IBIS #: Click here to enter text. Principal Investigator: Click here to enter text.

Study Title: Click here to enter text.

1. ***General Instructions for Use of this Form***

* *Use this template to prepare a document that provides information specific to the conduct of this study an UM/JHS only.*
* *Upload the sponsor’s protocol and this local addendum in the Protocol section of the Basic Information page in the IBIS New Study SmartForm.*

1. **Procedures Involved**
2. Please describe, in detail, procedures that will occur ***at this site*** if they are not already described in the protocol. This site-specific protocol addendum must be revised, as applicable, with study amendments and must accompany the protocol each time the protocol is submitted to the IRB.  
   Click here to enter text.
3. Are there any study components or sub-studies that are described in the protocol in which University of Miami/Jackson Health System subjects will not participate (e.g., pharmacokinetic studies enrolling subjects only at select sites, optional genetic testing, etc.)?   
   Yes No
   1. ***If yes,*** list which study components or sub-studies will not have subject participation at this site:

Click here to enter text.

1. Are there any site-specific differences to eligibility criteria (e.g., if enrollment of minors is permitted per the protocol, but minors will not be enrolled at this site)?  
   Yes No   
   1. ***If yes,*** list differences:  
      Click here to enter text.
2. Vulnerable Populations\*

If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

* If the research is DHHS, DOD, or DHS funded and involves pregnant women, review “CHECKLIST: Pregnant Women (HRP-412)” to ensure that you have provided sufficient information.
* If the research involves neonates of uncertain viability or non-viable neonates, review “CHECKLIST: Non-Viable Neonates (HRP-413)” or “HRP-414 – CHECKLIST: Neonates of Uncertain Viability (HRP-414)” to ensure that you have provided sufficient information.
* If the research involves prisoners, review “CHECKLIST: Prisoners (HRP-415)” to ensure that you have provided sufficient information.
* If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review the “CHECKLIST: Children (HRP-416)” to ensure that you have provided sufficient information.
* If the research involves cognitively impaired adults, review “CHECKLIST: Cognitively Impaired Adults (HRP-417)” to ensure that you have provided sufficient information.

1. **Setting**
2. Describe the sites or locations of the research activities at this site (i.e., where the study interventions, tests, and procedures will occur).

Click here to enter text.

1. **Local number of subjects**

Indicate the total number of subjects to be accrued locally

1. **Local Recruitment Methods**
2. Who will identify potential subjects and how will they be identified (e.g., medical record screening, approached in clinic)? *If you will conduct a medical record review to identify subjects, complete the request for a waiver of HIPAA authorization in Section VII, question 7 below.)*  
   Click here to enter text.
3. When and where will subjects (or their legally authorized representative) be approached about participation?  
   Click here to enter text.
4. **Informed Consent Process**
5. Does the study require a Waiver or Alteration of Informed Consent? *Review the HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process.*

Yes No   
  
If yes, please provide justification for the requested waiver.  
Click here to enter text. ***If yes, skip the following questions and go to Section VII.***

***(If the research involves a waiver of the consent process for planned emergency research, review the CHECKLIST: Waiver of Consent for Emergency Research (HRP-419) to ensure you have provided sufficient information for the IRB to make these determinations.)***

1. Does the study require a Waiver of Written Documentation of Consent? *Review the HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent.*  
   Yes No   
     
   If yes, please provide justification for the requested waiver and include a description of the information that will be provided to the potential participant prior to undergoing screening.  
   Click here to enter text.
2. Where will the consent process take place (e.g. a private clinic room)?  
   Click here to enter text.
3. Describe the timing of documenting consent (i.e., how long will subjects be given to consider participation):  
   Click here to enter text.
4. Will persons with impaired decision-making capacity be enrolled in the study?

Yes No

***If yes,*** specify:

* 1. Who will determine if the subject is able to provide informed consent?

Click here to enter text.

* 1. How will capacity to provide consent be determined?  
     Click here to enter text.
  2. Are subjects likely to regain capacity during the study, and if so, what will be the process to obtain consent?

Click here to enter text.

* 1. If subjects may lose decision-making ability during the study, describe the process to identify the Legally Authorized Representative (LAR), when this will be done, how the LAR will be notified, and how the LAR will be involved in the study. Also describe how decision-making ability will be monitored over the course of the study.  
     Click here to enter text.

1. Is it possible or anticipated that non-English speakers will be enrolled in this research study?

Yes No

***If yes,*** specify:

* 1. In what language(s), other than English, are translated documents anticipated to be required?

Click here to enter text.

