INSTRUCTIONS:

- You may use this document as a guide to write a protocol.
- You do not need to follow this document. You may use a different format, order, outline or template provided the necessary information is included.
- Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, delete them.
- If you use this template, delete the instructions.

1) Abstract of the study

Provide a summary of the study (recommended length: 250 words).

2) Protocol Title

Include the full protocol title as listed on the Application for Human Research.

3) Investigator

Include the principal investigator's name as listed on the Application for Human Research.

4) Objectives

Describe the study's purpose, specific aims, or objectives.

State the hypotheses to be tested.

5) Rationale and Significance

Describe the relevant prior research experience and the gaps in current knowledge.

Describe any relevant preliminary data.

Describe how this research study will add to existing knowledge.

6) Resources and Setting

Describe the source/location of the charts to be reviewed.

7) Prior Approvals

Describe any non-IRB approvals that will be obtained prior to commencing the research. (e.g., school, external site, or funding agency).

8) Study Design

a) Recruitment Methods

Describe how many charts will be needed. An approximate number is acceptable.

Describe which charts will be reviewed. Be sure to include any age ranges, billing codes, etc.

Additionally, be sure to include the specific date range of information to be collected. Note that if all data exists at the time of submission, you may be eligible for Exempt review which does not require annual renewal.

b) Inclusion and Exclusion Criteria

Describe the criteria that determine which charts will be included or excluded in the study. Examples include: age range, specific conditions/billing codes, etc.

c) Study Timelines

Describe:

- The duration anticipated to review all charts
- The estimated date that the investigators will complete the data analysis.

These timelines can be provided as estimates (ex. Approximately 2 years to review all charts)

d) Study Procedures and Data Analysis

Describe what variables will be recorded. Whenever possible, provide a data collection form or spreadsheet with columns for recorded data.

A recommended procedure for data collection and recording, which will minimize the need for IRB oversight is as follows:

1) Make a list of identifiers of subjects who meet (or might meet inclusion/exclusion criteria
2) Make a data collection form or spreadsheet listing the data to be recorded. On this form or spreadsheet include no identifiers, links to identifiers, or coded identifiers.
3) Pick an identifier from the list created in step 1 and confirm the subject meets inclusion/exclusion criteria
4) If the subject does not meet inclusion/exclusion criteria, mark the identifier on the list created in step 1 as completed. If the subject meets inclusion/exclusion criteria, record the d ata on the form or spreadsheet created in step 2, and mark the identifier on the list created in step 1 as completed.

5) Repeat steps 3 and 4 until all subject records have been reviewed.
6) At no time is the information recorded on the form or spreadsheet created in step 2 in such a manner that subjects can be identified directly or through links to identifiers.

If you need to retain temporary identifiers, codes, or links between the subject's identity and the data being recorded, describe this.

Describe how the data will be analyzed.

e) Privacy & Confidentiality

Describe whether the study will use or disclose subjects' Protected Health Information (PHI).

If the study uses or discloses PHI for a chart review, the PI must justify a waiver of HIPAA authorization. The criteria for a waiver of HIPAA authorization can be found in the "WORKSHEET: HIPAA Waiver of Authorization (HRP-428)."

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).

9) Risks to Subjects

List the reasonably foreseeable risks that are related to a subject's chart being involved in the research (ex. a breach of confidentiality).

10) Informed Consent

Waiver or Alteration of the Consent Process (consent will not be obtained in the event of a chart review)

- Review the "CHECKLIST: Waiver of Consent HHS (HRP-300)" to ensure you have provided sufficient information for the IRB to make these determinations.
- If the Human Research involves a waiver of the consent process that includes use or disclosure of protected health information (PHI), please review the "WORKSHEET: HIPAA Waiver of Authorization (HRP-428)" to ensure that you have provided sufficient information for the IRB to make these determinations.

Please specify whether your research involves any of the following:

- Subjects who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners