# INSTRUCTIONS:

* Use “TEMPLATE PROTOCOL (HRP-503)” to prepare a document with the information from following sections. This version is to be used for “more than minimal risk” studies only. You may use a different format, order, outline or template provided the necessary information is included. The IRB ultimately decides the risk level of a study, so the IRB may require revisions to the protocol if it is determined not to be more than minimal risk.
* Depending on the nature of what you are doing, some sections may not be applicable to your research. If so mark as “NA” or delete. For any items described in the sponsor’s protocol, grant, contract, or other documents submitted with the application, you may reference the title and page numbers of these documents.
* When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.
* Please delete any instructional text in red prior to submitting the protocol to the IRB.
1. Protocol Title

Include the full protocol title as listed on the application form.

1. IRB Review History\*

If you have submitted this protocol for review by an external IRB, provide the previous study identification number and provide details of the review including the IRB name, date of review, and IRB contact information.

1. Objectives\*

Describe the purpose, specific aims, or objectives.

State the hypotheses to be tested.

1. Background\*

Describe the relevant prior experience and gaps in current knowledge.

Describe any relevant preliminary data.

Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

1. Inclusion and Exclusion Criteria\*

Describe how you individuals will be screened for eligibility.

Describe the criteria that define who will be included or excluded in your final study sample.

Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the above populations as subjects in your research unless you indicate this in your inclusion criteria.)

* Adults unable to consent
* Individuals who are not yet adults (infants, children, teenagers)
* Pregnant women
* Prisoners
1. Number of Subjects\*

If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

1. Study-Wide Recruitment Methods\*

If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.

Describe when, where, and how potential subjects will be recruited.

Describe the methods that will be used to identify potential subjects.

*If the research team will access patient medical records or other identifiable health information to identify and recruit subjects for this study, you must obtain a waiver of the requirement for written authorization from the patients to access their medical records. To obtain this waiver, you must complete Section 32 of this protocol.*

Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

1. Study Timelines\*

Describe:

* The duration of an individual subject’s participation in the study.
* The duration anticipated to enroll all study subjects.
* The estimated date for the investigators to complete this study (complete primary analyses)
1. Study Endpoints\*

Describe the primary and secondary study endpoints.

Describe any primary or secondary safety endpoints.

1. Procedures Involved\*

Describe and explain the study design.

Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.

Describe:

* Procedures performed to lessen the probability or magnitude of risks.
* All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.
* The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)
* What data will be collected including long-term follow-up.

For HUD uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

1. Data and Specimen Banking\*

If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

List the data to be stored or associated with each specimen.

Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

1. Data Management\*

Describe the data analysis plan for this Study, including any statistical procedures that will be performed on (or including) the acquired data. Disclose who will be performing any statistical procedures on the received data.

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1. Provisions to Monitor the Data to Ensure the Safety of Subjects\*

This section is required when research involves more than Minimal Risk to subjects.

The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

Describe:

* The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.
* What data are reviewed, including safety data, untoward events, and efficacy data.
* How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
* The frequency of data collection, including when safety data collection starts.
* Who will review the data?
* The frequency or periodicity of review of cumulative data.
* The statistical tests for analyzing the safety data to determine whether harm is occurring.
* Any conditions that trigger an immediate suspension of the research.
1. Withdrawal of Subjects\*

Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

Describe any procedures for orderly termination.

Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

1. Risks to Subjects\*

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Include as may be useful for the IRB’s consideration, describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.

If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.

If applicable, describe risks to others who are not subjects.

1. Potential Benefits to Subjects\*

Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB’s consideration, the probability, magnitude, and duration of the potential benefits.

Indicate if there is no direct benefit. Do not include benefits to society or others.

1. 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 NIH-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: 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. Multi-Site Research\*

If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites, such as:

* All sites have the most current version of the protocol, consent document, and HIPAA authorization.
* All required approvals have been obtained at each site (including approval by the site’s IRB of record).
* All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.
* All engaged participating sites will safeguard data as required by local information security policies.
* All local site investigators conduct the study appropriately.
* All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.

Describe the method for communicating to engaged participating sites:

* Problems.
* Interim results.
* The closure of a study
1. Community-Based Participatory Research\*

Describe involvement of the community in the design and conduct of the research.

Note: “Community-based Participatory Research” is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

1. Sharing of Results with Subjects\*

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how it will be shared.

1. Setting

Describe the sites or locations where your research team will conduct the research.

* Identify where your research team will identify and recruit potential subjects.
* Identify where research procedures will be performed.
* Describe the composition and involvement of any community advisory board.
* For research conducted outside of the organization and its affiliates describe:
	+ Site-specific regulations or customs affecting the research for research outside the organization.
	+ Local scientific and ethical review structure outside the organization.
1. Resources Available

Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform their role. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.

If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify people by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not require prior approval by the IRB, provided that person meets the qualifications described above to fulfill their roles.

Describe other resources available to conduct the research: For example, as appropriate:

* Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?
* Describe the time that you will devote to conducting and completing the research.
* Describe your facilities.
* Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.
* Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.
1. Prior Approvals

Describe any approvals that will be obtained prior to commencing the research. (E.g., school, external site. funding agency, laboratory, radiation safety, or biosafety approval.)

1. Recruitment Methods

Describe when, where, and how potential subjects will be recruited. If you will be accessing patients’ medical records, complete Section 32 below to obtain a waiver of the requirement for a signed HIPAA authorization to access medical records.

Describe the source of subjects.

