and presented in a way that does not merely provide a list of isolated facts. Instead, the language must facilitate the prospective subject's understanding of why one might or might not want to participate. All required elements of consent in non-exempt studies may be found in HRP-314B-WORKSHEET- Requirements for Informed Consent. The requirements of consent for exempt studies, when applicable, can be found in HRP-403 – CHECKLIST – Exemption Determination.

Genetic Testing – State law (Section 760.40) has specific requirements that must be met before investigators can obtain samples, conduct genetic testing, or share results of genetic testing. More information on this law is found in Section 10.5 Florida “Protecting DNA Privacy Act” and Research.

Abuse, Neglect, Suicidality and/ or Sexual Misconduct: Some study activities may result in researchers becoming aware of Abuse or Neglect, Suicidality and/ or Sexual Misconduct. This awareness may result during or from interactions or interventions with human subjects, or from disclosure by study subjects. In Florida, UM researchers may be considered mandatory reporters, and must follow applicable law for reporting abuse or neglect. It is the responsibility of the Investigator to consider whether these topics might be addressed and:

- If there is an increased likelihood for mandatory reporting in your study, include information about this reporting in the consent document.
- Include in the protocol, the procedures to mitigate the risks and procedures to report to the proper authorities.

Diagnosis and/or treatment of STDs (including HIV and AIDS) – State law requires that practitioners report evidence of sexually transmitted diseases, including HIV and AIDS, to the county health department. For a list of reportable diseases, [click here](#). The PI must ensure that if his/ her study involves these diseases, it is reported.

As part of the consent process, prospective human subjects must be informed about researchers' mandated reporting responsibilities, with required reporting language included in the consent form (including child assent and parental permission).

7.4 Making a consent document readable

Regulations require that the consent information be in language understandable to the subject or their legally authorized representative. This means the document must be written in plain language, using lay terms, and in a language the subject understands. Language the subject understands is interpreted to mean at a level compatible with their reading comprehension.

The UM Institutional Review Boards (IRB) asks that research teams make every effort to ensure that informed consent documents be written at an approximate 8th grade level when tested against the Flesch-Kincaid (FK) grade level readability test. The IRB recommends the use of this tool as it is available as a feature within Microsoft Word's Spelling and Grammar check. The IRB recognizes that

some consent forms are of such a technical nature that it may not be possible to keep to an approximate 8th grade reading level. Investigators may discuss problems with keeping consent text at a low reading level with the staff at the HSRO. The job of submitting a quality finalized consent is the responsibility of the Investigator.

The FK is only one of many available readability formulas. Link [HERE](#) for information about other readability formulas.

Simplifying Consent Language

Drafting tips for preparing consent forms:

- Use words familiar to the non-medical reader.
- If possible, keep words to 3 syllables or fewer.
- Write short, simple, and direct sentences. Divide sentences when necessary.
- Keep paragraphs short and limited to one idea.
- Use active verbs.
- Use the second person (you) not third person (the participant) to increase personal identification.
- Use page numbers on protocol, consent, and any other documents.
- Use at least 12-point font and consider a larger font based on your audience.
- Check the text to see if each idea is clear and logically sequential.
- Highlight important points; use underline, bold, boxes rather than italics or all caps (not for compensation to emphasize payment).
- Avoid repetition.
- Avoid large blocks of printed text.
- Use photos, graphics, or tables if they will help clarify procedures.
- Be consistent with use of all terminology, such as drug/device names and abbreviations.
- Brand names of drugs or devices must be capitalized and include either the trademark or registered symbol the first time the drug name is mentioned.
- Generic drug or device names are lowercase.
- Use the appropriate abbreviation the first time a drug/device name is used in the consent.
- Abbreviations such as DNA, HIV and AIDS that have come to be accepted as standard by your proposed study population need not be spelled out.
- Do not use e.g. or etc., use instead, "for example," "so forth."
- Spell out acronyms when first used.

Drafting tips for Describing Study Procedures

- Avoid passive voice (you will be). Use active voice: "The study team will...." or "You will be asked to provide 2 tsps. of blood for a"

- Consent forms for projects that involve collection of blood or other fluids should include the amount(s) to be taken. Do not use ml. or cc. as a volume measure, give a volume equivalent in teaspoons or tablespoons. Rather than abbreviating such words as “teaspoon” and “tablespoon,” please spell them out.
- Do not use symbols such as ">"; use "greater than."
- Describe study design procedures such as "double blind," "randomized," and "placebo/controlled" when the concept(s) is/are first introduced. Example: "A placebo is an inactive substance that looks like the study drug but contains no medication."
- Do not use the words “treatment” or “therapy” to describe an investigational drug, device, or procedure. Use the term "study drug" not "study medication" when the drug is investigational. The word "medication" or "medicine" should only be used if the drug is commercially available for that condition.
- Do not use the term "treatment” or “therapy” if one of the study arms will be a placebo. Instead, use words like: “study product”, “study drug or placebo”, “study regimen” or “study procedure.”
- **Do not describe investigational drugs, devices, or procedures as “new.”** For investigational drugs or devices, state they are investigational or “experimental” and describe that term [e.g., the word "investigational" means the study drug is not approved by the U. S. Food and Drug Administration (FDA) and is still being tested in research studies.] Be consistent in using “investigational” throughout the consent form.
- Use "study doctor" (more understandable to a lay person) instead of “principal investigator."
- Use "research study," instead of "trial."
- Use the word "participant" in the consent form instead of “patient” since this is research. However, you may use “patient” when referring to the person prior to his/her entering the study. If possible, always refer to the participant as “you.”
- When describing randomization for 2 groups use, “like the flip of a coin,” for more than 2 groups, use "like drawing numbers from a hat."
- If the study may end early if the data shows futility or if the FDA may approve the IP while the research study is in process, include information on whether participants will be responsible for paying for the study drug if it is approved.
- For optional portions of the study (e.g., asking permission to store samples for future research), insert lines for initials to allow a subject to indicate his/her choice.
- For double-blind studies, include a statement that the blind can be broken in case of an emergency. Example: “In the case of an emergency, the study doctor can quickly find out to what study group you are assigned.”

NOTE: the following websites and word substitution file are helpful for drafting consent forms:

- Glossary of medical words: (<http://kidshealth.org/kid/word/>)*
- Clinical Research Glossary: (<http://www.firstclinical.com/icfglossary/>)*
- Glossary of lay terms: (<http://humansubjects.stanford.edu/general/glossary.html>)*

7.5 Translation Requirements for Consent Documents

The consent process involves providing information to subjects and the regulations require information given to subjects to be understandable to that subject.

Furthermore, to meet the regulatory requirements for approval, the IRB must find that the selection of subjects is equitable. The investigator must either justify the exclusion of people who have limited ability to understand English or develop a plan to allow their enrollment.

It may not be possible for individuals who are unable to understand English to participate when the study requires subjects to complete surveys, questionnaires, tests, diaries, etc. that are not available in other languages. Some tests are not validated in any other language than English (or Spanish).

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. Below are recommendations to assist investigators in determining whether translations are required and how proper consent may be obtained.

Subjects Abilities and Limitations	Consent Process
Subject cannot read English but can read another language	Consent document and other subject-facing documents must be in the language the subject can read
Subject cannot read. Subject can fully understand spoken English but subject primarily understands another language.	Ask the subject which language s/he prefers and read either the IRB-approved English version of the consent form or IRB-approved version of the consent form translated into the subjects' preferred language. Obtain the witness's signature on the consent document. Carefully document each step of the process in the research record.
The subject does not understand or read English. The subject speaks and understands a different language but cannot read documents written in that language.	Read the IRB-approved translated consent form to the subject in the presence of a witness. Obtain the witness's signature on the consent document. Note the subject's ability to (1) understand the different language and (2) the translated consent document was provided to the subject.

Exceptions to the above requirements:

- A subject requires rapid entry into a study for his/her well-being, but the study does not have a consent form translated in the subjects' language. A short form process may also be used and submitted by the Investigator for rapid entry. More information may be found in 7.7 Documenting Consent with the Short Form.

- You are uncertain whether non-English speaking subjects might enroll in the study or believe that the majority of subjects will speak/comprehend English. This instance is rare at the University of Miami.
- The IRB requires you to obtain consent from subjects with a revised consent document and the translated version is not yet available for a subject who does not speak or read English.

The IRB cautions that Investigators consider, prior to submitting a new study, what language(s), other than English, participants are likely to understand. Investigators must obtain IRB approval of translated consent documents and the short form process.

More information on the step-by-step process on how to properly translate IRB-approved documents and translation services may be found on the HSRO website.

<https://hsro.uresearch.miami.edu/researchers/translations/index.html>

7.6 Documenting Consent Using a Full Consent Document

Investigators must ensure informed consent from subjects, the legally authorized representatives of adults unable to consent, or the parents or guardians of children. The process begins when an individual identifies a subject as a potential candidate for a research study. The process ends when a subject or the subject's legally authorized representative provides legally effective informed consent or declines to do so. The process to document consent can be found at [HRP-090 – SOP – Informed Consent Process for Research](#).

To ensure the above information is documented, the HSRO recommends investigators to develop and use a consent checklist or template language to document informed consent.

7.7 Documenting Consent with the Short Form

A "short form" consent process is generally used when there is a language barrier, and a translated consent document is not immediately available. Investigators and research staff should carefully consider whether the potential participant must be enrolled until the IRB-approved translated version of the consent document is available. One risk of using the short-form process is that you will not obtain legally effective consent.

The following is an excerpt from guidance that explains the FDA's concern with ad hoc translations of consent documents:

In the case of non-English speaking subjects, the consent document should be the translated document. While a translator may be helpful in facilitating conversation with a non-English speaking subject, routine ad hoc translation of the consent document should not be substituted for a written translation.

If a non-English speaking subject is unexpectedly encountered, investigators will not have a written translation of the consent document and must rely on oral translation.

Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the participant does not clearly

understand the information presented, the subject's consent will not truly be informed and may not be legally effective.

Note that Miami-Dade County's language demographics can be found at [Miami Matters](#).

Below are the guidelines and considerations for using the Short Form Consent Process:

- If you believe you will enroll participants who do not understand English, describe the Short Form Consent Process in your protocol. If you are initiating the study, document this information in the main protocol. If an outside entity is sponsoring the study, document the process in the Local Protocol. Elements to include are:
 - When you will use the process,
 - How you will conduct the process,
 - How you will document the process, and
 - Your plan for obtaining consent with an IRB-approved translated consent document as soon as it is available (clinical trials).
- Use the short-form process **only** when
 - The IRB approved use of the short-form process for the study; and
 - (1) There is a potential for direct benefit to participants that is not available outside of the research; or
 - (2) The IRB approved a revised English version of the consent form, directed that currently enrolled participants sign the IRB-approved revised version; and the translated version of the document is not yet available
- Document your reasons for using the Short Form Consent Process. For example:

“This participant is unable to speak or read English. His native language is Spanish. Currently, there are no FDA-approved treatment options available for this participant that have demonstrated the potential efficacy that this investigational treatment offers (or these options carry more risk to participants than this study). Given the nature of the participant’s disease, s/he should not wait for a translated consent document. Instead, they should start investigational treatment as soon as possible (or start the screening process as soon as possible).”

