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| **MEDICAL CHART REVIEW RESEARCH**  **GENERAL INSTRUCTIONS**  This application template is for investigators at Catawba Valley Medical Center whose research consists of Medical Chart Review **ONLY**. With this template, create a detailed study protocol for submission to the Catawba Valley Med Cnt Institutional Review Board (IRB) for evaluation and action.  Use this template to create a **study protocol** as follows:   * **Red** text represents instructions to you – delete all red text from the final version. * Blue text represents guidance on suggested content – replace with the requested information using black font in the final version. * Black text represents section headings and is to remain in the final version. * Green text represents definitions or verbiage examples – delete.   Please make sure to complete the header on this page with your Surname and initials, followed by a colon, and an abbreviated protocol title. Also include the version number, colon, and date. Ensure page numbers remain in the footer, right side. The initial submission to the IRB is Version 1. Once an application is submitted to the IRB, should amendments or future protocol or study personnel changes be necessary, the version numbers of revised applications are indicated by the next ascending number. NOTE: The submitted application is to contain NO red, green, or blue text nor instruction boxes. The abbreviated information in the Protocol Summary will be fleshed out in the subsequent sections of the application. |

**Medical Chart Review Research IRB Application**

**Protocol Title:** complete

**Protocol Version Number:** 1, 2, etc.; see explanation in general instructions above

**Protocol Version Date:** day, month, year

**Principal Investigator (PI):** name

**Phone:** number

**E-mail:** address

**Co-Investigator(s):** name(s)

**Phone:** number(s)

**E-mail:** address(es)

**Research Sponsor:** name

**Phone:** number

**E-mail:** address

Investigator and Research Sponsor Responsibility Acknowledgements

I assure this study will be conducted in compliance with the approved protocol, applicable federal regulations, and the policies and procedures of the Catawba Valley Med Cnt IRB. By checking the box and typing my name below, I confirm this to be my electronic signature and the legal equivalent of my manual signature.

Investigator Signature: Date:

I assume responsibility for ensuring the Principal Investigator complies with the policies and procedures of the Catawba Valley Med Cnt IRB and federal regulations as applicable in conducting this research and the use of human subjects. By checking the box and typing my name below, I confirm this to be my electronic signature and the legal equivalent of my manual signature.

Research Sponsor Signature: Date:

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| **STUDY DESCRIPTION INSTRUCTIONS**  To allow the IRB, consisting of scientists and non-scientists, to understand this study completely use non-technical terms to describe the proposed research, i.e., avoid clinical jargon. Detailed information about the use of human subjects is necessary for the IRB to evaluate potential risks to subjects. The following definitions are key to understanding research involving human subjects as defined by 45 CFR 46.102.  (e)(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:  (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.  (2) *Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.  (3) *Interaction*includes communication or interpersonal contact between investigator and subject.  (4) *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).  (5) *Identifiable private information*is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.  (6) An *identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.  The information in Sections 2 through 9.1 must be provided in complete sentences. Bulleted information is not acceptable. First use of an acronym or abbreviation within Sections 2-9.1 must include its description. Thereafter, the acronym or abbreviation can be used alone. Pay close attention to the instructions for each section providing only the information requested as later sections may request related information. This will preclude duplicity in the application. |
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# List of Acroymns/Abbreviations

Complete this table with all abbreviations/acronyms used herein. Delete or add rows as needed.

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| **Acronym/Abbreviation** | **Definition** |
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# Protocol Summary

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| **Title:** | Study title. |
| **Population:** | Describe the targeted study participants. Detail any/all vulnerable populations or state no vulnerable individuals will be used. |
| **Study Purpose:** | State the purpose of the research. What question is being asked and what is the expected result (hypothesis/hypotheses)? |
| **Study Overview:** | Describe the study design (comparative, descriptive, retrospective, etc.). Include medical chart review as the general methodology. State the beginning date and ending date of the chart review. |
| **Overall Study**  **Duration:** | Provide the desired start date for the study and the expected end date through data analysis for this study. |

**If the following statement is true of the proposed research, check the box.**

This research seeks to utilize identifiable private information that was originally collected for nonresearch purposes.

