Study Title: *Insert Protocol/Study Title along with any protocol identifying number (if any) and date*

RETROSPECTIVE PROTOCOL FACE PAGE

INSTRUCTIONS:

- This form should be used for projects that are limited to research using existing data, including waiver of consent and waiver of HIPPA authorization
- All applications must be typewritten and submitted via TMH IRIS application

PART A. STUDY INFORMATION:

Principal Investigator Name:	
Principal Investigator Department/ Specialty:	
Co-Investigator(s) Name and Department/Specialty:	
Study Coordinator:	
Study Contact Name:	
Sponsor/Funder:	
Does this protocol include participants <18 years old?	YES NO
Is this a multicenter protocol?	YES NO
Anticipated Number of Records:	
Will you be requiring an Honest Broker?	YES NO

[Customize information specific to your study in italics]

1) Study Summary

This section acts like the abstract of a research paper. It should summarize the central elements of the protocol, for example: rationale, objectives, methods, populations, time frame, and expected outcomes. This section should stand on its own.

a) Study Background and Rationale

This section specifies the reasons for conducting the research in light of current knowledge. This should be a well documented statement of the need/problem that is the basis of this research project, the cause of this problem, and possible solutions. It is the equivalent to the introduction in a research paper and puts the proposal into context. This is the part of the protocol that answers the why this research needs to be done. Also include the magnitude, frequency, affected geographic area, ethnic, and gender considerations, etc of the problem.

b) Expected Outcomes

The protocol should specify how the study will contribute to advancement of knowledge, how the results will be utilized, not only in publications but also how they will likely affect health care, health systems, or health policies

2) Study Hypothesis, Goals and Objectives

State your study hypothesis; also include your study goals and objectives. Goals are broad statements of what the proposal hopes to accomplish. In contrast, the study objectives are statements of the research question(s). Objectives should be simple, specific, and stated prior to starting your study. The objectives will form the basis for your statistical analysis; hence, be mindful of the data you plan to collect to assure that you are able to answer your question once the data collection is completed.

a) Primary Objective

The primary research question should be driven by the hypothesis. Defines the specific endpoints and aims of the study and should be clearly stated. It is important for the study objectives to be focused on outcomes that are important to patients and clinically relevant.

b) Secondary Objectives

Include any additional study objectives.

3) Data Collection Plan

a) Study Design and Methodology

The scientific integrity of the study and the credibility of the study data depend significantly on the study design and methodology. Include information on the type of study, research population, inclusion/exclusion criteria, and dates of records.

b) Data Management and Statistical Analysis

The protocol should provide information on how the data will be managed, including data handling and coding for computer analysis, monitoring, and verifications. The statistical methods proposed for the analysis of the data should be clearly outlines, including reasons for sample size selected, power of the study, level of significance to be used, procedures for accounting for missing data, etc. If the study is qualitative, describe how the data will be analyzed.

i) Study Variables

(1) Listing of Data Variables

List the variables that you will be collecting and analyzing as part of this study. This is particularly important if you plan to utilize the honest broker as the Performance Improvement Office will need to determine the availability and feasibility of extracting this data.

Complete Appendix A: Data Variable List.

(2) Dates of Records

Please indicate the range of dates of the records that will be reviewed *(The dates must be retrospective)*

From: _____

To: _____

(3) Will data be linked to the source?

YES NO

(4) Data that are coded, where the key to the code is accessible to researchers, are considered protected health information (PHI) and are subject to HIPAA regulations. Will any of the following identifiers be recorded with or linked by code to the data? YES NO

Names

Medical Record Number

Account Numbers

Dates. All elements of dates (except year) for dats related to an individual, including birth date, admission date, discharge date, date of death, all ages over 89, and all elements of date indicative of age.

Any other unique identifying numbers, characteristics or codes

If any of the following identifiers are selected, a reason must be included below.

Vehicle identifiers and license numbers

Device identifiers and serial numbers

Biometric Identifiers

Full face photographs

All geographic subdivisions smaller than a state, including address, city, county, precinct, zip codes, and geocodes; except for initial 3 digits of zip

Telephone numbers

Fax numbers

E-mail addresses

Social Security numbers

Health plan beneficiary numbers

Account numbers

Reason for Request:

ii) Selection of Study Population

Describe the target population and how you will select them for inclusion in the study.

(1) Inclusion Criteria

These are the criteria that the patient must meet for inclusion into the study.

(2) Exclusion Criteria

Any of these criteria would exclude the patient for participating in the study.

