**RETROSPECTIVE RESEARCH PROTOCOL**

**Title of Study**

Hatton Number: YY-###

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| --- | --- |
| **Principal Investigator:** |  |
| **Research Team:** |  |
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| **Field** | **Description** |
| **Amendment Number** | Amendment 1 |
| **Date of Amendment** | 10AUG2025 |
| **Sections Modified** | Section 4.1 (Study Population), Section 7 (Sample Size Determination), and Section 8 (Ethical Consideration) |
| **Nature of Changes** | **Section 4.1** – Study Population  Language has been added to clarify that the estimated sample size should be stated based on feasibility assessments using tools such as Slicer Dicer or publicly available databases.  **Section 7** – Sample Size Determination  A note has been included specifying that sample size determination should be described if applicable, to ensure transparency in retrospective feasibility.  **Section 8** – Ethical Consideration  Revised wording to explicitly state that the study will use de-identified data for analysis.  Added language specifying that all documents will be maintained and destroyed in accordance with TriHealth Medical Records policies, ensuring compliance with institutional data governance. |

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# **List of Abbreviations and Definition of Terms**

|  |  |
| --- | --- |
| **Abbreviation/Term** | **Explanation** |
| ADL | Activities of Daily Living |
| ECOG | Eastern Cooperative Oncology Group |
| EDC | Electronic Data Capture |
| EHR | Electronic Health Record |
| FDA | Food and Drug Administration |
| ICMJE | International Committee of Medical Journal Editors |
| ICU | Intensive Care Unit |
| IRB | Institutional Review Board |

***NOTE: All examples and sentences in red should be removed once the protocol is finalized.***

# **SYNOPSIS**

Brief Summary: An overview of the study’s objectives, methodology, and expected outcomes. Key Dates: Study start date, anticipated end date, and any key milestones.

**Example:**

“This retrospective study aims to examine the mortality rates among heart failure patients admitted to the Intensive Care Unit (ICU) at Good Samaritan Hospital between January 1, 2015, and December 31, 2020. By analyzing patient records, the study will identify key factors associated with mortality, assess the effectiveness of different treatment strategies, and explore potential areas for clinical improvement. The study will utilize de-identified patient data, including demographic information, clinical characteristics, treatment details, and outcomes. The results will contribute to a better understanding of heart failure management in critical care settings and inform future clinical guidelines.”

# **BACKGROUND AND RATIONALE**

Background: Overview of the current state of knowledge and context of the study. Rationale: Justification for why this retrospective study is important and how it will contribute to the field.

**Example:**

“Heart failure remains a significant cause of morbidity and mortality worldwide, with acute decompensations often necessitating ICU admission. Despite advances in medical management, the mortality rate among heart failure patients in the ICU remains high. Previous studies have highlighted various risk factors, including comorbidities, treatment delays, and variations in care protocols. However, there is a need for more comprehensive data to understand these factors better and improve patient outcomes. This study aims to fill this gap by retrospectively analyzing the clinical data of heart failure patients treated in the ICU, providing insights into current practices, and identifying potential areas for intervention.”

# **OBJECTIVES**

**Sections 3.2 and 3.3 may not be applicable based on your study.**

## **Primary Objective**

**Example:**

“To determine the mortality rate of heart failure patients admitted to the ICU at Good Samaritan Hospital and identify the primary clinical and demographic factors associated with increased mortality risk.”

## **Secondary Objectives**

**Example:**

1. “To evaluate the impact of different treatment modalities on the survival of heart failure patients in the ICU.
2. “To analyze the length of ICU stay and its correlation with patient outcomes.
3. “To assess the role of comorbid conditions in influencing mortality rates among heart failure patients in the ICU.”

## **Exploratory Objectives**

**Example:**

1. “To explore the temporal trends in heart failure mortality in the ICU over the study period.
2. “To investigate potential disparities in treatment outcomes based on patient demographics such as age, gender, and ethnicity.
3. “To examine the effectiveness of novel or less common treatment approaches used during the study period.”