# Background, Rationale & Purpose

## Study Significance and Rationale

Describe the health condition the study will address. State the rationale for and potential significance of the research. Provide a concise background based on existing knowledge, published research, evidence-based practice guidelines, and/or current standard(s) of practice. Include any pertinent unpublished data if existent. Cite all sources numerically in the order of their appearance. Full citations are to be provided in Section 9 of this application.

## Purpose/Objective of the Research

State the purpose of the research. The purpose or primary objective is the reason for performing the study in terms of the scientific question to be answered. State secondary objectives if they exist. Secondary objectives are goals that may provide further information on the topic under investigation. Include your hypothesis/hypotheses regarding what the study findings may reveal and/or the practical application(s) of the research.

# Design & Outcome Measures

## Study Design

The scientific integrity of the study and the credibility of the data collected depend substantially on the study design. Describe the design/type of study to be conducted (e.g., comparative, descriptive, etc.) and the methodological approach (electronic medical record data mining, chart audit, etc.). Include a description of the target study population (e.g., inpatient/outpatient, subject groups) and the start and end dates for subject eligibility. Do not list inclusion/exclusion criteria.

## Outcome Measures

An outcome measure is a specific measurement used to assess the issue under study. Outcome measures should be prioritized and should correspond to the study objectives and hypotheses being tested. Generally, there should be just one primary outcome measure that will provide a clinically relevant, valid, and reliable measure of the primary objective. The primary outcome measure is the basis for concluding that the study met its objective. Secondary outcome measures are those that may provide supportive information or demonstrate additional effects on the disease or condition. Secondary outcome measures may include, for example, endpoints related to efficacy, safety, or both.

### Primary Outcome Measure

Give a precise and succinct description of the primary outcome measure.

### Secondary Outcome Measure(s)

List additional outcome measures if applicable or state there are no secondary outcomes.

# Study Population

5.1 Inclusion Criteria

To be eligible for participation in this study, a patient must meet all of the following criteria: list characteristics (e.g., > 18 years of age, condition, etc.). If the research includes persons considered to be a vulnerable population, then complete and include the Vulnerable Populations Form as an appendix to this application. Vulnerable populations can include, but are not limited to, pregnancy, dementia, psychiatric patients, mentally challenged and incarcerated persons.

5.2 Exclusion Criteria

Patients possessing any of the following criteria will be excluded from enrollment as study subjects: list characteristics. Exclusion criteria may include vulnerable populations, something that would exclude a potential subject even if they met all of the inclusion criteria (e.g., patient hospitalized for a shorter time than the primary endpoint), etc. Do not include antitheses of inclusion criteria (e.g., minors, patients without the condition under study, etc.).

5.3 Sample Size

State the desired number of study subjects. Include the lowest number sufficient for data analysis and the maximum number planned for enrollment. State how this sample size was determined (calculated a priori, historical, Rule of Thirty, etc.). In the case of calculated sample sizes, provide the information used to validate the calculations - i.e., values for all parameters used in calculations. Address the feasibility of achieving an adequate sample size for the study.

# Study Methods

## Procedures

Expand on the methodology provided previously. Describe the various specific sources of data and means of collecting the data (e.g., data mining report(s), medical record audit, etc.). List all data variables to be collected. If a variable (s) will be collected over time, provide the various time points of collection. A data collection tool can be appended to this application.

## Statistical Methods

Describe the statistical plan for analyzing the collected data, i.e., how the variables will be evaluated to assess the study objective(s). Detail the methods for organizing the data (descriptive statistical tests) and the inferential statistics that will be employed to determine statistical significance and the *p* value.