Considerations during the consent process:

- During the consent process, you will use:
 - A [“short form”](#) translated into the subject’s native language; and
 - The English version of the long consent form that the translator will read to the subject.
- The short form consent discussion includes five roles:
 - The potential participant;
 - The person obtaining consent;

- A witness who is fluent in English and the language the subject understands; and
 - A person who can translate the conversation for the subject, and
 - The person who is obtaining consent.
- The translator and witness may be the same person. The [University of Miami Hospital](#) (305-243-7885) and Jackson Health System (Guest Services Department 305-585-7341) offers interpreter services.
- Do not obtain consent from the subject until you have assessed and verified that the participant understands the information in the consent document. Assess comprehension by asking the participant the questions listed in the section above.
- Whenever possible, use an IRB-approved Short Form that is translated into a language the participant understands. If you use an untranslated Short Form, the translator must orally translate the entire English version of the Short Form in a language the participant understands

The Short Form Process

- A witness who is fluent in English and the language the subject understands must observe the entire consent process.
- The translator must orally translate the entire IRB-approved English version of the consent form to the participant in a language the subject understands.
- Provide a copy of the translated Short Form to the participant. If the participant is unable to read, the translator should read the Short Form to the participant.
- The potential participant should have time to ask questions, and the person obtaining consent should answer the questions. The translator should translate this conversation for both the participant and the person obtaining consent.
- The person obtaining consent should assess the participant's comprehension of the consent document, and the translator should continue to translate the consent discussion for the two parties.
- The person obtaining consent and the witness must sign the IRB-approved English version of the consent form.
- The subject and the witness to the consent process must sign the Short Form.
- The individual obtaining consent must give copies of the signed and dated consent form and the Short Form to the subject or the subject's LAR.
- The research team must place the original signed consent form and Short Form in the subject's research record.

The individual obtaining consent should document that consent was obtained as described above in the research record. The short form process is outlined in WORKSHEET: Short Form of Consent Documentation (HRP-317).

If consent is for a clinical trial, obtain consent from the participant with an IRB-approved translated consent form as soon as one is available.

7.8 Documenting Consent Obtained Remotely

Remote consent is available when circumstances require or other reasons. Investigators must describe the remote consent process in the protocol (local protocol).

The University provides two versions of REDCap. One version is for research that is not FDA-regulated. The other version is compliant with 21 CFR Part 11, for FDA-regulated research. It is important to use the FDA version for all research involving investigational drugs, biologics, vaccines and medical devices.

When to use CTSI e-Consent Template?

Use this version for all studies that can recruit participants via teleconference web meeting and *are not FDA regulated*.

When to use the CTSI Part 11 e-Consent Template?

Use for all FDA-regulated studies. These studies require 21 CFR Part 11 compliance. For access to this application, users must complete training on REDCap Part 11 e-Consent Framework.

Conducting the Consent Process

Informed consent is a process, not just a document. You must use video conferencing for remote consent whenever it is possible. **The University requires HIPAA-compliant Zoom for Healthcare** when collecting OR viewing either private identifiable information (PII) or protected health information (PHI) in research. Contact the Telehealth team at telehealth@miami.edu.

Steps to take (Detailed information can also be found at SOP: Electronic Signatures for Documentation of Consent SOP-093):

- Send a copy of the consent document to the participant or their LAR a few days before the discussion. This step will allow them to read, develop a list of questions, and discuss the research with family or friends. You may want to go over the document with potential participants before the conference call discussed below. If you must use teleconferencing instead of Zoom, include a *witness signature line block* on the consent document and the Authorization.
- Arrange a Zoom meeting or a conference call (if you cannot use Zoom) that includes:
 - Person obtaining consent
 - Participant and LAR, if applicable
 - Additional people requested by the participant (e.g., relative, friend)
 - If you are not able to use Zoom or if the participant will not be able to provide an electronic signature, include an impartial witness
- Identify everyone on the call or Zoom
- Confirm the identity of the potential participant or the LAR by viewing their driver's license or another form of identification. If you can confirm the identity visually, document that you

recognized the individual. Another alternative is to create and provide a passcode to the potential participant via text or email and ask them for the passcode during the meeting.

- Review and explain the information in the consent document.
- Answer any questions the participant/LAR have about the study
- Ask the participant/LAR questions about the study to confirm their comprehension
- Ask the participant/LAR if they consent to participate
- If the participant/LAR agrees, ask them to sign and date the consent document electronically
- If you are unable to obtain an electronic signature, ask the participant or LAR to:
 - Sign and date the consent document;
 - Take a picture of the signed copy of the consent document; and
 - Forward the images to you.
- If there is a witness to the procedure, have the witness sign and date a copy of the document (electronically or with wet ink) and provide a copy of the signed and dated document to you.
- Sign and date the consent document as the individual obtaining consent
- Repeat the process for HIPAA Authorization, if applicable
- If the participant signed electronically, explain how they will receive a copy of the signed documents.

Impartial Witness: A person not involved in research study. Can be clinical or research personnel (not working on the study).

Role of Impartial Witness: To attest that info in the ICF and any other info provided was accurately explained to, and apparently understood by, the subject/LAR. and that consent was freely given.

Document the remote consent process:

- Explain the rationale for obtaining remote consent and HIPAA Authorization
- Document the date and time you obtained the participant's consent
- Document the list of attendees by name and role
- Document whether you obtained consent via a Zoom meeting or phone call
- Document the electronic platform used to obtain consent (REDCap)
- Document how you confirmed the participant's identity
- Document that you answered all of the participant/LAR's questions.
- Document that you assessed comprehension by asking the participant/LAR questions, and the Participant/LAR was able to answer the questions correctly and apparently understood.
- Document that the participant/LAR verbally agreed to participate or permit the participant to participate.

- Print the signed and dated copies or images and maintain a copy in the research record and upload to EPIC, if applicable. If you are using an electronic platform as a regulatory binder, transfer the images and documents electronically into the electronic platform and follow requirements for [certified copies](#).
- Document how you provided a copy of the signed and dated consent form and HIPAA authorization to the participant/LAR if you obtained an electronic or wet signature and date. You may use email to send the consent document if you include “SECURE” in the subject line with the participant’s or LAR’s permission.
- Document the circumstances if you were unable to obtain a signature and date.

7.9 Documenting Parental Permission

In Florida, minors (those under 18 years of age) generally may not consent to medical care or treatment, or research involving medical care or treatment, without a parent or legal guardian’s consent. Unless Florida law waives parental permission, researchers must obtain parental permission from the parents or the child’s guardian before involving their child in research.

A parent means biological or adoptive and a guardian means an individual authorized under state or local law to consent on behalf of the child. A guardian is the equivalent of a legally authorized representative (LAR) acting on behalf of an incapacitated adult. If you have any questions on who can consent for a minor, the HSRO recommends you contact the University of Miami, Office of General Counsel at 305-284-2700 gc.receptionist@miami.edu.

The IRB may approve a waiver of parental permission **only** for research involving retrospective or prospective record review studies when the regulatory requirements are met.

IRBs are required to make adequate provisions for soliciting the permission of each child’s parent(s), LAR, or legal guardian, based on the level of risk and expected direct potential benefit to the child, as noted below. The IRB may not require less than outlined below but may determine that more stringent requirements are appropriate.

Regulatory Category of Permitted Research with Children	Requirements for Parental Permission
Minimal Risk [45 CFR 46.404, 21 CFR 50.51]	One parent/legal guardian may be sufficient.
Greater than Minimal Risk, Direct Benefit to Subject [45 CFR 46.405, 21 CFR 50.52]	One parent/legal guardian may be sufficient, but IRB must determine whether one or two is required
Greater than Minimal Risk, No Direct Benefit to Subject, but Likely to Yield Generalizable Knowledge about Subject’s Condition [45 CFR 46.406, 21 CFR 50.53]	Both parents/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.

Greater than Minimal Risk, No Direct Benefit to Subject, but Results May Alleviate Serious Problems of Children's Health or Welfare [45 CFR 46.407, 21 CFR 50.54]	Both parents/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child
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IMPORTANT NOTE: When only one living parent or a guardian has sole custody after a divorce, the IRB may determine that single-parent or single guardian permission is sufficient.

If there are two parents available to give permission and they disagree about allowing their child to participate in the study, the child may not be enrolled unless the parents come to an agreement that the child join the study. This rule applies to all permissible categories--even if only one parent's signature is required. When both parents are involved in the decision, they must agree to enroll the child. If a parent who was not involved or available for the original consent later becomes available, the two parents must agree.

Foster Children & Wards of the State: Generally, foster parents may NOT consent for treatment or research participation for children. While State law is clear regarding consent for medical treatment, it is silent regarding consent for biomedical or behavioral research. The Department of Health has informally opined that it will not approve research involving foster children without parental permission unless the parental rights have been severed.

If children who are wards (or foster children) are to be included as research subjects, the investigator must provide the IRB with information about the proposed permission/assent process, as well as the identity and authority of the individuals who will provide consent/permission for the ward/foster subjects.

Any researchers considering research with this vulnerable population should consult with the Florida Department of Health for more specific guidance.

If the subject or their parents/guardians are non-English speaking, either the consent form must be translated into the native language, or a Short Form consent process must be used.

Before obtaining permission from an individual who is not a parent, investigators should contact the University of Miami Office of General Counsel.

7.10 Obtaining and Documenting Assent

Obtaining Assent from Children

The Federal regulations require that "adequate provisions [be] made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent... [taking] into account the ages, maturity, and psychological state of the children involved" [45 CFR 46.408; 21 CFR 50.55(a)].

In most instances, a child's refusal to participate in a research study should be honored. Mere failure to object should not, absent affirmative agreement, be construed as assent. Parents may overrule a child's

dissent only when the IRB waives the requirement for assent. The IRB may waive the requirement for assent only when:

- The capability of some or all of the children is so limited that they cannot reasonably be consulted (this limitation can be due to age and cognitive ability); or
- The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.

When research involves the provision of experimental therapies for life-threatening diseases such as cancer; however, researchers should understand that parents may wish to go to extremes, even when the likelihood of success is marginal, but the probability of extreme discomfort is high. Should the child not want to undertake such experimental therapy, and if, for example, the child is a mature adolescent and death is imminent, researchers should respect the child's wishes.

There is no regulatory requirement for a child to sign an assent document. It is up to the IRB to determine when assent is required and how assent should be documented. The abilities and needs of children vary widely and investigators should provide the information in a format tailored to the child in front of them. In some situations, the IRB may require the investigator:

- to provide written information for the child to read, or
- to rely on the individual obtaining assent to explain the study to the child, assess the child's comprehension, and obtain the child's agreement when the child can relate sufficient information about the study to demonstrate adequate understanding.
- ask the child to indicate their assent by signing a document such as an Assent Form or by signing a signature block on the Informed Consent form.
- to require the individual obtaining assent to document in the research record or on the informed consent document that the child assented.

More information on obtaining assent from children can be found: CHECKLIST: Children HRP-416.

When a child is enrolled in a study with permission from a parent or guardian and becomes an adult, you must not conduct any procedures done solely for research until you obtain consent from the new adult.