# **STUDY DESIGN**

## **Study Population**

Study Type: Retrospective observational study.   
Study Population: Description of the population from which data will be collected (e.g., patients treated at a specific hospital between certain dates. Specify full start and stop dates).   
All dates should be in the past due to the retrospective nature of the study.

Sample Size: Include an upper-end estimate of the total number of patients/charts that will be included.

**Example:**

“This is a retrospective observational study. The study population will consist of all patients admitted to the ICU at Good Samaritan Hospital with a primary diagnosis of heart failure between January 1, 2015, and December 31, 2020. This population will include diverse demographic groups and clinical presentations to provide a comprehensive analysis of heart failure management in a critical care setting. After review of preliminary data in SlicerDicer, we estimate that up to 1,000 patient records will be accessed and reviewed.”

## **Inclusion and Exclusion Criteria**

Detailed criteria for including or excluding records from the study.

**Example:**

**Inclusion Criteria:**

1. “Patients aged 18 years and older.
2. “Patients with a primary diagnosis of heart failure confirmed by clinical and diagnostic criteria.
3. “Patients admitted to the ICU at Good Samaritan Hospital between January 1, 2015, and December 31, 2020.
4. “Patients with complete medical records, including demographic information, clinical data, and treatment outcomes.”

**Exclusion Criteria:**

1. “Patients with incomplete or missing medical records.
2. “Patients transferred to the ICU from outside hospitals without complete transfer documentation.
3. “Patients admitted to the ICU for reasons other than heart failure as the primary diagnosis.
4. “Patients under the age of 18.
5. “Patients who are pregnant. “

# **DATA SOURCES**

## **Data Collection**

Describe the sources of data (e.g., electronic health records, patient charts) and how data will be extracted.

**Example:**

“Data will be collected retrospectively from the electronic health records (EHR) of Good Samaritan Hospital. The study period includes all patients admitted to the ICU with a primary diagnosis of heart failure between January 1, 2015, and December 2020. Relevant patient data will be extracted using a standardized data collection form. The form will capture demographic information, clinical characteristics, treatment details, and outcomes. Data extraction will be performed by trained research assistants under the supervision of the principal investigator.”

## **Data Variables**

List of variables to be collected and analyzed (e.g., demographic information, clinical outcomes). Variables may vary depending on the study.

**Example:**

* **“Demographic Information**:
  + “Age
  + “Gender
  + “Race
  + “Ethnicity
* **“Clinical Characteristics**:
  + “Date of diagnosis
  + “Date of ICU admission
  + “Comorbid conditions (e.g., diabetes, hypertension, renal disease)
  + “ECOG performance status
* **“Treatment Details**:
  + “Medications administered (e.g., inotropes, vasodilators)
  + “Mechanical ventilation (yes/no)
  + “Duration of ICU stay
  + “Interventions (e.g., dialysis, surgical procedures)
* **“Outcomes**:
  + “Date of biomarker testing
  + “Date of death or discharge
  + “Survival status at discharge
  + “Readmission to ICU (if applicable)
  + “Survival time from diagnosis to event (death or last follow-up)”

# **DATA MANAGEMENT**

## **Data Handling**

Procedures for data collection, entry, storage, and management.

**Example:**

“All collected data will be entered into a secure, password-protected database. The database will be accessible only to authorized research personnel. Data entry will be performed in duplicate to ensure accuracy. Any discrepancies will be resolved through consensus. De-identified data will be used for analysis to maintain patient confidentiality. Regular backups will be performed to prevent data loss.”

## **Data Quality Control and Confidentiality**

Methods for ensuring data accuracy and consistency. Measures to ensure the privacy and confidentiality of the data (e.g., de-identification procedures).

**Example:**

“To ensure data quality, the following measures will be implemented:

* “Double data entry and verification processes to minimize errors.
* “Regular audits of the data collection process by the research team.
* “Training sessions for research assistants on data extraction and entry protocols.
* “Use of standardized data collection forms.

“Patient confidentiality will be maintained by:

* “De-identifying all patient data prior to analysis.
* “Storing the de-identified data in a secure, restricted-access database.
* “Complying with all relevant privacy laws and institutional guidelines for data protection.”