(3) Sample Size

What is the sample size your study needs to recruit to achieve statistical significance? Also, include how the sample size was calculated and any statistical software used.

(4) Protection of Confidential Information

Describe how the study data will be kept confidential.

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4) Project Management

This section should describe the role and responsibility of each member of the research team.

5) Finance

a) Budget

Provide any source of funding and study budget. If there is no funding, just state that your study is unfunded.

b) Costs

Detail any costs associated with this study to patient and to the hospital.

6) Curriculum Vitae of Investigators and Ethics Training

The CV of the Principle Investigator and each co-investigator and research staff should be attached to study protocol via IRIS.

Also, each member of the research team will be required to complete ethics training and provide certificate of completion to Performance Improvement Office. Researchers can satisfy this requirement by completing either Collaborative Institutional Training Initiative (CITI) Program Human Subjects Research or NIH: Protecting Human Research Participants. CITI training can be accessed by following this link: https://about.citiprogram.org/en/series/human-subjects-research-hsr/. NIH is a free training that can be accessed here: https://phrp.nihtraining.com/users/login.php.

7) Conflict of Interests

Clearly identify any conflicts of interests (COI) that the study PI, Co-PI(s), or research personnel may have when completing this study. If there are no COI then simply state that fact. Please note: Each investigator MUST submit a COI form along with the study protocol. The COI form is located in the IRIS application under My Assistant → Operating Procedures. Under Operating Procedures in the Forms section you will find the Conflict of Interest Form (Word document) for completion and submission along with your protocol for IRB review. Upload this form as part of your IRIS IRB application.

8) References

Include a well researched and robust literature review. Can be in either APA or MLA format, just be consistent.

PART B. REQUEST FOR WAIVER OF INFORMED CONSENT

1) Select or explain why/how this research involves no more than minimal risk to the participants or their privacy. (Minimal risk defined as the probability and magnitude of harm or discomfort as being no greater than those encountered in daily life).

   Research involves individual or groups characteristics or behavior

   Collection of data through non-invasive procedures

   Research involving materials (data, documents, records)

   Collection of data from voice, video, digital, or image recordings made for research purposes

   Other:

2) Select or explain why the waiver or alteration will not adversely affect the rights and welfare of the participants.

   The research involves minimal risk to the participants

   The research involves non-invasive procedures

   Data will be deidentified and destroyed upon completion of the project

   Other:

3) Select or explain why the research could not practicably be carried out without the waiver.

   The research requires the identification of participants for inclusion(alive and/or deceased)

   The research requires collection of information of research participants over an extended period of time.

   Other:

4) Select or explain how, whenever appropriate, the participants will be provided with additional pertinent information after participation

   Attempts to contact participants will be made if life threatening results are found

   Other:

PART C. REQUEST FOR WAIVER OF HIPAA AUTHORIZATION

1) Select or explain why the research could not practically be conducted without access to and use of the protected health information (PHI):

The PHI is needed to answer the retrospective research question

The PHI is needed to determine participant eligibility in the study

The PHI is needed to conduct the research analysis

Participant records are needed to verify treatment and outcomes

Other:

2) Select or explain why the Protected Health Information (PHI) to be used or disclosed is the minimum necessary to accomplish the research objectives:
Only PHI needed to answer research question will be used

Other:

3) Select or explain why the user disclosure of the PHI involves no more than minimal risk to the privacy of the individuals (check all that apply) :

Limited identifiable information

Information (data) maintained in a secure/network location

No plans to distribute identifiable information outside Tallahassee Memorial HealthCare

Other:

4) The identifiers must be destroyed at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. Select or describe the plan for destroying the identifiers at or before the conclusion of the study or provide a justification for long term or permanent retention of the identifiers:

No hard copies will be maintained, all data files will be destroyed upon completion of the project.

All hard copies will be shredded

All electronic files will be destroyed and/or deleted from secure network drive

Other:

5) Describe the measures you will take to ensure the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research approved by the IRB:

As noted above, all records will be destroyed and not maintained for future use

Other:

Appendix A:

Data Variable List Template

1. Study Hypothesis:

1.1. *Provide your study hypothesis to better help our database administrators understand your data request.*

2. Study Objectives:

2.1. Primary Objective:

Provide your study objectives to assure that we are answering the research questions you are asking.

2.2. Secondary Objective

Variable	Data Source	Definition
Variable name	*Location of data; example PowerCharts, Allscripts, SurgiNet*	*Definition of your variable, this may be a name or formula. Be as detailed as possible.*