Assent from Adult Subjects

The Common Rule and FDA regulations do not discuss how to obtain consent from adult subjects who cannot personally consent; however, ICH E6(R2) Section 4.8.12 requires investigators to obtain assent from these subjects after informing them about the trial to the extent compatible with their understanding. When an adult does not have the capacity to consent to the procedures involved in the research, then they cannot participate without the consent of their legally authorized representative (LAR). (7.1 Categories of Consent/Assent Processes and Documents). If an individual has the capacity to consent, then they must consent to their own participation in the research.

In Florida, a competent adult may designate an individual of their choice to serve as their LAR (proxy). If the individual loses the ability to consent due to a temporary situation (surgery, trauma), their LAR may act on their behalf.

The investigator must develop a plan to determine whether or not the prospective adult subject has the capacity to consent and if they do not, there must be a method to determine whether there is a designated LAR who can consent on the adult's behalf.

Furthermore, the IRB recommends the Investigator to consider whether the study involves long-term interventions or interactions with participants who have a progressive condition such as Alzheimer's and method to determine an ongoing consent process on the adult's behalf.

Whenever possible the Investigators will obtain the assent of adults who are not capable of consenting for themselves. When assent is obtained, it will be documented in the consent form. To have the capacity to assent, the subject must be able to understand the general purpose of the research and the nature of the procedures and must be able to understand the concept of voluntariness. If the capability of some of the participants is limited so that they cannot reasonably be consulted, assent will not be obtained; the investigators will document it on the consent form.

More information on obtaining assent from Cognitively Impaired Adults can be found: CHECKLIST: Cognitively Impaired Adults (HRP-417).

When an adult subject who was enrolled through the proxy consent process from an LAR regains capacity to consent, you must obtain consent from the adult subject before conducting any procedures solely for research purposes.

7.11 Deception or Incomplete Disclosure

The IRB recognizes that deception and incomplete disclosure may be practical research methodologies. At times, especially in social and behavioral research, deception or incomplete disclosure is necessary to avoid study bias or test a hypothesis that requires the participant's misdirection.

Deception is when researchers purposely mislead participants by providing overt misdirection or false information about some aspect of the research, whether it is in the procedures or the purpose of the study. An example of deception might include:

Subjects complete a quiz, and the researchers tell them that they did very poorly, regardless of their actual performance.

Incomplete disclosure is when researchers withhold information about some aspect of the research, whether it is in the procedures or the research purposes. For example:

As a research procedure, subjects complete a quiz, but the researchers do not tell them that the research question involves how background noise affects their ability to concentrate.

Researchers ask participants to read a list of words or view a series of images, but the researchers do not tell them that they will test the participant's memory.

Using deception or incomplete disclosure presents challenges for the ethical conduct of research. It could interfere with the participant's ability to decide whether or not to participate in the study.

When is deception allowed?

In keeping with federal regulations and ethical codes, the IRB will consider the following points when reviewing research involving the use of deception or incomplete disclosure:

- Whether the proposed study involves only minimal risk.
- Whether the deception or incomplete disclosure is justified in the protocol. The researcher must show that they cannot perform the study in the absence of deception, and the benefits of the research will sufficiently outweigh any risks that deception may create.

Deception will not be approved when:

- The research could use alternative methods that will yield valid study results.
- The deception deprives participants of the opportunity to protect their own interests, which would cause them physical or emotional harm.
- The missing information affects the participants' ability to assess the risks of participation or their willingness to participate.
- The deception puts participants in a position of engaging in illegal or stigmatizing behavior.

Consent & Deception/ Incomplete Disclosure:

If you use deception or incomplete disclosure, you must obtain consent before engaging a participant in any study procedures. Investigators must submit a copy of the initial informed consent document, script, or information sheet. The IRB will consider the research and determine if the study meets the requirements for an alteration of the consent process. See 7.1 Categories of Consent/Assent Processes and Documents (Waiver of Informed Consent or Alternation of the Requirements for Informed Consent) for more information (CHECKLIST: Waiver or Alteration of Consent Process HRP-410).

Whenever possible, investigators should inform participants that information is being withheld or is not completely accurate as part of the consent process. Advance knowledge of the deception or incomplete information allows the participant to agree to these conditions before participating.

Sample language when deception language can be a part of the consent process:

For scientific reasons, this consent form does not have all the details about the research questions [or study procedures] we are testing. After you complete the study, we tell you everything about the study. You will have a chance to ask all the questions you have.

Debriefing

Debriefing explains the rationale for using deception as a research technique and must be presented to participants as early as possible.

Investigators must explain the debriefing process in the protocol they submit. The protocol must indicate (1) how participants will be debriefed, (2) who will debrief them, and (3) when the research team will debrief them. The HSRO developed a [Deception Addendum](#) for this purpose.

Investigators must also include a debriefing sheet/script with the IRB submission documents. You can find a [sample script](#) on the HSRO website.

Debriefing as an Educational Tool: Some participant pools recommend that researchers solicit feedback after the study concludes to further educate participants instead of giving previously withheld or false information. This feedback is not debriefing in the sense of the IRB ethics review and the regulations. In such cases, the original consent may mention that the research will ask for feedback.

Exceptions to Debriefing: There may be rare instances when debriefing would be inappropriate, such as when doing so would cause more harm than good or when the researchers cannot locate or contact participants. If you use deception and request not to debrief participants, you must provide a compelling rationale in your protocol for not debriefing. For example, the research chose participants because of an unattractive physical characteristic or "negative" behavior such as bias, bigotry, or an unattractive physical trait.

7.12 Re-Consent or Notification of Subjects About Significant New Findings after study approval

Obtaining a signature on a consent form does not complete the consent process. Maintaining informed consent requires that the investigator provide subjects with any new information that arises during the study that may impact their participation or their decision about whether to continue participation in the study.

When new information related to the study becomes available, new risks are identified, significant study alterations are made, or the initial consent process is found to be inadequate, the IRB has the authority to require investigators to re-consent or notify subjects.

Three notification methods that are commonly used in the IRB are:

- **Verbal notification:** The subjects can be notified verbally in person or via a phone call. The discussion must be documented in the research record.
- **Letter notification:** The subjects can be notified via email (if permission was obtained to communicate by email)/U.S. letter. The Investigator must obtain IRB approval before using it.
- **Re-consent:** The Investigator must re-consent subjects who want to continue in the research study with the revised consent form that includes all the new information.

For increased study risks, the investigator should notify the subjects promptly (within 30 days) and re-consent the subjects after the availability of the IRB-approved updated consent document. The changed risks should be highlighted in the consent document presented to the subjects.

The table below is to aid in determining notification requirements.

Table: Considerations for Notification of Subjects

<i>Type of information</i>		<i>Active subjects*</i>	<i>Subjects has completed procedures and all study visits*</i>	<i>Suggested Notification Methods*</i>
New risk or increase risk of drug/study procedures	Short-term/immediate risks	Yes	Not likely	Phone Letter Reconsent
	long term or late-occurring risk	Yes	Yes	Phone Letter
Decreases in expected benefit are identified		Yes	Not likely	Reconsent
New alternative options available.		Yes	Not likely	Phone Reconsent
Procedural changes that are added that increase risks or burdens of participants		Only for subjects will undergo.	Not likely	Reconsent
Changes to remuneration/reimbursement		Yes	Not likely	Reconsent
Changes to injury-related compensation		Yes	Not likely	Reconsent
New identified Conflict Interest		Yes	Not likely	Reconsent
New research findings at UM or elsewhere		Yes	Yes	Phone Letter Reconsent
Changes in study contact/PI		Yes	Yes	Phone Letter
Subjects who may lose the capacity to consent for themselves over the course of the study and will require surrogate consent if they still meet the inclusion criteria		NA	NA	Reconsent
When a child is enrolled in a study with permission from a parent or guardian and becomes an adult		NA	NA	Reconsent

** Notification requirements may be altered by the IRB under certain circumstances.*

Chapter 8

Required IRB Reports

The IRB requires investigators to submit reports of events as part of the IRB's responsibilities to oversee the study. The IRB will review the information, determine if it must require changes in the protocol or consent document. The IRB will also determine if the study meets the [definition](#) of any of the following:

- Serious Non-compliance
- Continuing Non-compliance
- Unanticipated Problems Affecting Subjects or Others

The IRB must report the following to institutional officials and regulatory authorities such as the FDA or the Office for Human Subject Protections:

- Serious Non-compliance
- Continuing Non-compliance
- Unanticipated Problems Affecting Subjects or Others
- Suspension of the study or of any study procedures such as enrollment
- Termination of IRB approval

Further guidance of reporting requirements can be found at: SOP: New Information (HRP-024)

- ***For studies under the external IRB, please refer to the guidance in Chapter 4 Reliance and Cooperative Agreements for IRB Oversight.***

8.1 Reports of New or Increased Risk (Submit within 10 business days)

Investigators are required to submit reports of unanticipated problems involving risks to subjects or others (UPIRSTO) to the IRB within ten business days. Well-written protocols anticipate and delineate the likely serious events and list the ones that will not be reported. A UPIRSTO is any event that is:

- Unexpected (incidence rate/severity beyond expected);
- Related to the study; and
- Indicates there is a risk to the subjects or others that was not previously known.

The following are various methods sites receive information about new or increased risk. If you are reporting one of these events, select "Risk" on the RNI Form.

Examples of New or Increased Risk:

1. An updated Investigator Brochure or package insert includes revisions to risk profile or expected adverse reactions
2. A sponsor or safety monitoring report or letter identifies a new adverse event that is now considered expected.
3. An investigator finding indicates revisions to the risk profile or new expected adverse reactions
4. A harm (physical, psychological, economic or social harms - than was previously known or recognized) experienced by a subject/other individual, which the sponsor believes is unexpected and probably related to the research procedures.
5. A protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
6. A withdrawal, restriction, or modification of a marketed

8.2 Reports of External Serious Adverse Events/IND Safety Letters

Do not submit reports of external adverse events that the sponsor has not analyzed, and when the sponsor does not state:

- (3) The event is unexpected;
- (4) The event is related or probably related to the study; and

- (5) The event's existence means there is a new risk to subjects or others that was previously not known.

