Chart Review Protocol Template

Guidance

This protocol template is a tool to assist researchers in the development of protocols limited to chart review procedures. If your study involves procedures beyond chart reviews, please utilize the standard protocol template.

1. Protocol Template instructions and sample text appear in *italics*. As you complete the information requested in the template for your study procedures, please delete the italicized text and/or instructions prior to submission for review. Please also delete this Guidance cover page.
2. Sample text should be modified as necessary or appropriate to meet the scientific aims of the protocol.
3. It is recommended that the primary section headings found in **bold** on the template be retained to ensure adequate information is being provided for IRB review. If not applicable for a given protocol, please insert, “Not Applicable” after the section heading.

Chart Review Protocol Template

Principal Investigator:

Title:

Site(s) where study will be performed:

Funding Sponsor:

Version Date:

# Introduction and Purpose

Describe why this research project will be done. Clearly state the overall objectives, specific aims, hypotheses and rationale for performing the study.

# Background

* State the purpose of the research and describe the related theory/data supporting the intent of the study.
* Indicate whether the research is confirming or an extension of previous work, or whether it is pioneering with little prior information. Include an evaluation of existing knowledge and identify the information gaps that the project intends to address.
* Describe published research with animals and/or humans that supports the study hypothesis or objectives. Include a bibliography of key references/citations as applicable.
* Clearly describe the need for research and why it is necessary to generate further knowledge that will contribute to existing knowledge or confirm the basis for additional future research.

# Study Design and Objectives

* Provide a brief description of the study design and indicate how the design will fulfill the intent of the study.
* Provide the total number of subjects to be studied (number at UTRGV and the overall total) and approximately how long the study will last.
* Specify the age range of participants.

# Study Methods and Procedures

* Provide a chronological description of all study procedures.
* Specify the source (locations) of records to be reviewed, how the charts will be identified, and who will identify charts to be reviewed.

# Criteria for Inclusion of Subjects

* Describe the characteristics of the subject population, including demographic characteristics, specific disorders or diseases under study, etc.
* Explain the rationale for the use of special classes of subjects who are more likely to be vulnerable, such as pregnant women, children, cognitively impaired people, non-English speakers or prisoners.
* Note: Additional consideration and procedures could possibly be required for chart reviews involving vulnerable populations, particularly prisoners.

# Criteria for exclusion of subjects

Describe the exclusion criteria; list specific contraindications, symptoms, diagnoses, etc.

# Sources of Research Material

* Identify the source(s) of materials/data to be used in the research, such as information or specimens from medical records, databases, repositories or other sources.
* Please indicate the dates from which data or samples will be extracted (start and stop dates).
* Please indicate if this is a retrospective or prospective chart review.

***Retrospective*** *-Research involving materials (data, documents, records, or specimens) that have been collected solely for non-research purposes (such as medical treatment or diagnosis) in existence prior to the initial submission of the IRB protocol.*

***Prospective****-Research involving materials (data, documents, records, or specimens) not yet in existence when the protocol is submitted to the IRB for initial review.*

NOTE: If you are proposing to conduct a retrospective chart review study and only de-identified information will be accessed, then the study would qualify for Exempt review. De-identified means the data contains no information which would allow researchers to link it to an individual. However, if a link to other data exists (Subject ID number/key that links to the data), the data would be considered coded, and the study would not qualify for Exempt Review. Likely, the protocol will meet the criteria for Expedited Review*.*

# Potential Risks

A confidentiality breach is a risk associated with chart review research. Please indicate this risk and specify the procedures implemented to minimize this risk.

# Potential Benefits

Describe the potential benefits of the research to the subjects, to others with similar problems, and to society. The subjects’ whose charts are reviewed are not likely to receive any direct benefit from the proposed research. If there is no prospect of direct benefit to the subjects, state how society *will benefit from the knowledge gained.*

# Confidentiality and Data Monitoring Procedures

* An Essential element of a chart review is a description of the process by which subjects and their protected health information (PHI) will be managed and thus confidentiality maintained. Information about study subjects must be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Describe the plan for monitoring study data collected to protect subject safety and data integrity.
* Describe how data/specimens will be collected and stored and the security methods in Specify how long collected data will be stored.
* Specify who will have access to collected subject data.
* Note: the more sensitive the study data, the more sophisticated the methods should be to maintain confidentiality.
* If data/specimens will be disclosed to outside persons or entities, list the entities and the method used to code or de-identify the data/specimens.
* State if you intend to apply for a Certificate of Confidentiality from the NIH.

# Statistical Considerations

* Specify when, where, and how data will be analyzed, and by whom.
* Describe the statistical methods to be used for determining the sample size, stating the rational for the number of charts that will be reviewed.