

**CHART REVIEW PROTOCOL TEMPLATE**

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| **Full study title** |
| **Name(s), Title(s), and Department of Principal Investigator** |
| **Collaborators (institutions and departments), if any** |
| **Sponsor(s), if any** |
| **Protocol version number and version date** |

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| **Revision History** |
| **Version No.** | **Effective Date** | **Description** |
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**INTRODUCTION AND BACKGROUND**

A summary of the primary hypothesis, purpose, scholarly rationale, and prior literature. Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data. Provide the scientific or scholarly background for, the rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

**STUDY DESIGN**

☐ Retrospective chart review ☐ Prospective chart review ☐ Both: retrospective 7 prospective chart review

Date range (start to end)

**SOURCE OF RECORDS**

Please, be specific and consider the following:

* How are the records selected?
* Can you narrow the scope by tapering groups by dates, diagnosis, procedures, etc. rather than requesting access to all records?
	+ Could a deidentified dataset work?
	+ Could a limited dataset (with a data sharing agreement) work?

**CHART SELECTION**

Target population inclusion/exclusion criteria with justifications:

* Describe and include rationale for the specific population exclusions.
* Vulnerable Populations, if any
	+ If the research involves individuals who are vulnerable to coercion or undue influence, state this.
	+ Note whether the dataset will include data from minors, employees, cognitively impaired individuals, or other vulnerable groups.

**PROCEDURES**

Procedures for medical record data collection, what is the data to be collected, and how will the data be obtained. Describe where and how long the data will be stored and who will have access to that data.

**Data Analysis**

Describe the data analysis plan, including any statistical procedures or power analysis (may include the minimum number of charts needed).

Describe the steps that will be taken to secure the data (e.g., password protection, encryption, certificates of confidentiality, Data Use Agreements, etc…)

Describe how data will be handled study-wide (if multisite):

* What identifiers will be included in that data?
* Where and how will the data be stored?
* How long will the data be stored?
* Who will have access to the data?
* Who is responsible for the receipt or transmission of the data?
* How will data be transported?

**Informed Consent**

If you are requesting a waiver of informed consent for this research please address how your request meets the following criteria:

* The research involves no more than minimal risk to the subjects.
* The waiver or alteration will not adversely affect the rights and welfare of the subjects.
* The research could not practicably be carried out without the waiver or alteration (impracticability normally requires justification beyond inconvenience or cost)
* Whenever appropriate, the subjects will be provided with additional information about their participation in the research (often not necessary or feasible).
* If the data includes that of minors, note if you are also requesting a waiver of assent and parental permission.

***If your study does not meet the criteria for waiver of informed consent (more likely for prospective chart reviews), explain how and when consent will be obtained.***

**HIPAA**

List the specific HIPAA identifiers you will record in your research files.

**HIPAA waiver:** If you are recording identifiers from subjects who are still living, and it is not practicable to obtain their HIPAA authorization for your study, state that you are requesting a HIPAA waiver. Also, you must address how your request meets the following criteria for a waiver, **with protocol-specific details**:

Provide sufficient information below to support elements A-C below:

(A) That the use of disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

i. An adequate plan to protect the identifiers from improper use and disclosure;

ii. An adequate plan to destroy the identifiers 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; and

iii. Adequate written assurances that the PHI will not be reused 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 would be permitted by this subpart;

(B) That the research could not practicably be conducted without the waiver or alteration; and

(C) That the research could not practicably be conducted without access to and use of the protected health information.

**Risk to Participation**

Include the risk of breach of confidentiality if any identifiers remain on the data/samples. Do not state that there are no risks.

**Benefits** to future subjects or science, if any

**Confidentiality**

Plan to protect the privacy of subjects and confidentiality of data. The plan needs to answer the following questions:

• What identifiers will be kept with the data?

• If codes, where will the key linking the codes to identifiers be kept? Will other parties help create and/or host the database? How will data be securely stored?

• Will other parties help with statistical analysis, and if so, will identifiers be stripped off first?

• What are plans for protecting the data or disposing of it once the study is completed?

# REFERENCES/BIBLIOGRAPHY