# INSTRUCTIONS:

* You may use this document as a guide to write a protocol.
* You may deviate from the suggested inclusionary elements provided in 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 (the sections in RED).
1. **Abstract of the study**

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

1. Protocol Title

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

1. Investigator

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

1. Objectives

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

State the hypotheses to be tested.

1. 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.

1. Resources and Setting

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

1. Prior Approvals

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

1. Study Design
	1. Recruitment Methods

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

Describe which charts will be reviewed.

Be sure to include:

* Age Ranges:
* Billing Codes:
* Date Range:

Note: If all data exists at the time of submission, you may be eligible for Exempt review which does not require annual review.

* 1. Inclusion and Exclusion Criteria

Describe the criteria that determine which charts will be included or excluded in the study. Example: All patients (18 years and older) who have undergone total knee arthroplasty, ICD-9 Code 81.54 at Temple University Hospital between Jan.1, 2005 and March 31, 2015 will be eligible for inclusion

* 1. 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)

* 1. 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 (remove or modify the table if identifiers will be stored beyond data collection or the table’s methodology will not be used):

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

If the identifiers, codes, or links will be maintained beyond the initial data collection, specify for how long and provide a justification for keeping them.

Describe how the data will be analyzed.

* 1. Privacy & Confidentiality

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

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).

Specify that any identifiable data must be stored in a HIPAA compliant (e.g., password protected and encrypted within the hospital firewall, stored in REDCap, etc.)

Note the following are considered identifiers as per HIPAA:

* Names
* Any address element more specific than the first 3 digits of ZIP code
* All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, 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
* Telephone numbers, fax numbers, or email addresses
* Vehicle identifiers and serial numbers, including license plate numbers
* Device identifiers and serial numbers
* Social security numbers
* Internet Protocol (IP) addresses
* Medical record numbers
* Biometric identifiers, including finger and voice prints
* Health plan beneficiary numbers
* Full-face photographs and any comparable images
* Account numbers
* Certificate/license number
1. Risks to Subjects

List the reasonably foreseeable risks that are related to a subject’s chart being involved in the research (ex. The only anticipated risk to the subjects is a breach of confidentiality).

1. 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.
	+ Provide a short justification for needing the waiver (e.g., patients may lost to follow-up or deceased, etc.)
	+ Verify that only IRB approved personnel (i.e., listed in the Application for Human Research) will have access to identifiable data.

**Please specify whether your research involves any of the following:**

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