* 1. Will the documents be formally translated to the above languages?  
     Yes No
     1. If documents will not be translated and you are requesting authorization to use the written Short Forms for consent, please indicate the maximum number of times you intend to use the short forms: Click here to enter text.   
        *NOTE: Authorization to use the short forms is up to the discretion of the IRB and not guaranteed.*

1. If study will involve enrollment of minors,
   1. Will assent be obtained from the minors?

Yes, all minors  No, none of them   
 Yes, some of them; Explain: Click here to enter text.

* 1. Will minors enrolled in this study reach 18 years of age while in the study? If children enrolled in this study will reach the age of majority (18) before their study participation ends, describe the plan and process for obtaining their consent to continue.

Yes No

* 1. Justify any “No” answers above:  
     Click here to enter text.

1. **Confidentiality**

*In this section you will describe how data acquired for this research in any form (e.g., paper and electronic) will be stored to safe-guard confidentiality. You will also describe the steps that will be taken secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.*

Please note: Any data, including Personally Identifiable Information (PII) and/or Protected Health Information (PHI), acquired from JHS with a waiver of HIPAA Authorization may only be stored in the **secure JHS SharePoint environment provided by JHS**. The Study Team is not permitted to copy or store JHS data in any other system. Please contact the JHS Office of Research for additional information or clarification.

*Protected Health Information (PHI) is defined under HIPAA in 45 CFR 160.103. The following list of identifiers of an individual, employers, or household members of the individual, are defined under HIPAA as:*

*(A) Names;*

*(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:*

*(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and*

*(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.*

*(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;*

*(D) Telephone numbers;*

*(E) Fax numbers;*

*(F) Electronic mail addresses;*

*(G) Social security numbers;*

*(H) Medical record numbers;*

*(I) Health plan beneficiary numbers;*

*(J) Account numbers;*

*(K) Certificate/license numbers;*

*(L) Vehicle identifiers and serial numbers, including license plate numbers;*

*(M) Device identifiers and serial numbers;*

*(N) Web Universal Resource Locators (URLs);*

*(O) Internet Protocol (IP) address numbers;*

*(P) Biometric identifiers, including finger and voice prints;*

*(Q) Full face photographic images and any comparable images; and*

*(R) Any other unique identifying number, characteristic, or code.*

*Describe with specificity the type of Personally Identifiable Information (PII) and/or Protected Health Information (PHI) that will be acquired to accomplish the research or if none of the 18 direct identifiers will be used. You may include a data collection sheet as a separate document.*

*If the Study is a multi-center Study outside UM/JHS, what type of data, including Personally Identifiable Information (PII), and/or Protected Health Information (PHI), will be shared by the Study Team and with whom? Be specific. Name all institutions/entities and collaborators who will receive the data (including PII and/or PHI). The Data Collection Sheet (or similar document or file) that will be sent to another entity must be referenced here by specific name and attached in the “supporting documents” for the IRB submission.*

Choose the statements below that are applicable to this research:

1. **(a).**  Data will be collected from the EMR or subjects at UHealth and/or JHS.

If checked, answer the following:

Research Subjects will sign a HIPAA Authorization before the research will collect this data.

Research Subjects will not sign a HIPAA Authorization for this data collection and the research is requesting a waiver of HIPAA authorization from the IRB. (Complete question 7 below)

1. **(b).** Data collected:

Will not include Protected Health information or Personally Identifiable Information

Will include Protected Health information or Personally Identifiable Information

1. **(c).** How will the research store the data?

On a University of Miami electronic device (e.g. encrypted, password-protected computer)

On a cloud-based storage system that is approved by the University of Miami.

Other, specify: Click here to enter text.

1. **(d)** Select one of the following:

The Principal Investigator (and/or Study Team members) will record (e.g. write down, abstract) data acquired in a manner that **does not include any** indirect or direct identifiers (listed in the instructions for Section VII of this protocol), and the recorded data will not be linked to the individual’s’ identity.

*OR*

The Principal investigator (and/or Study Team members) will record (e.g. write down, abstract) the data collected in a manner that does not include any direct identifiers (see list in the instructions for Section VII of this protocol) of any subject. Instead, the Principal Investigator and/or Study Team members shall will assign a code (that is not derived in whole or in part from any direct or indirect identifiers of the individual) to each study subject and link the code to the study subject’s identity. The link to each subject’s identity and/ or other identifiable information will be maintained on a document separate from the research data.

1. Biospecimens

Not applicable. No biospecimens will be collected

Biospecimens obtained for this research will be stored without any direct or indirect identifiers.

Biospecimens obtained for this research will be stored in a de-identified coded manner.

When required to transport data or biospecimens for this research, the research team will transport the data and biospecimens in a de-identified (or anonymous) manner with a link to the individual subject’s identity maintain separately from the data and/or biospecimen.

1. Data will be collected from the EMR of subjects at UHealth and/or JHS. Data will be stored locally:

On a University of Miami electronic device (e.g. encrypted, password-protected computer)

On a cloud-based storage system that is approved by the University of Miami

Other, specify: Click here to enter text.