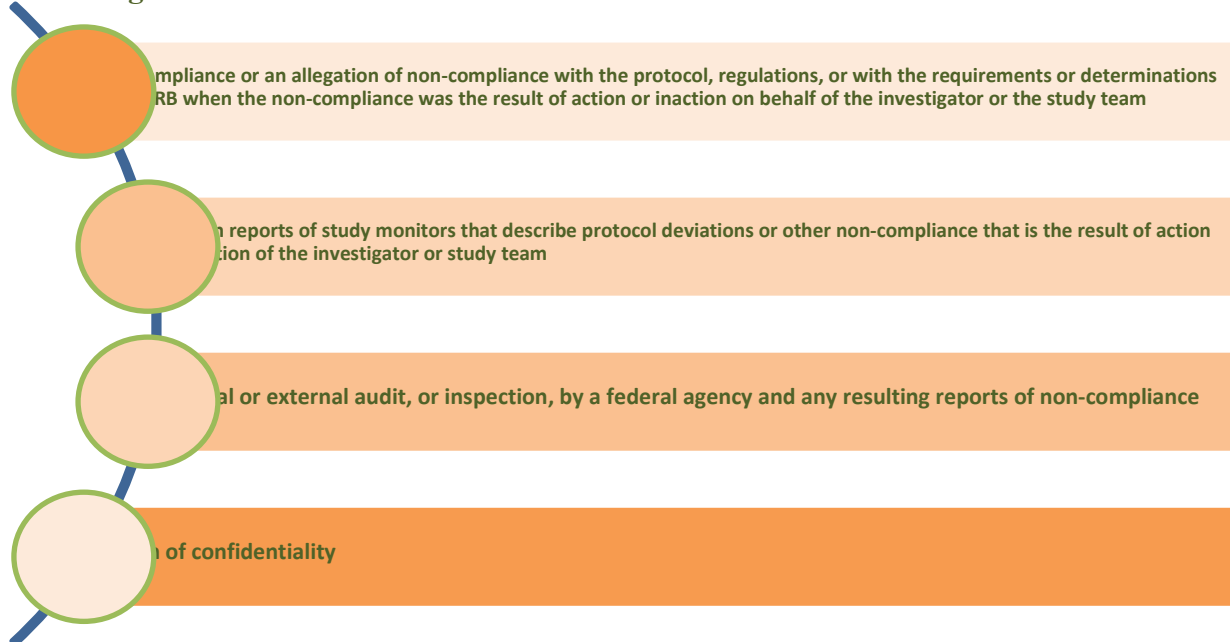
Refer to [FDA guidance](#) for more information on this requirement.

8.3 Reports of Non-Compliance (Submit within 10 business days of knowledge)

Investigators must submit reports of non-compliance that result from an action or inaction of an investigator or study team member. If a research participant is frequently or continuously non-compliant with study requirements, you must address the non-compliance or consider withdrawing the participant. Please contact the HSRO for guidance “Study team member” includes departments that support the research, such as the laboratory, nursing, or Investigational Drug Services.

The University of Miami must inform Jackson Health Systems of noncompliance that occurs at a JHS facility. You must report the location of deviations and other non-compliance.

Examples of Non-Compliance that must be reported within ten (10) business days of knowledge



8.4: Protocol Deviations/ Violations

Protocol deviations or violations are any alteration or deviation from the IRB-approved research plan as defined in the study protocol. Protocol deviations are not usually anticipated and those that result in harm or have the potential for harm are considered UPIRSTO.

When writing the protocol, try to anticipate where problems might occur and add flexibility to avoid protocol deviations. In particular, there should be a reason for each inclusion and exclusion criteria and these criteria should be adhered to rigidly. Study visit windows and blood draw windows should be wide enough to prevent inadvertent protocol deviations when subjects can't keep visit appointments.

When protocol deviation/violations occur, an RNI Form should be submitted in IBISResearch within 10 business days and should include:

- A summary of what happened;
- An analysis of why (root cause) the event occurred; and
- An action plan describing the steps that have been or will be taken to prevent recurrence of the same or similar events.

Planned protocol deviation:

Note: An investigator may deviate from the protocol **whenever necessary to protect the subject's health, rights, or welfare**. For example, a study medication should be stopped if a subject develops a medically significant adverse reaction during administration. The physician should provide whatever medical treatment is needed necessary to the subject, without regard to whether the medications are permitted in the protocol.

Whether the request is for a "planned deviation" which is really a request for a "single subject" or "one-time" protocol change or future requests for the same deviation, then the protocol should be amended via an IBISResearch Modification Form.

In non-urgent/emergent situations, the investigator must obtain IRB-approval for the planned deviation via an IBISResearch Modification Form. This modification should include the detailed deviation, the reason as to why the deviation is necessary, approval from the sponsor, etc.

In urgent/emergent situations when there is not sufficient time to obtain IRB-approval, i.e., an immediate change is necessary to eliminate an apparent hazard to the subjects who are in imminent risks, the investigator may implement the changes before IRB approval. An RNI report must be submitted within **5 business days** following the guidance for emergency use (**Chapter 11**).

8.5 Other Required Reports (Submit within ten (10) business days of knowledge)

1. A subject's complaint that the study team cannot resolve
2. Premature suspension or termination of the protocol by the sponsor, investigator, or institution.

Quick Reference for submissions of reports; See WORKSHEET: Review of Information Items (HRP-321) for more information.

Type of Information	Reporting Mechanism
Modification to IRB-approved protocol, research plan, consent document, or recruitment material	Modification
Planned Protocol Deviation- Single Participant and one-time use	Modification
*Updated Investigator Brochure/ package insert. <i>Note: Consider whether the updates warrant a modification to the IRB-approved protocol, research plan, and/ or consent documents prior to submitting to the IRB.</i> ** Updated Investigator Brochure or package insert includes revisions to risk profile or expected adverse reactions when an updated consent is unavailable at the same time	*Modification ** RNI
Reports of New or Increased Risk (Submit within 10 business days)	RNI
DSMB Report, Letter from Sponsor (Dear investigator letter, Change to the study status, etc.)	RNI (or may be submitted at continuing review if no new risks)
Certificate of Confidentiality (COC), if the Investigator actively applies for a COC	Modification
Translated Consent Forms	Modification
External IND Safety Report/SAE	Do Not Report
Executed Clinical Trial Agreement or Budget	Do Not Report
Notice of New Grant Award	Modification
Disclosure of New Financial Interest	Modification (w/i 30 days)
Emergency Use (see Chapter 11)	RNI

Chapter 9

Investigator Responsibilities

9.1 General Responsibilities

Principal Investigators (PI) are required to conduct and supervise the Human Subject Research **personally**. Although the PI may delegate tasks to members of his/her research team, s/he retains the ultimate responsibility for the conduct of the study. The process starts with the decision to perform the study, the design of the study, the communications with the IRB, the oversight of the study execution, the analysis and reporting of data, and the storage of the study data after study completion. In addition, the PI is responsible for complying with the requirements listed below.

1. Protect the rights, safety, and welfare of subjects involved in the research.
2. Do not start Human Research activities until:
 - a) You have received and read the final IRB approval letter and HSRO acknowledgment notice, when applicable;
 - b) The clinical trial agreement is finalized; and
 - c) You have received all other [required institutional ancillary approvals and Department approval](#).
3. Ensure that there are adequate resources to carry out the research safely. Resources include sufficient investigator time, appropriately qualified research team members, equipment, and space.
4. Before delegating research staff to conduct protocol-related procedures, ensure each staff member is qualified to perform research procedures. “Qualified” means a research staff member has:
 - a) Has the necessary licensure or other qualifications to fulfill the role;
 - b) Completed the disclosure certification process using the [UDisclose](#) as required (See Chapter 2).
 - c) Completed all required [institutional training](#); and
 - d) Received training on the specific research procedures they will conduct and has demonstrated an ability to comply with the requirements.
 - e) Investigators should meet regularly with their research teams to review the progress of the research, and to encourage discussion of any concerns about the research in general, or about a specific research subject.
5. Update the IRB office with any changes to the list of study personnel after ensuring study personnel have satisfied all the requirements in #4 via a Modification Form in IBISResearch.

6. Comply with the most current version of the IRB-approved protocol, applicable federal regulations, local laws, institutional requirements, and IRB requirements. Do not **purposefully** deviate from the protocol unless the situation meets one of the following requirements:
 - a) The deviation is necessary to protect a subject from imminent harm; or
 - b) If the study is under an IND or IDE, the sponsor, IRB, and FDA must approve of the deviation in advance. (See Section 8.3: Protocol Deviations/ Violations and reporting requirements)
7. Do not modify any IRB-approved document or make any revisions to the Human Research protocol without prior IRB review and approval unless the revision is **necessary to eliminate** apparent immediate **hazards** to subjects.
8. When required by the IRB, ensure that consent is obtained as outlined in the relevant current IRB-approved protocol, applicable regulations and HSRO SOPs.
9. Maintaining adequate and accurate research subject records to reflect adherence to protocol specific requirements.
10. Maintaining adequate, current, and accurate records of research data, outcomes, and reportable new information to permit an ongoing assessment of the risk/benefit ratio of study participation.

PIs conducting a clinical investigation of an investigational drug, device or biologic must comply with their responsibilities to supervise the clinical investigation. The HSRO recommends that investigators read and adhere to the FDA Guidance – Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects

9.2 Additional Responsibilities for FDA-regulated products

Clinical investigations involving investigational drugs and devices are subject to FDA jurisdiction and must be conducted in compliance with FDA regulations:

- [21 CFR §50](#) Protection of Human Subjects (includes the requirements for informed consent and involvement of children in a clinical trial)
- [21 CFR § 54](#) Financial Disclosures by Clinical Investigators
- [21 CFR § 56](#) Institutional Review Boards
- [21 CFR § 312](#) Investigational New Drug Applications (includes requirements for conducting a clinical investigation of an investigational drug or biologic)

- [21 CFR § 812](#) Investigational Device Exemptions (includes the requirement for conducting a clinical investigation of an investigational device).

Investigators must be familiar with and understand the information included in these regulations, when they are applicable to the research being conducted. Specifically, the investigator must understand:

- IRB Review and Oversight
 - Must be obtained before starting a clinical investigation or before implementing changes to an investigation unless the change is needed to eliminate an imminent hazard to subjects. Note: According to the FDA, planned protocol deviations such as enrolling a participant who does not meet inclusion criteria require prior-IRB approval.
- Supervision of the Clinical Trial
 - Investigators are required to personally supervise clinical investigations, including:
 - Training, delegation and oversight of study team members; and
 - Protecting the rights, welfare and safety of subjects in the investigation
 - Ensuring the data collected are reliable.
- Investigational Product Control and Accountability
 - Investigators must follow FDA requirements for control of the investigational product¹
 - Administer the product only to subjects under the investigator's personal supervision or under the supervision of a sub-investigator responsible to the investigator.
 - Do not provide an investigational drug or device to any person not authorized to receive it.
 - Maintain records of receipt and disposition of the investigational product, including dates, quantity, and use by subjects.
 - Return or dispose of unused supplies of the investigational product as directed by the sponsor.
- Comply with the Protocol
 - Ensure that you and your research team understand the protocol and the procedures the team member is delegated to perform.