Describe the methods that will be used to identify potential subjects.

Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

Describe the amount and timing of any payments to subjects.

1. Local Number of Subjects

Indicate the total number of subjects to be accrued locally.

If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

1. Confidentiality

*In this section, you will describe how data received in any form (e.g., paper and electronic) will be stored to safe-guard confidentiality (e.g. in a locked cabinet, password protected computer).*

*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 (without a signed 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, or of relatives, employers, or household members of the individual, are defined under HIPAA in 45 CFR § 164.541:*

|  |
| --- |
| (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.*

*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:

26(a). Will the research collect protected health information or personally identifiable information from the EMR or from subjects at UHealth and/or JHS?

[ ]  Yes (If checked go to 26(b))

[ ]  No (If checked, go to Section 27)

26(b). Check the box next to the correct statement below

[ ]  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. *(If checked, complete Section 17 below)*

26(c). How will the research store the data? *(See Section 26(e) below)*

[ ]  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

[ ]  On the secured JHS SharePoint environment *(required for protected health information or identifiable information collected from JHS records without a waiver of authorization from an IRB.)*

[ ]  Other, specify: Click here to enter text.

26(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 26 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 26 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.

26(e) Additional requirement for Jackson Health System Data:

This section applies to data that will be collected from JHS under a waiver of HIPAA authorization (without a signed HIPAA Authorization from the participant).

[ ]  Not-applicable, no data will be acquired from JHS under a waiver of authorization.

[ ]  JHS data, including Protected Health Information (PHI) and/or Personally Identifiable Information (PII), acquired from JHS for this research under a waiver of authorization 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 for Section 26 of this protocol.

27. Biospecimens

[ ]  Not applicable. No biospecimens will be collected

[ ]  Bio-Specimens obtained for this research will be stored without any direct or indirect identifiers.

 [ ]  Bio-Specimens obtained for this research will be stored in a de-identified coded manner.

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

1. Provisions to Protect the Privacy Interests of Subjects

Describe the steps that will be taken to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information.

Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

Indicate how the research team is permitted to access any sources of information about the subjects.

1. Compensation for Research-Related Injury

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

Provide a copy of contract language, if any, relevant to compensation for research-related injury.

1. Economic Burden to Subjects

Describe any costs that subjects may be responsible for because of participation in the research.

1. Consent Process

Indicate whether you will you be obtaining consent, and if so describe:

* Where will the consent process take place
* Any waiting period available between informing the prospective subject and obtaining the consent.
* Any process to ensure ongoing consent.
* Whether you will be following “SOP: Informed Consent Process for Research (HRP-090).” If not, describe:
	+ The role of the individuals listed in the application as being involved in the consent process.
	+ The time that will be devoted to the consent discussion.
	+ Steps that will be taken to minimize the possibility of coercion or undue influence.
	+ Steps that will be taken to ensure the subjects’ understanding.

**Non-English Speaking Subjects**

* Indicate what language(s) other than English are understood by prospective subjects or representatives.
* If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

**Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)**

* Review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” to ensure you have provided sufficient information for the IRB to make these determinations.

**Subjects who are not yet adults (infants, children, teenagers)**

* Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)
	+ For research conducted in the state, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “children.”
	+ For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “children” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”
* Describe whether parental permission will be obtained from:
	+ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
	+ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
* Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.
* Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.
* When assent of children is obtained describe whether and how it will be documented.

**Cognitively Impaired Adults**

* Describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require children to sign assent documents.

**Adults Unable to Consent**

* List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)
	+ For research conducted in the state, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “legally authorized representative.”
	+ For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “legally authorized representative” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”
* Describe the process for assent of the subjects. Indicate whether:
	+ Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.
	+ If assent will not be obtained from some or all subjects, an explanation of why not.
	+ Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

**Adults Unable to Consent**

For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.

1. Process to Document Consent in Writing

Describe whether you will be following “SOP: Written Documentation of Consent (HRP-091).” If not, describe whether and how consent of the subject will be documented in writing.

If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

(If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” to ensure that you have provided sufficient information. You may use “TEMPLATE CONSENT DOCUMENT (HRP-502)”to create the consent document or script.)

1. Authorization for Use and Disclosure of Protected Health Information (HIPAA)

 *If the research team will access patient medical records or other identifiable health information for this research, you must obtain a waiver of the requirement for written authorization from the patients to access their medical records.*

Type of Request:

*[ ]* Waiver of Authorization for access to medical record for subject identification/recruitment.

*[ ]* Waiver of Authorization for access to medical record to obtain data for the research.

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 under a waiver of authorization, you must read the paragraph below and sign the signature block to indicate your agreement:*

[ ] Not applicable. This research will not collect data from JHS record under a waiver of authorization

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 Signature Date

1. Drugs or Devices

If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

* Identify the hold of the IND/IDE/Abbreviated IDE.
* Explain procedures followed to comply with FDA sponsor requirements for the following:

|  |  |
| --- | --- |
|  | ***Applicable to:*** |
| ***FDA Regulation*** | ***IND Studies*** | ***IDE studies*** | ***Abbreviated IDE studies*** |
| ***21 CFR 11*** | *X* | *X* |  |
| ***21 CFR 54*** | *X* | *X* |  |
| ***21 CFR 210*** | *X* |  |  |
| ***21 CFR 211*** | *X* |  |  |
| ***21 CFR 312*** | *X* |  |  |
| ***21 CFR 812*** |  | *X* | *X* |
| ***21 CFR 820*** |  | *X* |  |