# INSTRUCTIONS:

* TEMPLATE PROTOCOL (Research with Existing BioSpecimens) (HRP-503(e)” This version is solely for research using biospecimens that are already existing (e.g. obtained from standard care, previous research, a repository, etc.).
* When you complete this protocol, keep an electronic copy. You will need to use that copy if you when making changes.
* **Please delete all 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.

1. Description of the Bio-Specimens Used for this Research and Confidentiality Provisions

**4.1. Describe the criteria that define the type of bio-specimens to be included or excluded in your final study sample.**

The bio-specimens used in this research will come from:

[ ]  Standard Care

[ ]  Previous research

 If the previous research was conducted at the University of Miami, include the eProst number(s) and protocol titles(s)

Click here to enter text.

[ ]  Bio-Repository

 Describe the Bio-Repository

 Click here to enter text.

[ ]  Other

 Describe

 Click here to enter text.

 **4.2. Was consent for the research (or future research) obtained from the individuals from whom the specimens were obtained?**

 [ ]  Yes. Informed consent for future research of any type was obtained.

 [ ]  Yes. Informed consent for research on was obtained.

 [ ]  This research comes from standard care procedures. The main hospital consent document includes consent for use of bio-specimens for research.

 [ ]  No. Consent for use of the bio-specimens was not obtained.

 [ ]  I do not know if consent was obtained.

 **4.3. If the bio-specimens are from a previous research study, are any research personnel on this study also research personnel for the previous study?**

 [ ]  Yes

 [ ]  No.

 [ ]  I do not know.

**4.4. Describe how the bio-specimens will be labeled when the study receives them.** See Section 4.5 below for a list of identifiers that must not be included on the specimen label to designate the specimen anonymous or de-identified.

[ ]  The specimens will be completely anonymous.

 [ ]  The specimens will be labeled with a code. An individual outside of the research will maintain a link to the individual’s identity and no one who is part of this research will be able to identify the individual from whom a specimen was obtained.

 [ ]  The specimens will be identifiable when the research obtains them.

 If data or specimens will be coded, who will have access to the link between the code and the individual’s identity?

 [ ]  Principal Investigator at UM/JHS
 [ ]  Sponsor/funding entity
 [ ]  Other, specify: Click here to enter text.

**4.5. Will any information about the individuals be included with the specimens?**

 [ ]  No. If checked, go to Section 5.

 [ ]  Yes. If checked, complete Section 4.5 below.

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).

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.

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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 |

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.

**Check all that apply:**

 Data will be collected from the EMR or 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.

[ ]  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 4.5 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 4.5 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.

**Additional requirement for Jackson Health System**

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 check and 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 4.5 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. Procedures Involved

Describe and explain the study design. Describe how you will analyze the specimens.

1. Data Management

Describe the data analysis plan, including any statistical procedures.

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.

1. Risks/Benefits

This study is limited to the analysis of specimens involving minimal risk. *If specimens are identifiable include (otherwise delete):* The only risk to subjects is loss of confidentiality

*If you are not informing subjects of the results include (otherwise delete):* There is no direct benefit to subjects.

*If you will be informing subjects of the results include (otherwise delete):* Subjects may directly benefit from the knowledge that may result from the specimen analysis; however, there is no guarantee.

*(Include)* The research might lead to benefit to others if the analysis of the data leads to new alternatives for diagnosing, treating or mitigating disease.

1. Resources Available

Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform their role. Provide enough information to convince the IRB that you have qualified staff for the proposed research.

1. Consent Process

This study involves analysis of exiting specimens and includes no interactions or interventions with human subjects. As a result, the study team is requesting a Waiver of Consent.

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

*[ ]*  This section is not application; the research is not request a waiver of authorization.

*Include this section only if the research team will access identifiable specimens or patient information without obtaining a HIPAA Authorization from the subject.*

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:*

[ ]  This statement is 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. References

*Provide the citations for all publications and presentations referenced in the text of the protocol.*