¹ <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.61>

- Develop tools to ensure that resources are available for each study visit.
- Develop checklists for study visits to ensure that each required procedure is performed.
- Do not implement any revisions to the protocol without obtaining IRB and sponsor approval unless the revision is necessary to eliminate an imminent hazard to subjects.
- Case Histories
 - Maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation. Case histories include:
 - Case report forms and supporting data including
 - Signed and dated consent forms
 - Medical records
 - Physician progress notes
 - Checklists used to maintain compliance
 - Nurses' notes.
 - The case history for each individual must document that informed consent was obtained before the participant was involved in any procedures done solely for research.
- Investigator Reports
 - All clinical investigations
 - Financial Disclosure
 - The investigator and each study team member must submit financial disclosure statements annually and within 30 days of acquiring an interest.
 - Provide the sponsor with sufficient accurate financial information to allow complete and accurate certification or disclosure statements as required under [21 CFR § 54 Financial Disclosure by Clinical Investigators](#)
 - DSMB Reports, even if they do not propose any revisions to the research
 - Progress reports to the sponsor for collecting and evaluating the results obtained.
 - Final report to the sponsor shortly after completion of the investigator's participation in the investigation.
 - Continuing Review, reports of unanticipated problems involving risks to subjects or others and all other reports required by the IRB.
 - Investigations of drugs and biologics
 - Adverse event reports to the sponsor
 - Serious adverse events must be reported promptly
 - Investigations of Devices

- [Unanticipated adverse device effects](#) to the sponsor and IRB no event later than 10 working days after the investigator first learns of the effect.
 - Deviation from the protocol to protect the life or physical well-being of a subject in an emergency to the sponsor and IRB for device studies within 5 working days.
 - Withdrawal of IRB approval: To the sponsor, within 5 working days, a withdrawal of approval **of a device study** by the IRB.
 - Informed consent. If an investigator uses a device without obtaining informed consent, the investigator must report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.
- Record Keeping and Record Retention (See Section 10.5)

9.3 ICH Guideline for Good Clinical Practice E6(R2)

Most industry sponsors require investigators to comply with [ICH Guideline for Good Clinical Practice E6 \(R2\)](#) (ICH). This guideline is guidance in the United States but is considered law in some other countries. You should review the protocol to see if your study must comply with ICH. Sponsors who want to submit marketing applications in countries that require compliance with this guideline must ensure investigators understand and comply with the guidance during the conduct of their trials.

Much of the information in this guidance is like the FDA regulations discussed above. However, in several areas the guidance differs or includes much more detail on the requirements. For example, the guidance includes a section entitled, *Essential Documents for the Conduct of a Clinical Trial*, which describes the documents that must be available for “evaluation of the conduct of the trial and the quality of the data produced.” You must ensure that you maintain the documents exactly as outlined in this guidance when you study must comply with ICH. The HSRO will review your clinical trial to see if it complies with ICH when the protocol requires such compliance, with the following exceptions:

- The IRB will not require the consent document to include a description of the risks of alternative treatments.
- The IRB will approve a consent form that includes a request to the participant to informing his/her regular physician about the participants’ involvement in the research, but will not add the language if the sponsor’s template doesn’t include it.

If your protocol requires you to comply with ICH, you and your study team must carefully read the guidance so you are aware of the requirements.

9.4 Issues to Consider when a Participant Withdraws From a Study

1. For research subject to FDA regulations, investigators cannot remove the data collected on the participant to the point of withdrawal. These data remain part of the study database.²
2. Investigators are allowed to retain and analyze already collected data relating to any participant who chooses to withdraw from a research study or if the investigator terminates the participants' involvement in the study when the analysis falls within the scope of the analysis described in the IRB-approved protocol. This statement is true, even if that data includes identifiable private information about the participant.
3. For research not subject to the FDA regulations, you should consult with the funding entity to decide whether to honor a research participant's request to destroy the participant's data or exclude the participant's data from any analysis.
4. When a participant decides to withdraw from a clinical trial, the investigator conducting should ask the participant to clarify whether they want to withdraw from all trial components or only from the interventional part of the trial. If the participant chooses the latter, research activities, such as follow-up data collection activities (imaging, laboratory studies, etc.), for which the participant previously gave consent may continue.
5. Suppose a participant withdraws from the interventional portion of the study but agrees to continue with follow-up of associated clinical outcome information as described in the previous bullet. In that case, you should document the subject's decision. In some instances, such as when the main consent form doesn't discuss remaining in the study after stopping study treatment, you should consider obtaining additional consent from the subject. If you have questions about a specific situation, contact the HSRO for guidance.
6. If a participant withdraws from the interventional portion of a study and does not consent to continued collection of clinical outcome information, you must not access the participant's medical record or other confidential records for study-related purposes from the point that they withdraw their consent.
7. OHRP also recommends that the investigator explain to the subject who wishes to withdraw the importance of obtaining follow-up safety data about the subject. The consequences of withdrawal from a clinical trial must be outlined in the Informed Consent Form. OHRP recommends that IRBs consider whether and how the withdrawal of a subject should be reported to the IRB. While not required under the Common Rule, such reporting to the IRB may be most appropriate for biomedical research involving more than minimal risk. Depending on the circumstances, it may be appropriate to submit an individual report of a subject's withdrawal promptly or to document this occurrence in the next continuing review report. For example, it may be appropriate to submit a report of a subject's withdrawal promptly if the withdrawal was related to an unanticipated problem involving risks to the subject.

² <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126489.pdf>

9.5 Maintaining Research Records

Principal investigators are required to create and maintain research records and documents. These records and documents (including data collected pursuant to research) are the property of the University. You must not remove or destroy research records until you are sure the retention requirements no longer apply. You must maintain human research records for the time specified by federal regulations, clinical trial agreements and University policy. If the requirements between the regulations, agreements and policies differ, you must maintain the records for the maximum time required. Guidance for quality improvement in research for Investigators can be found at: CHECKLIST: Investigator Quality Improvement Assessment (HRP-430). The following are the requirements for maintaining specific documents:

Jurisdiction	Document Examples	Time Frame
Federally funded Human Research Records	All research documents, including protocols, signed and dated consent documents, source documents, etc.	At least 3 years from study closure date
Research under FDA Jurisdiction	All research documents, including protocols, signed and dated consent documents, source documents, etc.	At least 2 years after the date a marketing application is approved for the drug under study; or, if no application will be filed or is not approved for such indication, 2 years after the study is discontinued and FDA is notified. If industry sponsored, you should comply with the Clinical Trial Agreement and contact the sponsor before destroying records.
Documents subject to the Federal Privacy Rule (HIPAA)	Signed authorizations for use and disclosure of protected health information.	Six years after completion of the research
Research covered by a clinical trial agreement or other funding agreement	All research documents, including protocols, signed and dated consent documents, source documents, etc.	As required by the agreement – As a best practice, you should contact the sponsor before destroying records

9.6 Conducting Research Outside of the United States

When conducting research outside of the US, investigators should ensure that participants have the same level of protection as those in the US. Investigators must know about the local laws and customs that apply to the research and the cultural context in the area. When the IRB determines that the research is exempt from the requirements of 45 CFR 46, the investigators are responsible for ensuring that research complies with local regulations and requirements.

The IRB will consider the experience of the UM investigator in working in this area or region and the investigator's knowledge of the area or region as it relates to the research.

When you are conducting research outside the United States, you should consider:

- **Will you obtain review by an IRB/research ethics committee located in the country where you will be doing research?** Some countries do not have IRBs/research ethics committees, and in some countries the IRBs review only biomedical research – we understand that IRB review in another country is not always possible, but expect that investigators obtain review by an IRB/research ethics committee in the country where research will take place whenever possible – it is the PI's responsibility to determine whether there is an IRB/research ethics committee that can review proposed research in the countries where they plan to collect data.

The Office of Human Research Protection (OHRP) provides a compilation of regulations and guidelines governing human subjects in other countries. (see [OHRP International Compilation of Human Subject Protections](#)). OHRP requires researchers to ensure that people outside the US have the same protections as participants in the US. For federally funded research, the regulations of the funding agency apply; it is not sufficient to provide "equivalent" protections.

- **Could sociocultural factors affect the consent process in the countries/regions where you will do research?**
 - Culture, customs, law, low rates of literacy may affect a researcher's ability to obtain consent from potential subject.
 - The risks associated with the research may differ (be greater) due to social norms.
 - Are there risks to subjects that would be greater than if the research were conducted in the US, etc?

HHS regulations allow IRBs to waive the requirement for a signature on a consent document for minimal risk research conducted in a community where signing consent forms is not the norm.

- If you will conduct human research with personal data about individuals located in (but not necessarily citizens or residents of) the European Union member states and the

European Economic Area, GDPR will apply. See 10.4 General Data Privacy Rule (GDPR).

- If you will be collecting data that are sensitive, you must use good data security practices to collect, store, and transport your data. Keep in mind that officials in other countries, as well as U.S. Customs and Border Protection, could potentially try to access data stored on a phone, laptop, or other device.

9.7 NIH Genomic Data Sharing (GDS) Policy Requirements

The [GDS Policy](#) applies to all National Institutes of Health (NIH) funded research that generates large-scale human or nonhuman genomic data and of these data for subsequent research. If your research involves large-scale genomic data and the NIH is funding it through a grant, contract, or cooperative agreement, you must comply with the policy.

Large-scale data include:

- **genome-wide association studies (GWAS),**
- **single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data.**

Contact your NIH Program Officer as early as possible to discuss data-sharing expectations and timelines for a proposed study.

Office of the Vice Provost for Research + Scholarship (OVPRS) and IRB Roles

Under the GDS Policy, individuals who provided the samples for the research must have been informed that the research will use their samples for genetic and genomic research. They must also know that researchers will share genomic data from the research broadly for secondary research. To ensure the requirements are met, the IRB and institutions must certify that the consent document adequately informed research participants.

Consent Form Requirements

- **For tissue collected before January 22, 2015 – The language should not prohibit data-sharing.**
- **For tissue collected after January 22, 2015 – The language should describe data-sharing. [Click Here](#) for guidance.**
- **For new studies or modifications, include the template language from Part 3, Genetic/Genomic Data Sharing language from the [Biomedical Template Consent Document](#).**

The IRB and institution must also consider whether sharing the data will place individuals at risk because they are:

- In a small sample size,
- From an isolated or identified geographic region,
- Part of a rare disease community, or
- Part of a group with potentially stigmatizing traits.

Investigator Requirements

- Include a [Genomic Data Sharing Plan](#) in your proposal.
- Provide a more detailed data sharing plan to the NIH with your Just-In-Time submission.
- Ensure your consent form complies with the GDS Policy.
- Submit the following to HSROletterrequest@miami.edu:
 - Completed [GDS Certification Form](#);
 - Copies of all approved consent documents.
 - If you will use biological samples collected for another purpose, obtain a copy of the consent form that was used to acquire the samples from the individuals who donated them.

- The Human Subject Research Office (HSRO) will review the documentation and forward it to the Vice Provost for Research and Scholarship (VPRS) for signature with the IRB's opinion on whether the data sharing requirements are appropriately met.

Once the OVPRS's signature has been obtained, the certification will be returned to the Principal Investigator for submission to the NIH.

Chapter 10

Privacy and Confidentiality

Investigators must take steps to ensure that protections are in place to protect participants' privacy and confidentiality. Before approving research involving human subjects, the IRB must determine that the participants' privacy and confidentiality are protected.

Privacy is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. For example, persons may not want to be seen entering a place that might stigmatize them, such as a substance abuse treatment center or a pregnancy counseling center that is clearly identified by signs on the front of the building. The evaluation of privacy also involves consideration of how the researcher accesses information from or about potential participants (e.g., recruitment process). IRB members consider strategies to protect privacy interests when investigators recruit, intervene or interact with participants, and when the research accesses their private information.

When conducting research, you must consider that people want to control the following:

1. The time and place where personal information is obtained or given;
2. The nature of the information obtained or given;
3. What they will experience when providing personal information;
4. Who will receive and use the information.

What is private depends on the individual and can vary according to gender, ethnicity, age, socio-economic class, education, ability level, social or verbal skill, health status, legal status, nationality, intelligence, personality, and the individual's relationship to the researcher.