1. Select one of the following:

The Principal Investigator (and/or Study Team members) will record (e.g. write down, abstract) data acquired in a manner that **does not include any** indirect or direct identifiers (listed in the instructions under the Confidentiality Section VII of this protocol), and the recorded data will not be linked to the individual’s’ identity.

*OR*

The Principal investigator (and/or Study Team members) will record (e.g. write down, abstract) the data collected in a manner that does not include any direct identifiers (see list in the instructions under the Confidentiality Section VII of this protocol) of any subject. Instead, the Principal Investigator and/or Study Team members shall will assign a code (that is not derived in whole or in part from any direct or indirect identifiers of the individual) to each study subject and link the code to the study subject’s identity. **The link to each subject’s identity and/ or other identifiable information will be maintained on a document separate from the research data.**

1. **Jackson Health System**
   1. If data will be collected from JHS, please affirm the following:

JHS data, including Protected Health Information (PHI) and/or Personally Identifiable Information (PII), acquired from JHS for this research shall only be stored on the secured JHS SharePoint environment made available by JHS. I and the Study Team members shall not copy or store the JHS sourced personally identifiable information (PII), including protected health information (PHI) data to any other system, including any systems maintained or provided by the University of Miami. I and the Study Team shall only copy or transfer JHS-sourced data that has been properly de-identified in accordance with all requirements contained in the HIPAA Rules by removing all of the identifiers listed in the instructions under the Confidentiality Section VII of this protocol.

* 1. **Choose one of the following:**

The Principal Investigator (and/or Study Team members) will record (e.g. write down, abstract) data acquired in a manner that **does not include any** indirect or direct identifiers (listed in the instructions under the Confidentiality Section VII of this protocol), and the recorded data will not be linked to the individual’s’ identity.

*OR*

The Principal investigator (and/or Study Team members) will record (e.g. write down, abstract) the data collected in a manner that does not include any direct identifiers as defined by HIPAA (see list in the instructions under the Confidentiality Section VII of this protocol) of any subject. Instead, the Principal Investigator and/or Study Team members shall will assign a code (that is not derived in whole or in part from any direct or indirect identifiers of the individual) to each study subject and link the code to the study subject’s identity. **The link to each subject’s identity and/or other identifiable information will be maintained on a document separate from the research data.**

If this study includes JHS data, including Protected Health Information (PHI), then the link and/or key to each subject’s identity shall only be maintained in the secure JHS SharePoint environment made available by JHS.

1. If research data, documents, reports, scans, and/or specimens be sent outside of the UM/JHS, list the recipients below:

Click here to enter text.

If identifiable data or specimens will be sent outside of UM/JHS,

* 1. What information will be sent to the parties identified above?

Click here to enter text.

* 1. How the information will be sent (via e-mail, hand delivered, FedEx, USPS, courier, etc.)?

Click here to enter text.

* 1. Describe procedures to protect confidentiality of information being sent:

Click here to enter text.

1. Will this study access the electronic medical record or other protected health information without obtaining a signed HIPAA authorization from the subject or the subject’s legally authorized representative (LAR)?

Yes. To identify potential subjects for recruitment purposes only *(partial waiver of HIPAA for recruitment)*

Yes. To obtain study data

Yes. To identify potential subjects for recruitment and to obtain study data *(full waiver of HIPAA)*

No. This study will not access the electronic medical record or other protected health information without first obtaining a signed authorization from the subject or the subject’s LAR.

1. **If you answered yes to Question 7 above, confirm the following:**

Confirm that you will destroy the Protected Health Information (PHI) you and/or your Study Team acquire receive from JHS and/or UHealth at the earliest opportunity.

*I confirm*

Confirm that the Protected Health Inform (PHI) you acquire 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.

*I confirm*

*If you are collecting health information from JHS, you must read the paragraph below and sign the signature block to indicate your agreement:*

Notwithstanding the preceding “I confirm” statements above, I agree that neither I nor any member of the study team listed on the IRB submission for this Protocol shall ever re-use or re-disclose any of the information acquired from Jackson Health System in any format, whether **identifiable or de-identified,** to any individual or entity without first obtaining written permission from Jackson Health System, even if such re-use or re-disclosure is permissible by law (e.g., HIPAA).

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PI Name Date

**Drug/Device**

1. Where will the study drug(s) and/or device(s) be stored:  
   Click here to enter text.
2. Describe accountability procedures as they relate to drugs or devices:   
   Click here to enter text.
3. State who will interact with the pharmacy (drugs) or sponsor (devices) for acquisition of investigational product(s):  
   Click here to enter text.

**Other site-specific issues**

Please describe any other site-specific amendments or details not otherwise included above:

Click here to enter text.