# INSTRUCTIONS:

* Use “TEMPLATE PROTOCOL (MinRisk) (HRP-503)” to prepare a document with the information from following sections. This version is to be used for “no 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 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. Objectives\*

Describe the purpose, specific aims, or objectives.

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 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 below 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. Procedures Involved\*

Describe and explain the study design.

Provide a description of all research procedures being performed and when they are performed.

Describe procedures such as:

* 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.
* Surveys or questionnaires that will be administered.
* Date range for the collection of data.
1. Data and Specimen Banking\*

[ ]  This section is not applicable. This research is not banking data or specimens for future use.

Required ONLY 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, including any statistical procedures.

1. Risks to Subjects\*

List the reasonably foreseeable risks, discomforts, or inconveniences to the subjects related the subjects’ participation in the research. Consider physical, psychological, social, legal, and economic risks.

1. Potential Benefits to Subjects\*

Describe the potential benefits that individual subjects may experience from taking part in the research. 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 involves pregnant women, review “[CHECKLIST: Pregnant Women (HRP-412)](https://hsro.uresearch.miami.edu/_assets/pdf/hrp-412---checklist---pregnant-women.docx)” to ensure that you have provided sufficient information.
* If the research involves prisoners, review “[CHECKLIST: Prisoners (HRP-415)](https://hsro.uresearch.miami.edu/_assets/pdf/hrp-415-checklist-prisoners.docx)” 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](https://hsro.uresearch.miami.edu/_assets/pdf/hrp-416---checklist---children.docx))” to ensure that you have provided sufficient information.
* If the research involves cognitively impaired adults, review “[CHECKLIST: Cognitively Impaired Adults (HRP-417)](https://hsro.uresearch.miami.edu/_assets/pdf/hrp-417---checklist---cognitively-impaired-adults.docx)” to ensure that you have provided sufficient information.
1. Setting

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

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.

1. Prior Approvals

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

1. Recruitment Methods

Describe when, where, and how potential subjects will be recruited. **If you plan to identify and recruit subjects in a medical record, complete section 17 below to request a waiver of HIPPA Authorization.**

Describe the source of subjects.

Describe the methods that will be used to identify potential subjects. If you plan to access medical records to identify and recruit subjects, you must complete Section 17 below.

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. Confidentiality

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

In this section you will 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.

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| (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 |

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:

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:

 15(a). [ ]  Data will be collected from the EMR or subjects at UHealth 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 Section 17 below)

 15(b). Data collected:

[ ]  Will not include Protected Health information or Personally Identifiable Information

[ ]  Will include Protected Health information or Personally Identifiable Information

 15(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.

**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 15 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 15 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.

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.

**15d. Jackson Health System additional requirement**

[ ]  This section is not applicable because the research is not collecting health information from JHS under a waiver of authorization (without obtaining a HIPAA authorization from the participant)

If health information, including Protected Health Information and/or Personally Identifiable Information are collected from JHS without a signed authorization from the subject (with a waiver of authorization from an IRB or Privacy Board), you must agree to the following:

[ ]  JHS data, including Protected Health Information (PHI) and/or Personally Identifiable Information (PII), acquired from JHS for this research with a waiver of the requirement for an authorization under HIPAA 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 15 of this protocol.

If the data obtained for this research will be acquired from a retrospective “chart review” involving health information from JHS with a waiver of authorization (without obtaining an signed HIPAA authorization from the subject) then the data and 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. 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.

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

[ ]  This section is not applicable, we are not requesting a waiver of authorization.

*If the research team will access patient medical records or other identifiable health information for this research* *without or prior to obtaining a signed HIPAA authorization from the subject or the subject’s legally authorized representative (LAR), you must obtain a waiver of the requirement for written authorization from the patients to access their medical records.*

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:*

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. Consent Process

Indicate whether you will you be obtaining consent, and if so describe where, when and how the consent process will take place.

**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)](https://hsro.uresearch.miami.edu/_assets/pdf/hrp-410-checklist-waiver-or-alteration-of-the-consent-process.docx)” 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.)
1. Process to Document Consent 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 or subject information sheet.)