For example, protecting the privacy interests of a young child might mean having a parent present at a session with a Researcher. Protecting a teenager's privacy interests might mean having a parent absent during a session.

Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be shared with others without permission. For example, when recording research data, the HSRO usually requires investigators to remove the identifiers from the information, apply a code as needed and maintain the link between the participant's identity and the code in a separate location.

Steps to protect confidentiality include:

1. Use participant codes to label data instead of using names, and keeping a separate list of code-to-name match-ups.
2. Encrypt research data.
3. Limit access to only those that require access and have been identified within an approved IRB protocol.
4. Obtain and use only the minimum information needed to conduct the study.
5. Ensure you have a strong password and change it regularly
6. Obtain a Certificate of Confidentiality (COC), when appropriate. Note: If the study is sponsored by HHS, an automatic COC is issued by the NIH.

UM Studies in which identifiable data is being shared outside of the University of Miami or being stored in systems not provided and maintained by the University of Miami may be subject to review by the Data Security Ancillary Committee (DSAC) prior to receipt of IRB approval. Any studies requiring DSAC approval will be routed to the DSAC by IBISResearch. If DSAC approval is required, you must complete the [Research Data Security Assessment Form](#) and upload the form onto the Local Site Documents section on IBISResearch in Other Attachments. For more information, you may contact the Data Security Ancillary Committee at dsac@miami.edu.

De-identified, Coded, or Anonymous:

- Data are **coded** when a link will exist between a unique code and individual subjects' identifiers such as name, medical record number, email address or telephone number. Generally, the data is collected with a "Study ID," and a linkage file is maintained where the Study ID is associated with the subject's identifiers. The code should not be a combination of information related to the individual, such as initials, date of birth, etc.
- Data are considered **de-identified** when any direct **or** indirect identifiers (codes) linking the data to the individual subject's identify **are destroyed or there is no potential for deductive disclosure**. De-identification can occur by removing the code from the dataset or destroying the linkage file. At this point, no data can be linked back to an individual. A list of the 18 direct identifiers can be found in Section 10.1 HIPAA Privacy and Security Rules.
- Anonymous: OHRP describes coded and de-identified and does not define anonymous in the regulations. Data are anonymous if no one, not even the researcher or a third party or vendor, can connect the data to the individual who provided it through direct identifiers such as name, address, IP address or any type of identification number or indirect identifiers (i.e., other unique individual characteristics like age, race, socioeconomic level, etc.) that might make it possible to identify an individual from a pool of subjects. 10.1 HIPAA Privacy and Security Rules

All University of Miami data are classified according to the Data's sensitivity, value, criticality, and associated risks. The classification of Data shall consist of identifying, sorting, defining, and assigning each item of Data into one of four classifications: Confidential, Private, Sensitive, or

Public; and ensuring adequate and reasonable levels of protection and privacy for all classification levels of Data as required and needed. (Link to: UM Policy “Data Classification”, PolicyStat ID 11935009)

10.1 HIPAA Privacy and Security Rules

The HIPAA Privacy and Security Rules affect research that uses, creates, or discloses Protected Health Information (PHI).³ The Health Insurance Portability and Accountability Act (HIPAA), also known as “The Privacy Rule,” set standards and regulations to protect patients from inappropriate disclosures of their protected health information (PHI) that could cause harm to their insurability, employability and/or their privacy.

HIPAA allows for researchers to access and use PHI when necessary to conduct research. Not all research is subject to HIPAA regulations; **HIPAA only affects research that uses, creates or discloses PHI.**

The difference between PII (private identifiable information) and PHI (private health information) is that PHI is a subset of PII ; PHI is any information in the medical record or designated record set that can be used to identify an individual **and** that was created, used or disclosed in the course of providing a health care service such as diagnosis or treatment. PII data are **not**: (1) obtained or generated as part of a health care service (treatment, payment, operations, medical records), (2) entered into a medical record, or (3) used to make treatment decisions. Also, health information by itself without the 18 identifiers (see below) is not considered to be PHI.

Your approval letter will identify which method(s) the IRB approved.

PHI may be available in any form, including physical records, electronic records (ePHI), or spoken information. Investigators are responsible for identifying in the IRB application all proposed access to PHI which will occur during the research, including:

- Access to medical records to identify and screen potential participants; Any intended access and addition of information into medical records;
- Any collection or use of human specimens with individually identifiable health information attached.
- **Any radiologic images that combine sets or series of images with a description of the patient and the modality. Together they are considered PHI.**

The IRB will determine whether you can access PHI while conducting research at the UM by these methods:

- Authorization - Each participant (or the participant’s legally authorized representative) signs and dates a completed written authorization, permitting the use and disclosure of the participant’s information for the research purposes. When obtaining an authorization, an

³ Any identifiable health information that is used, maintained, stored, or transmitted by a HIPAA-covered entity (ce)

participant's ability to receive research-related treatment as part of a research study is conditioned upon the individual's agreement to sign the authorization form. However, in presenting the authorization form to prospective subjects, researchers must not suggest that failure to sign the form will limit access to any treatment that may be available outside the study. Any questions about the availability of treatment outside the study should be referred to the prospective subject's physician(s);

- [Limited Data Set with Data Use Agreement](#) - The Privacy Rule permits a covered entity (CE), without obtaining an Authorization or a waiver of Authorization, to use and disclose PHI included in a limited data set. A limited data set (LDS) is described as health information that excludes certain, listed direct identifiers (Name, Medical Record Number (MRN), Telephone number, email etc.) but that may include city; state; Zip Code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers. A data use agreement (DUA) is the means by which the CE can obtain satisfactory assurances that the recipient of the limited data set will use or disclose the data set only for specified purposes,
- [Certification for Reviews Preparatory to Research \(FORM E\)](#) – Permits access to PHI for participant identification, assessing feasibility and other activities in preparation for research after submitting the Certification to the IRB and receiving an acknowledgement;
- [Investigator Certification for Research with Decedents' Information \(Form D\)](#) – Access to PHI relating to deceased individuals is permitted when an investigator submits a completed and signed [FORM D](#) to the IRB and receives an acknowledgement from the IRB;
- Waiver of Authorization – A waiver of authorization may be granted in situations where an individual's authorization to access their PHI will not be obtained. The IRB may waive authorization for an entire study or just for recruitment purposes. The waiver may only be approved by the IRB when specific regulatory requirements are met. The IRB will also expect the PI to provide an attestation that:
 - o o The PI will destroy the Protected Health Information (PHI) he/she and/or the Study Team acquires or receives from JHS and/or UHealth at the earliest opportunity.
 - o o The PI will confirm that the Protected Health Inform (PHI) he/ she acquired from JHS and/or UHealth will not be re-used or disclosed to any other person or entity, except as required by law or for authorized oversight of the research study or for other research for which the use or disclosure of PHI is permissible.

Your approval letter will identify which method(s) the IRB approved.

Patients have a right to receive an accounting of disclosures of PHI except for disclosures for treatment, payment, healthcare operations, pursuant to an authorization and disclosures in a limited data set. Investigators must follow UHealth policies when accessing PHI through a waiver of authorization or through one of the other exceptions listed above.

De-identified health information is not subject to HIPAA. Information is considered de-identified under HIPAA when it does not include any of the identifiers listed below.

- Name
 - Geographic subdivisions smaller than a state (address, city zip code)
 - Dates relating to the subject except for year for individuals < age 90
 - Telephone numbers
 - Fax numbers
 - Email addresses
 - Social Security Numbers
 - Medical record numbers
 - Health plan beneficiary numbers
 - Account numbers
 - Certificate/license numbers
 - Device identifiers and serial numbers
 - Web Universal Resource Locators (URLs)
 - Internet Protocol (IP) address numbers
 - Biometric identifiers, including finger and voice prints
 - Full face photographic images and any comparable images;
 - Any other unique identifying number, characteristic, or code except a code assigned to allow for information de-identified to be re-identified by the covered entity.
- Vehicle identifiers, serial numbers, including license plate numbers

“[SOP: Privacy & Security Procedures For Human Subject Research \(HRP-098\)](#)” describes the procedures investigators, IRB Members and HSRO staff must follow when research involves the use or creation of PHI.

10.2 Federal Education Records Act (FERPA)

The purpose of the Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; [34 CFR Part 99](#)) is to protect all student and parent information maintained in an Education Record.

The law applies to all schools that receive funds from the U.S. Department of Education (ED). FERPA regulates the disclosure of Personally Identifiable Information from youth. The purpose of FERPA is to protect all student and parent information maintained in an Education Record.

Education Records are records that contain information directly related to a student and maintained by an educational agency or institution or by a party acting for the agency or institution. Protected records include Education Records held by public elementary and secondary schools, school districts, intermediate education agencies, state education agencies, and any public or private agency or institution that uses funds from ED.

Investigators are responsible for adhering to the requirements of FERPA when accessing Education Records. FERPA stipulates that an educational institution has the authority to determine

what information may be accessed from an Education Record. If an institution denies an investigator access to information in an Education Record, the IRB cannot overrule the decision.

FERPA regulations specify that a parent or adult student must provide a signed and dated written consent before the institution can disclose Personally Identifiable Information from Education Records, unless the disclosure falls within one of few exceptions allowed under FERPA. Before accessing education records, you must discuss the access with the [UM Registrar](#), even when the records are already in your possession.

The HSRO will comply with FERPA requirements when reviewing research protocols that involve access to student Education Records. In most instances, the IRB will not be able to waive consent for access to student records for research purposes.

10.3 Certificates of Confidentiality

A Certificate of Confidentiality (CoC) adds a layer of privacy protection for participants enrolled in research involving sensitive information. A CoC primarily protects against compulsory legal demands, such as court orders, warrants, and subpoenas, for identifying information or identifying characteristics of a research participant. All human subject research funded by the NIH have a CoC. Investigators can apply for a CoC for studies that not NIH-funded (see below) when the research gathers information about subjects that might be damaging, and which will only exist in the research study records (that is, the information is not already in other records that are subject to subpoena).

If your study is NIH-funded, the research has a Certificate of Confidentiality. You must comply with the requirements and protect the participants' data from access. You must include the required CoC language in the consent document.

If a CoC covers your study, you must understand and comply with the [responsibilities associated with the CoC](#). One main responsibility is to protect the subject identifiers from access.

Another responsibility is to include language about the CoC in the consent document. The required language is included in the [HRP 502 – TEMPLATE CONSENT DOCUMENT](#).

You should consider obtaining a COC when your research gathers information about subjects that might be damaging, and which will only exist in the research study records (that is, the information is not already in other records that are subject to subpoena). Also, during its review of research for which an investigator has not identified the need for a COC, the IRB may require CoC as an appropriate protection for the proposed research.

How to Obtain a CoC for Non-NIH Funded Studies:

You should apply for the CoC at least three months before you plan to start enrolling subjects. The CoC must be in place before you collect any data about human subjects. You need to obtain IRB approval before you apply for the CoC.

