INSTRUCTIONS:

* You should use this document as a guide to write a protocol.
* After completing a section, delete the instructions (the RED text).
* If a section or subsection is not relevant to your research, please keep the section, but write N/A.

# Study Title:

# Principal Investigator:

# Abstract

# *Provide a brief summary of the study (~150 words). Include an overview of study design, the population of interest, and the aim of research.*

# Objectives

Describe the purpose, specific aims, or objectives, including any hypotheses being tested.

# Background

* 1. **Study rationale:**

# *Provide the rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.*

* 1. **Sensitive data justification:**

If highly sensitive data (e.g., HIV status) will be collected, provide a justification for this collection.

# Inclusion and Exclusion Criteria

* 1. **Criteria:**

Describe the criteria that define who will be included or excluded in your final study sample. If using ICD-10 codes, please list them.

* 1. **Data date range:**

Describe the period in a date range that data/specimens will be selected from. Note: If you will be collecting data or samples that do not yet exist (i.e., prospective chart/specimen review), you will likely be required to obtain consent and HIPAA Authorization.

* + 1. Example: Only data from patient encounters between 12/01/2010 and 06/30/2020 are eligible for data collection.

# Local number of subjects

# *Anticipated N:*

# *Provide the Approximate number how many charts / individuals’ files that will need to be reviewed. Please note this is consistent with the N in the e-form (New Application for Human Research).*

# *N Justification:*

# *Provide a justification for that number of charts. If justified via power analysis, simply state, “See Statistics section.”*

# Methods

# *Data source(s):*

# *Briefly list and describe the source(s) of where the data and or specimens will come from (e.g., EPIC, AxiUm, CoPath, Departmental QI database, tissue repository, etc.)*

# *Briefly describe how the data will be obtained:*

# *How will the charts be identified?*

# *E.g., Service Now, an honest broker (name them), departmental finances, etc.?*

# *Who will be collecting the data?*

# *E.g., manual chart review, complete dataset from an honest broker/Service Now, or a combination.*

# *Describe how the chart review will be conducted such that at no point will direct identifiers (e.g., name, MRN, SSN) be in the same file as the data. Note: if a key or linking file will be maintained, so that data can be re-identified by investigators, clearly state this.*

# *If there will be multiple sources of data describe if/how they will be joined into your dataset.*

# *Variables:*

# *Provide a fully comprehensive list of the variables to be collected or upload a data collection sheet or data dictionary. Note: “medical history” is insufficient detail, because of HIPAA’s minimum necessary standard. The list must be comprehensive and specific.*

# Data Management and Confidentiality

# *Data storage:*

# *Describe where data, and any key/linking file that could re-identify the data, will be stored. It is highly recommended to use REDCap, a HIPAA-compliant data storage application.*

# *Additional data security steps:*

# *Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, and separation of identifiers and data, storing ages over 90 as 89+ to reduce identifiability as per HIPAA, etc.).*

# De-identification:

# *If a key will be used/maintained to conduct this research, describe when the key/linking file will be destroyed (such that you can no longer re-identify any of the data). If the key will be maintained beyond data collection, justify why it could not be destroyed earlier. Note: this is a key piece of the IRB’s ability to approve a waiver of documentation of consent.*

# Informed Consent and HIPAA Authorization

# *Requesting a waiver of consent and HIPAA Authorization:*

# *If requesting a waiver of consent and HIPAA Authorization provide brief justifications / reasons for the following:*

# *Why is does the use or disclosure of the requested PHI minimal risk with regards to the privacy of the individuals’ whose records are being accessed?*

# *Verify that identifiers will not be used or disclosed except for as described above in the “Data Management and Confidentiality” section.*

# *Describe why can the research not practicably be conducted without this waiver.*

# *Describe why will this waiver not adversely affect the rights and welfare of the subjects.*

# Obtaining consent/HIPAA Authorization:

# *If you will obtain consent and HIPAA Authorization, describe how that will be done, including the medium(s) (e.g., paper, electronic, phone) that the process will use.*

# Statistics

# *Briefly described the planned statistical analyses and include any power analysis that was performed to determine the appropriate number of charts to be accessed.*

# Research involving sharing/receiving data outside of Temple

# *If this research will not involve sharing or receiving data from outside of Temple, then simply put N/A.*

# *Provide a list (or separately attached data dictionary / variable sheet) of the variables that will be shared or received. If any HIPAA identifiers (including any non-date shifted dates), ages >89 years old, zipcode, MRN, etc.) will or may be included in the shared dataset, then include language that no data will be shared or received without a fully executed Data Use Agreement (DUA)*

# Attestations: *Note - these must be checked for the IRB to approve this study*

# [ ]  The study (particularly data collection and storage) will be conducted exactly as described above.

# [ ]  The PI has read and understands both [HRP-070 and HRP-071](https://research.temple.edu/research-compliance/institutional-review-board-irb/investigator-quick-links) as they relate to this research.

# [ ]  The PI and research team will not broaden the date range or add new variables to be collected without first obtaining IRB approval via an Amendment.

# [ ]  I verify that only IRB approved personnel will have access to identifiable (to HIPAA standards) data.

# [ ]  I verify that the research team is aware that HIPAA identifiers include dates, zip code, ages above 89, etc.

# [ ]  Research occurring off-site or in collaboration with another institution’s investigator will be done in accordance with their requirements and will not involve the sharing of identifiable information unless described in section 12 above.