## Data Handling and Confidentiality

Explain how the data will be recorded, whether entered electronically or on hardcopy data collection forms, and de-identified. State the procedures for maintaining subject confidentiality of the data. Example confidentiality verbiage: electronic data will be stored under two levels of password protection on a facility private server. Collected data will be de-identified alphanumerically prior to analysis and study findings reported in aggregate.

## Participant Risk(s) & Benefit(s)

6.4.1. Foreseeble Risks & Mitigation Strategies

List foreseeable risks to study subjects participating in this research. Documented Protected Health Information (PHI) can be associated with inadvertent risk prior to de-identification. Example verbiage: There is the potential for an inadvertent breach of confidentiality during the data collection phase of the research. Means to prevent such a breach include: 1) using a non-public computer, 2) locking the computer screen when briefly called away from the computer, and 3) locking the screen when non-research persons have visual access to the computer screen.

6.4.2. Potential Benefits

Although there are no potential benefits for study subjects in retrospective medical chart review reserach, future patients may benefit from the study findings. Benefits to future patients, the field of inquiry, or to society as a whole may be included after stating that study subjects will not benefit as a result participating in the study.

## Dissemination

Indicate dissemination intentions for the study findings. Include the proposed dissemination type and the audience or setting. For example, poster and/or podium presentation at a departmental meeting and/or a professional organization conference. thesis, manuscript, etc.

## Study Records Retention

Summarize the record retention plan applicable to the study. Take into consideration any Departmental requirements, if applicable. The Catawba Valley Med Cnt IRB requires that study records be retained for at least three years after completion of the study. Please note that research records will be made available to regulatory bodies when requested, e.g., OHRP, FDA.

# Ethics/Protection of Human Subjects

# This study is to be conducted according to applicable US federal regulations and institutional policies (which are based in federal regulations, guidance, and ICH Good Clinical Practice guidelines). This protocol and any amendments will be submitted to the Catawba Valley Med Cnt Institutional Review Board for formal approval. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator. Commencement of the study cannot begin until written notification of approval or exemption has been received. A copy of the IRB letter will be provided to the sponsor.

By checking the box below, I acknowledge my responsibility to conduct this research in accordance with all regulatory and ethical protections as pertaining to the human subjects enrolled in this study, and I further guarantee the study will not commence until and when an IRB decision of approval or exemption has been provided to me. When in doubt with regard to any regulation, I will confer with my Study Sponsor for guidance. I confirm that my typed name below serves as my electronic signature is the legal equivalent of my manual signature.

Investigator Signature: Date:

# 8 Waiver of Informed Consent

Research conducted by retrospective medical chart review may be eligible for waiver of informed consent. Complete the information contained in this section to ensure this research qualifies for waiver of study subject informed consent. **If all requirements are not met, procedures for obtaining informed consent must be provided along with the informed consent form, and any other pertinent information in the application appendices.**

8.1 Request for Waiver of Informed Consent

Informed consent can be waived or altered under 45 CFR 46.116(f) if an IRB finds all of the following conditions have been met. Check all items that apply to this research.

The research involves no more than minimal risk to the subjects;

The research could not practicably be carried out without the requested waiver or alteration;

If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

The waiver of alteration will not adversely affect the right and welfare of the subjects; and

Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

# Literature References

Provide a listing of all literature references cited in numerical format in Sections 3-6. Example formats for various types of sources: <http://www.nlm.nih.gov/bsd/uniform_requirements.html>.

# Appendices

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| **Yes** | **Y** | Good Clinical Practice Education Completion Certificate(s) |
| **Yes** | **Y** | HIPAA Education Completion Certificate(s) |
| **Yes/No:** | **Y/N** | Study Design Schematic |
| **Yes/No:** | **Y/N** | Standard of Practice or EBP Guideline Document(s) |
| **Yes/No:** | **Y/N** | Informed Consent Waiver or Alteration Form |
| **Yes/No:** | **Y/N** | External IRB Decision Notification |
| **Yes/No:** | **Y/N** | Other: describe |