1. Include language about your intent to obtain a CoC in the protocol.
2. Include description of the CoC in your consent document using the language in the [HRP 502 – TEMPLATE CONSENT DOCUMENT](#).
3. Submit your research for IRB approval.
4. When you receive IRB approval, complete the on-line NIH CoC application by following the directions in the [CoC Kiosk](#). Include the following:
 - a. Include a copy of the IRB approval letter and the approved consent document.
 - b. You must also submit an assurance document.
 - c. Send the Assurance letter signed by the PI to HSROletterrequest@miami.edu who will return the signed CoC to the PI for submission to the NIH.
5. When you receive the CoC Approval letter, forward a copy to the HSRO office via a Modification. **Enrollment may start after the HSRO acknowledges/ approves the modification.**
6. If the research project will extend beyond the expiration date on the CoC, you may submit a written request to the Certificate Coordinator for extension of the date. If the request is approved, an amended Certificate will be issued. You must forward the amended CoC Approval Letter to the IRB when you receive it.
7. If a significant change in the research project is proposed after a CoC is issued, you must inform the Certificate Coordinator of the Institute issuing the certificate by submitting an amended application for a CoC (in the same form and manner as the original application for a Certificate). Significant changes include: major changes in the scope or direction of the research protocol, changes in personnel having major responsibilities in the project, or changes in the drugs to be administered (if any) and the persons who will administer them.

How should researchers respond to requests for CoC protected data?

Researchers who receive a legal request for protected research data (public records or FOIA request, subpoena, etc.) should immediately contact the HSRO at (305) 243-3195. Additional guidance on CoCs is found on the [NIH Website](#).

10.4 General Data Privacy Rule (GDPR)

The GDPR applies to human research involving personal data about individuals located in (but not necessarily citizens or residents of) the European Union member states and the European Economic Area. The GDPR also regulates personal data processed by entities located in the European Union and European Economic Area. The following countries adopted the GDPR:

Austria	Belgium	Bulgaria	Croatia
Republic of Cyprus	Czech Republic	Denmark	Estonia

Finland	France	Germany	Hungary
Greece	Ireland	Italy	Latvia
Lithuania	Luxembourg	Malta	The Netherlands
Poland	Portugal	Romania	Slovakia
Slovenia	Spain	Sweden	

When research data about human subjects is transferred to one of the countries listed above, the recipient must comply with the GDPR.

The GDPR is much broader than the HIPAA Privacy and Security Rules and applies to most information that directly or indirectly could identify an individual, including names, addresses, phone numbers, dates of birth, IP addresses, cookie identifiers, device information, advertising identifiers, financial information, geo-location information, social media information, consumer preferences, etc.

In most instances, the GDPR requires consent and/or notice to individuals before investigators can process (collect, create, use or share) personal data subject to the GDPR.

For additional GDPR resources and information please visit the UM Compliance [website](#). For questions regarding GDPR please contact the Privacy Office at 305-243-500 or email at privacy@miami.edu.

10.5 Florida “Protecting DNA Privacy Act” and Research

A Florida law, effective October 1, 2021, makes the results of a DNA analysis the exclusive property of the person who was tested.

This law ***requires express consent*** from individuals in Florida, their individual's legal guardian, or their authorized representative before researchers can:

- collect a biological sample to perform a DNA analysis;
- analyze their DNA;
- submit their biological sample for DNA analysis or conduct or obtain said analysis; and
- sell, disclose or transfer the DNA sample or the genetic testing (DNA) results to a third party.

This law considers each of the above actions a separate crime. Performing any one of the above activities without express consent could result in felony charges.

To obtain express consent, you must obtain an affirmative agreement from them after you disclose to the individual the following, when applicable:

1. The method you will use to collect the sample for DNA analysis;
2. The purpose(s) for collecting the sample or conducting the DNA analysis;
3. How you (or others) will use the sample and the resulting analysis;
4. How you will retain and maintain the sample and the analysis;
5. Whether and how you will share the sample;
6. Whether and how you will disclose the DNA analysis.

The HSRO has included the language in the consent template for biological studies and studies involving biological samples. You must obtain the individual's signature and date on a consent document to demonstrate their affirmative agreement.

There are some exceptions to the requirements for express consent, including research funded by the National Institutes of Health (NIH) and research of investigational drugs, biologics, vaccines and medical devices subject to FDA regulations.

What about ongoing research?

This new law applies to any of the activities listed above that occur on or after October 1, 2021. After September 30, 2021, investigators must have express consent or must qualify for an exception from the express consent requirement to collect biological samples for DNA analysis, perform a DNA analysis or share the samples or the data from the analysis.

10.6 Secondary Subjects in Research

When private, identifiable information is obtained about individuals other than the primary participant, then these individuals become secondary subjects of the research. Private information must be individually identifiable (i.e., the identity of the subject is known or may readily be ascertained by the investigator or associated with the information) in order for the investigation to constitute research involving human subjects. In general, private information is individually identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that by their nature a reasonably knowledgeable person could ascertain the identities of individuals.

Examples of activities involving secondary subjects include:

- Collecting family medical history on specific family members;
- An unemployed person provides household income information for a two-person household in which only one household member is employed.
- A subject in a clinical trial provides pregnancy information about his pregnant partner.

When investigators involve secondary subjects in research, they must consider that subject's privacy and consent requirements. The IRB may waive the requirement for consent or a signature on a consent document if the regulatory requirements are met.

Chapter 11

Emergency/Treatment Use of an Unapproved Drug, Biologic or Device

11.1 Emergency Use of an Unapproved Drug, Biologic or Device

The regulations allow clinicians to use an unapproved drug, biologic or device without IRB approval in limited circumstances; however, the clinician must comply with FDA requirements in these situations.

When seeking to use an unapproved product, it is critical that the patient and his/her licensed physician consider all possible risks because the FDA has not determined whether the products are safe. Such products may, or may not, be effective in the treatment of the condition.

When you decide that the investigational product is the best option for the patient:

- Contact the sponsor and obtain authorization;
- Contact the FDA to obtain approval.
 - a) For an investigational drug or biologic call (888) 463-6332 or email druginfo@fda.hhs.gov
 - b) For an investigational device call (301) 796-7100 or email dice@fda.hhs.gov.
- If time permits, submit an [Emergency Use Request Form](#) to the IRB via email at cmg345@med.miami.edu or contact an IRB Chair to discuss the use.
- If time permits, you must obtain informed consent from the patient using [TEMPLATE CONSENT DOCUMENT – Expanded Access \(HRP 502\)](#). If the patient is not able to provide informed consent due to incapacity and there is insufficient time to obtain consent from a legally authorized representative, see the instructions below.

You must **report the use** of the unapproved drug, biologic or device to the IRB through an IBISResearch submission within five business days using the electronic Report of New Information Smart Form (RNI). Regulations require that you submit this report even when you discussed the use of the investigational product with the sponsor and IRB Chair. If you fail to submit the report within five days, you will be restricted from submitting new Human Research until the IRB receives this report. Use the form, [Emergency Use Report](#), to report the use. Please upload this report to the RNI.

You must submit the completed
Emergency Use Report Form within five days of
using an FDA-regulated investigational
product without approval from a convened IRB.

Finally, according to the FDA, the emergency use regulation, you can only administer an investigational product once without IRB approval. If there is any possibility that you will need to use the same investigational product with the same patient or with a different patient, you must submit a protocol to the IRB and obtain an IND or IDE from the FDA. The FDA regulations have provisions for expanded access use through a treatment protocol.

Physicians must limit their use of an investigational product for a single indication. If the course of treatment will last longer than a month, you must submit an expanded access protocol to the IRB. If there is a likelihood that

See [SOP Emergency Use and Expanded Access \(HRP-023\)](#) and [FDA Guidance on Expanded Access](#) for additional information.

11.2 Exception to Informed Consent Requirement for Emergency Use

The FDA regulations allow physicians and investigators to use an investigational product without obtaining informed consent when the investigator, and a physician who is not involved in the study, certify the following in writing:

1. The human subject is confronted by a life-threatening situation necessitating the use of the test article;
2. Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from the subject;
3. Time is not sufficient to obtain consent from the subject's legal representative; and
4. There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

If the investigator is not able to obtain the second opinion due to time constraints and the above requirements are met, the investigator must:

1. Make and document the required determinations above;
2. Have a physician who is not part of the research review record and evaluate the documentation;
3. Have the physician sign the document indicating his/her concurrence;
4. Submit the document to the IRB by completing the form, [Emergency Use Report](#), and submitting it with an RNI in IBISResearch within five business days of using the investigational product without informed consent.
5. If the investigational product is a device, the investigator must submit a report of the event to the sponsor.

11.3 Treatment (Compassionate) Use

Under FDA regulations ([21 CFR § 312.300](#)), expanded access (often referred to as “treatment use” or “compassionate use”) is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device).

This access is for treatment outside of a clinical trial when no comparable or satisfactory alternative therapy options are available. While expanded access is not a clinical investigation, you must obtain an FDA IND or IDE and IRB approval.

The IRB will require an IBISResearch submission for initial review that includes:

- Protocol
- [TEMPLATE CONSENT DOCUMENT – Expanded Access \(HRP 506\)](#), completed to describe the investigational product and the procedures
- Information about the investigational product such as an investigator brochure.

If the need for the investigational product is urgent, the IRB will forego the requirement for a formal protocol but will require sufficient information to render the determinations required under [21 CFR § 56.111](#). In these instances, the IRB will require:

- Information about the efficacy and risks of the investigational product;
- Information about the patient’s condition supporting a finding that the patient has a condition for which no other comparable treatment or therapy is available ;
- FDA approval of use of the investigational product (IND or IDE);
- The procedures the physician will follow, including the procedures to monitor patient safety during and after use of the investigational product.

Click [HERE](#) for information about the FDA’s requirements,

11.4 Right to Try

The “Right to Try Act” ([H.R.878 - Right to Try Act of 2017](#)) allows investigational drugs, biological products or devices without FDA approval.

UM strongly encourages physicians to use the expanded use pathway initiated by the FDA (described above) for patients who seek unapproved medications for life-threatening diseases or conditions. Therefore, physicians should gently inform patients who invoke the Right to Try Act of the following:

- The Act does not require institutions to accede to requests for unapproved drugs
- UM follows Federal research regulations, and
- Efforts to obtain unapproved drugs should be made to the FDA under its emergency use expanded access program.

To be eligible for “Right to Try,” the patient must:

- Have a life-threatening disease or condition;

- Have exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug; and
- Must provide written informed consent for use of the investigational drug. The patient's LAR may provide this consent if the patient is not capable.

The licensed physician who is in good standard with their licensing organization must certify that the requirements above are met and must not be compensated directly by the manufacturer for the certification.

The investigational drug or biologic must meet the following criteria:

- A Phase 1 clinical trial must have been completed;
- The drug/biologic/device must not have been approved FDA approved for any use;
- One of the following must be met:
 - An application has been filed with the FDA;
 - The drug/biologic is undergoing a clinical trial subject to an IND that is intended to provide data to support FDA; or
 - Clinical trials are ongoing and have not been discontinued or placed on hold by the FDA.

11.5 Humanitarian Use Device (HUD)

“A Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease that affects fewer than 8,000 individuals in the United States per year. To be considered for HUD status, a device sponsor must complete a humanitarian device exemption (HDE) application with the FDA.

An approved HDE application authorizes the applicant to market the HUD, but the approval is based on evidence of safety and probable benefit (rather than the “higher” standard of reasonable assurance of effectiveness). The labeling for the HUD must state that the device is a HUD and that the effectiveness of the device has not been demonstrated.

