

PROTOCOL TITLE:

**INSTRUCTIONS:**

- *Use “TEMPLATE Chart Review PROTOCOL (OCR 903b)” to prepare a document with the information from the following sections.*
- *Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “NA”.*
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
- *As you are writing the protocol, remove all instructions in italics so that they are not contained in the final version of your protocol.*

**PROTOCOL TITLE:**

*Include the full protocol title.*

**PRINCIPAL INVESTIGATOR:**

*Name  
Department  
Telephone Number  
Email Address*

**VERSION NUMBER/DATE:**

*Include the version number and date of this protocol.*

**REVISION HISTORY**

<b>Revision #</b>	<b>Version Date</b>	<b>Summary of Changes</b>	<b>Consent Change?</b>

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## 1.0 Study Summary

<b>Study Title</b>	
<b>Study Design</b>	
<b>Primary Objective</b>	
<b>Secondary Objective(s)</b>	
<b>Research Intervention(s)</b>	
<b>Study Population</b>	
<b>Sample Size</b>	
<b>Study Specific Abbreviations/ Definitions</b>	

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## **2.0 Objectives\***

2.1 *Describe the purpose, specific aims, objectives, or research questions.*

2.2 *State the measurable hypotheses to be tested.*

## **3.0 Background\***

3.1 *Describe the relevant prior experience and gaps in current knowledge.*

3.2 *Describe any relevant preliminary data.*

3.3 *Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.*

## **4.0 Study Design: Retrospective Chart Review\***

*This study is a retrospective chart review using the electronic medical record.*

4.1 *Describe what data will be collected during the study*

4.2 *Describe how that data will be obtained.*

## **5.0 Study Timelines\***

5.1 *Describe the anticipated start and end date for the chart reviews*

5.2 *Describe the length of time for which each subject's electronic medical record will be accessed and reviewed (such as "The subject's record will be reviewed for 12 months prior to the procedure to 12 months after the procedure)."*

5.3 *Describe the estimated date for the investigators to complete this study (complete primary analyses)*

## **6.0 Subject Population\***

6.1 *Describe generally the individuals that will be included in your study.*

6.2 *Describe any subject populations that will be specifically targeted, or specifically excluded from your sample.*

6.3 *Indicate specifically whether you will include or exclude any of the following special populations: (You may not include members of these populations as subjects in your research unless you include them in the description of your subject population.)*

- *Adults unable to consent*
- *Individuals who are not yet adults (infants, children, teenagers)*
- *Pregnant women*
- *Prisoners*

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## **7.0 Vulnerable Populations\***

7.1 *If the research involves individuals identified as a vulnerable population, describe additional safeguards included to protect their data.*

- *pregnant women (OCR 812),*
- *neonates (OCR 813)”.*
- *prisoners (OCR 815)*
- *persons who have not attained the legal age/children (OCR 816)”*
- *cognitively impaired adults (OCR 817)*

## **8.0 Local Number of Subjects**

8.1 *Indicate the planned total number of subjects whose charts will be reviewed.*

8.2 *If applicable, distinguish between the number of subjects who are expected to be screened, and the number of subjects whose charts will be reviewed (i.e., numbers of subjects excluding screen failures.)*

8.3 *Justify that the planned enrollment goal is feasible within the specified study timelines given the population available.*

8.4 *Describe the statistical rationale for the sample size (power analysis, effect size, screen failures).*

## **9.0 Data Management\* and Confidentiality**

9.1 *This is a retrospective chart review involving minimal risk.*

9.2 *List the reasonably foreseeable data-related risks associated with this retrospective chart review.*

9.3 *Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.*

9.4 *Describe any procedures that will be used for quality control of collected data.*

9.5 *Describe how data will be handled study-wide:*

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

## **10.0 Provisions to Protect the Privacy Interests of Subjects**

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10.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

10.2 Indicate the information about the subjects that the research team is permitted to access.

## 11.0 Waiver of Consent Process

*Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)*

Review the "CHECKLIST: Waiver or Alteration of Consent Process (OCR 810)" to ensure you have provided sufficient information for the IRB to make these determinations.

## 12.0 Setting

12.1 Describe the sites or locations where you/your research team will conduct the research.

12.2 Describe the composition and involvement of any community advisory board, if applicable.

12.3 For research conducted outside of the organization and its affiliates describe:

- Site-specific regulations or customs affecting the research for research outside the organization.
- Local scientific and ethical review structure outside the organization.

## 13.0 Resources Available

13.1 Describe the resources available to conduct the research: For example, as appropriate:

- Describe the time that you will devote to conducting and completing the research.
- Describe your facilities.
- Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.
- Indicate if the study includes a budget or is funded, please include a statement. If the study is funded, include the name of the sponsor.
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## 14.0 Data Analysis Plan

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- *Describe the data analysis plan.*
- *Descriptive Analysis: What data will be presented to describe the sample.*
- *Quantitative analysis: statistical procedures/tests for testing hypotheses or answering research questions; statistical software (R, SAS, SPSS, etc); who will do analysis; timeline for data analysis*
- *Qualitative Analysis: qualitative procedures for answering research questions; qualitative software (such as Atlas.ti, Excel); who will do analysis; how will inter-rater validity be determined; timeline for data analysis*