# INSTRUCTIONS:

* Use “TEMPLATE PROTOCOL (Chart Review) (HRP-503)” to prepare a document with the information from following sections.
* This version is to be used for “chart review” **retrospective Studies only.**
* When you write a protocol, keep an electronic copy. You will need to modify this copy when making modifications.
* **Please delete any and 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 IRB application form for the research project (“Study”).

1. Objectives

Describe and clearly articulate the purpose, specific aims, and objectives of the retrospective Study.

1. Background

Describe any relevant prior experience and gaps in current knowledge.

1. Inclusion and Exclusion Criteria

Describe the criteria that define the type of charts to 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 target members of the below populations as subjects in your research unless you indicate this in your inclusion criteria.)**

* Individuals who are not yet adults (infants, children, teenagers)
* Pregnant women
* Prisoners
1. Procedures Involved & Data Sources

*Number of Jackson Health System (JHS) records/charts requested for review: \_\_\_\_\_\_\_\_\_\_\_. Provide the date range of the chart review (if this is a retrospective chart review, the end date must come before the IRB submission date):*

mm/dd/yyyy to mm/dd/yyyy.

Number of University of Miami Health (UHealth) records requested for review \_\_\_\_\_\_\_\_\_\_\_\_. Provide the date range for the chart review (if this is a retrospective chart review, the end date must come before the IRB submission date):

mm/dd/yyyy to mm/dd/yyyy.

Describe how the records/charts will be identified and reviewed. Who will provide you with the data, and who originally collected the data.

What is (are) the source(s) of the data?
List all data sources with specificity (precise name, location, method, etc.).

**Describe the type(s) of data to be acquired; attach a Data Collection Sheet or Data Collection Form to the Supporting Documents section of the IRB application. List the specific data elements that will be collected.**

**The Data Collection Sheet must be de-identified by removing all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members. For further detail on what elements must be removed to de-identify information under HIPAA, see section 6.**

**If you are unsure whether the data you plan to analyze would be considered de-identified, please contact the IRB.**

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.

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.

How will data, including any Personally Identifiable Information (PII) and/or, Protected Health Information (PHI), be linked back to an individual (if applicable)?

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.

NOTE: Data providers often require that the researcher enter into a data sharing agreement or other type of agreement setting forth data security requirements. A Data Use Agreement (DUA) must be in place for the sharing of a Limited Data Set and/or Personally Identifiable Information, and a Data Transfer Agreement (DTA) must be in place for the sharing of De-identified Data. Describe whether use of the data requires any special permissions, restrictions, and/or agreements (e.g., DUA, DTA). If there is a DUA, DTA, or other type of agreement, upload the agreement in Supporting Documents in the application form. The agreement must be submitted to HIPAA Privacy Office for review and signature.

1. Risks/Benefits

This Study is a retrospective chart review and the Study Team will review private, identifiable information about human subjects, including Personally Identifiable Information (PII) and/or, Protected Health Information (PHI). The main risk is to Study subjects’ confidentiality should an individual outside of the Study Team access or receive the Study data.

There is no direct benefit to Study subjects. This research might lead to benefits to future patients should the analysis of the data lead to new treatment alternatives.

1. Resources Available

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

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).

If the data have identifiers associated with them, but identifiers will be removed prior to starting your analysis: who did or will de-identify the data. Are the data/specimens linked to an individual by a code? If yes, will anyone on the research team have access to the key linking the codes to individuals? If the research team will have access to the key, where will the key linking the codes to identifiers be stored?

Please note: Any data, including Personally Identifiable Information (PII) and/or Protected Health Information (PHI), acquired from JHS 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.

Describe any other information relevant to how you will protect the confidentiality of the data.

**University of Miami (check all that apply)**

 Data will be collected from the EMR or subjects at UHealth. 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 6 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 6 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.

**Jackson Health System**

 Data will be collected from JHS.

[ ]  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 for Section 6 of this protocol.

**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 for Section 6 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 for Section 6 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 retrospective “chart review” 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. Consent Process

This Study involves the retrospective review of medical records. There will be no prospective contact with potential study subjects prior to acquisition of the requested data. As a result, the Study Team is requesting a waiver of consent in accordance with 45 CFR §46.116(f)(3) and a HIPAA Waiver of Authorization in accordance with 45 C.F.R. §164.512(i).

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.*

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 Signature Date

1. References

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