Before a HUD, under an approved HDE, can be used at the University of Miami/Jackson Health System for clinical care, approval by an IRB is required, except for emergency use. A HUD is the only situation where federal regulations require the IRB to approve and monitor an activity that is clearly not research. The primary reason for this requirement may be to give notice to the institution that the HUD will be used. It should be noted that the IRB's approval for the use of a HUD at a facility to treat or diagnose patients while providing clinical care does not mean that there is IRB approval of a clinical investigation involving the HUD.

The IRB has the discretion to determine the conditions of HUD use. The IRB may approve the use of the device in general, in a specific number of patients, only under specific circumstances.

The regulations require that an IRB conduct both initial and continuing reviews of a HUD. **The initial review of HUDs must be done at an IRB's convened meeting (21 CFR 56.108).** The regulations do not require informed consent to use a HUD outside the setting of a research

protocol; however, the IRB generally requires informed consent to be obtained, when appropriate. The IRB will specifically ask for a statement from the local user that the HUD is not being used as a part of a research project or clinical investigation designed to collect data to support an FDA pre-market approval application.”

Chapter 12

Requirements for Federally Funded Research

12.1 Department of Defense (DOD)

When Human Research is conducted or funded by the Department of Defense (DOD), the University of Miami commits to apply the Department of Defense (DOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D. The University of Miami will comply with the terms of the DFARS clause or comparable language used in the agreement with the Department of Defense (DOD) Component supporting the research involving human subjects.

1. Service Members Service members may need to obtain permission to participate in research involving human subjects, even when the service member is off-duty.
2. Payments to Subjects
 - DOD employees may not be able to legally accept payments to participate in research and should check with their supervisor before accepting such payments.
 - Military personnel must not receive payment for participating in research procedures during duty hours.
 - Military personnel may receive payment for participating in research procedures when not on duty.
 - Federal employees may receive up to \$50 for blood each blood draw, even while on duty.
3. Reporting Requirements

The following must be reported promptly (within 30 days) to the DOD human research protection officer:

 - When significant changes to the research protocol are approved by the IRB.
 - The results of IRB continuing review
 - Change of reviewing IRB
 - When the institution or investigator is notified by any Federal Department, agency or national organization that any part of the HRPP is under investigation for cause involving a DOD supported research protocol.

Other specific requirements of the Department of Defense research be found in the “Additional Requirements for Department of Defense (DOD) Research” section in the HSRO’s [“WORKSHEET: Additional Federal Criteria \(HRP-318\)”](#) and in [“SOP: NEW INFORMATION \(HRP-024.\)”](#)

12.2 Department of Energy (DOE)

When Human Research is conducted or funded by the Department of Energy (DOE), this Institution commits to applying the Department of Energy (DOE) O 443.1C which includes the requirements to apply 10 CFR §745 and Subparts B, C, and D of 45 CFR §46, as applicable.

1. Research that involves one or more of the following is considered by DOE to be *human subjects research* and requires IRB review:
 - Intentional modification of the human environment
 - Study of human environments that use tracer chemicals, particles or other materials to characterize airflow.
 - Study in occupied homes or offices that:
 - Manipulate the environment to achieve research aims.
 - Test new materials.
 - Involve collecting information on occupants' views of appliances, materials, or devices installed in their homes or their energy-saving behaviors through surveys and focus groups.
2. If the research includes use of personally identifiable information, investigators must complete and submit to the IRB and the DOE [“DOE Institutional Review Board Template for Reviewing Human Subjects Research Protocols that Utilize Personally Identifiable Information \(PII\).”](#)
3. The IRB must report the following to the Department of Energy human subjects research program manager within 48 hours:
 - Any significant adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken or to be taken
 - Any suspension or termination of IRB approval of research
 - Any significant non-compliance with Human Research Protection Program procedures or other requirements; and
 - Any compromise of personally identifiable information.
4. Requirements for human participant protections for classified research apply to all research conducted or supported by the DOE, including contracts, and including Human Terrain Mapping research.

Other specific requirements of the Department of Energy (DOE) research can be found in the “Additional Requirements for Department of Energy (DOE) Research” section in the HSRO’s [“WORKSHEET: Additional Federal Criteria \(HRP-318\).”](#)

12.3 Department of Justice (DOJ) and Bureau of Prisons

When Human Research is conducted or funded by the Department of Justice (DOJ), the University of Miami commits to apply 28 CFR §22. When Human Research is conducted with the federal Bureau of Prisons (DOJ), the Institution commits to comply with 28 CFR §512.

1. The Department of Justice (DOJ) has not joined the 2018 revisions to the Common Rule. All DOJ funded research must follow the old 2018 Common Rule.
2. DOJ funded research projects must:
 - Not involve medical experimentation, cosmetic research, or pharmaceutical testing.
 - Comply with policies for the operation of prison facilities and protection of human subjects.
 - Research conducted in the Bureau of Prisons must be reviewed and approved by the Bureau Research Review Board.
3. Any investigator who is a non-employee of the Bureau of Prisoners must sign a statement in which the investigator agrees to adhere to the requirements of 28 CFR §512.
4. Payments to Subjects
 - The only incentives allowable to confined inmate subjects are soft drinks and snacks to be consumed at the test setting.
 - Nominal monetary compensation for time and effort may be offered to non-confined research subjects who are no longer in custody.
5. Records and Confidentiality
 - DOJ funded research must have a privacy certificate approved by the National Institute of Justice Human Subjects Protection Officer
 - Under a privacy certificate, investigators and research staff do not have to report child abuse unless the subject signs another consent document to allow child abuse reporting.
 - All researchers and research staff are required to sign employee confidentiality statements, which are maintained by the principal investigator.
 - The consent document must indicate that the National Institute of Justice is the funding agency.
 - The confidentiality statement on the consent document must state that confidentiality can only be broken if the subject reports immediate harm to subjects or others.
 - A non-employee of the Bureau of Prisons may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as statistical research or a reporting record is provided to the agency.
 - Written consent from the subject is required before investigators release or share any identifiable information for any reason, including judicial, administrative or legislative proceedings.
 - Records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system. Thus, all data must be stored in a de-identified, coded manner.

- All investigators and research staff are required to sign employee confidentiality statements, which are maintained by the investigator.
- The following must be sent to the National Archive of Criminal Justice Data in a de-identified manner:
 - All data
 - Informed consent document
 - Data collection instrument
 - Surveys
 - Other relevant research materials.

6. IRB Application

For research conducted within the Bureau of Prisons, investigators must submit a summary statement to the Bureau of Prisons IRB, which includes:

- Names and current affiliations of the investigators
- Title of the study
- Purpose of the study
- Location of the study
- Methods to be employed
- Anticipated results
- Durations of the study
- Number of subjects (staff or inmates) and the amount of time required from each
- Description of risk or discomfort involved as a result of participation.
- A Comprehensive statement that includes the following:
 - Review of related literature.
 - Detailed description of the research method.
 - Significance of anticipated results and their contribution to the advancement of knowledge.
 - Specific resources required from the Bureau of Prisons.
 - Description of all possible risks, discomforts, and benefits to individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur.
 - Description of steps taken to minimize any risks.
 - Description of physical or administrative procedures to be followed to:
 - i. Ensure the security of any individually identifiable data that are being collected for the study.
 - ii. Destroy research records or remove individual identifiers from those records when the research has been completed.
 - Description of any anticipated effects of the research study on institutional programs and operations.
 - Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.

7. Reporting Requirements

- Progress Reports to the Chief, Office of Research and Evaluation, are due annually.
- At least 12 working days before any report of findings is to be released, you must distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance.
 - An abstract must be included in the report of findings.

8. Requirements for publication

- Investigators must acknowledge the Bureau's participation in the research project in all publications
- Investigators must expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
- Prior to submitting for publication, the results of a research project conducted under this subpart, You must provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

Other specific requirements of the Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP) can be found in the “Additional Requirements for Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP)” section in the HSRO’s [“WORKSHEET: Additional Federal Criteria \(HRP-318\).”](#)

12.4 Department of Education (ED)

When Human Research is conducted or funded by the Department of Education (ED), this Institution commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.

1. Each school at which the research is conducted must provide an assurance that they comply with the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA).
2. The school in which the research is being conducted must have policies regarding the administration of physical examinations or screenings that the school may administer to students.
3. Parents or children involved in ED funded research must be able to inspect copies of all surveys and instructional material used in the research.

Other specific requirements of the Department of Education (ED) Research can be found in the “Additional Requirements for Department of Education (ED) Research” section in the HSRO’s “WORKSHEET: Additional Federal Criteria (HRP-318).”

12.5 Environmental Protection Agency (EPA)

When Human Research is conducted or funded by, or when the results of research are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA), this

Institution commits to applying 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.

1. Research conducted, supported, or intended to be submitted to EPA is subject to Environmental Protection Agency Regulations and must be approved by the EPA Human Subjects Research Review Official (HSRRO) before the research may begin.
2. Research involving intentional exposure of pregnant women or children to any substance is prohibited.
3. Observational research involving pregnant women and fetuses are subject to additional DHHS requirements for research involving pregnant women ([45 CFR §46 Subpart B](#)) and additional DHHS requirements for research involving children ([45 CFR §46 Subpart D.](#))
4. If proposed research involves children, the risk of the research must be minimal or there must be a potential for direct benefit to the child.

Other specific requirements of the Environmental Protection Agency (EPA) Research can be found in the "[Additional Requirements for Environmental Protection Agency \(EPA\) Research and Research Intended to be submitted to the Environmental Protection.](#)"

Chapter 13

HSRO Resources and Contact Information

Much of the information you need can be found on the HSRO website, including:

[HSRO Forms and Templates](#) – This is where you will find the following forms:

- HIPAA Forms (Form D and Form E)
- Cooperative Research Forms – External IRB Reliance Application, External Site Application, IRB Authorization agreement
- Emergency Use Request and Emergency Use Report (including translated forms), cooperative research, and emergency use of an investigational product. Corporate Research forms, & Emergency Use forms.
- Protocol Templates
- Consent Templates

HSRO Standard Operating Procedures – This where you can find this manual and copies of the HSRO Standard Operating Procedures.

For general questions about submission and procedures, call (305) 243-3195 or visit the [HSRO Contact Page](#).

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Chair, HSRO, Institutional Office (IO)/Institutional Operator (OO), Legal Counsel or Department Chairs.

Chapter 14

Obtaining Additional Information

14.1 Common Rule

[2018 45 CFR 46](#)

[Pre-2018 45 CFR 46](#)

14.2 FDA Regulations

[21 CFR 50](#) – Protection of Human Subjects, Informed Consent, Additional Safeguards for Children in Clinical in Clinical Investigations

[21 CFR 56](#) – Institutional Review Boards

[21 CFR 312](#) – Investigational New Drugs

[21 CFR 812](#) – Investigational Device Exemptions

[21 CFR 812 Subpart H](#) – Humanitarian Use Devices

14.3 [**FDA Information Sheet Guidance for Institutional Review Boards \(IRBs\), Clinical Investigators, and Sponsors**](#)

14.4 [ICH E6\(R2\) Good Clinical Practice](#)