# **STATISTICAL ANALYSIS**

Sample Size Determination: *If relevant,* include any calculations used to determine sample size.

Analysis Plan: Detailed plan for statistical analyses to be conducted.   
Software: Specify the statistical software to be used.  
Handling Missing Data: Procedures for dealing with missing or incomplete data.

**Example:**

“Statistical analysis will be performed using SPSS software (version 27.0 or later) or a similar statistical package. Descriptive statistics will be used to summarize demographic and clinical characteristics. Survival analysis will be conducted using Kaplan-Meier estimates and log-rank tests to compare survival curves between groups. Cox proportional hazards regression models will be used to identify factors associated with mortality. Correlations between ECOG scores and survival times will be assessed using Pearson or Spearman correlation coefficients, as appropriate.

“Alpha will be set at p < 0.05 to determine statistical significance. Additional analyses may be considered based on the findings from the above analysis. Missing or incomplete data will remain missing. There will be no imputation for this study.”

# **ETHICAL CONSIDERATIONS**

Ethical Approval: Details of the ethics committee or Institutional Review Board (IRB) approval. Risk-Benefit Analysis: Assessment of potential risks and benefits to participants.

**Informed Consent: Explain how consent will be handled. i.e.,**

* **Minimal Risk: The study involves the analysis of existing data, which poses no more than minimal risk to participants.**
* **Impracticability: It is impractical to obtain consent from individuals due to the retrospective design and the large number of subjects involved.**
* **No Adverse Effect on Rights and Welfare: The waiver will not adversely affect the rights and welfare of the participants.**
* **Confidentiality: All data will be anonymized and handled with strict confidentiality to protect participant privacy.**

**Example:**

“This study will be conducted in accordance with the Declaration of Helsinki and approved by the TriHealth Institutional Review Board (IRB). As this is a retrospective study we will use de-identified data for analysis. We are requesting a waiver of Informed Consent and Authorization. will be waived. However, we will ensure that all data is handled with the highest level of confidentiality and integrity. Ethical approval will include a thorough review of the data management and security protocols. All documents will be maintained & destroyed in accordance with TriHealth Medical Records policies”

# **LIMITATIONS**

Potential Biases: Discussion of potential biases inherent in retrospective studies and how they will be mitigated. Limitations: Any limitations of the study design and data sources.

**Example:**

* “Retrospective design: The study relies on existing records, which may have incomplete or missing data.
* “Single-center study: The findings may not be generalizable to other settings.
* “Potential for selection bias: Inclusion criteria based on available records may introduce bias.
* “Lack of control over confounding variables: Unmeasured confounding factors may influence the results.”

# **DISSEMINATION PLAN**

Publication: Plan for disseminating study findings, including potential journals and conferences.   
Authorship: Criteria for authorship and contributors.

**Example:**

“The findings of this study will be disseminated through various channels:

“Submission of manuscripts to peer-reviewed journals for publication.

* “Presentation at national and international conferences focused on cardiology and critical care.
* “Sharing results with the medical community at Good Samaritan Hospital through internal seminars and workshops.
* “Engaging with patient advocacy groups to inform them of the findings and implications for patient care.

“Authorship on the study's publications will be based on substantial contributions to the research and manuscript preparation, as per the guidelines provided by the International Committee of Medical Journal Editors (ICMJE).”

# **REFERENCES**

A comprehensive list of references cited in the protocol, including key studies and guidelines related to heart failure management and ICU care.  
Bibliography: List of all references cited in the protocol.   
Appendix A: Data collection forms or templates.  
Appendix B: Additional supporting documents

**Example:**

1. “Smith, J. A., & Doe, J. B. (2020). Management of heart failure in the ICU. *Journal of Critical Care Medicine, 35*(2), 123-130.
2. “Brown, R. C., et al. (2018). The impact of comorbid conditions on heart failure outcomes. *American Heart Journal, 176*(3), 456-462.”

# **APPENDICES**

**Example:**

“Appendix A: Data Collection Form

* “A template of the standardized data collection form used in the study.

“Appendix B: Additional Supporting Documents

* “List of diagnosis or procedure codes (e.g., ICD-10, CPT)”