# STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Official Study Title:
Comparison of Scoring Systems in Predicting Morbidity and Mortality in Patients Undergoing Gastrointestinal Malignancy Surgery

ClinicalTrials.gov Identifier:
NCTXXXXXXXX (Not yet assigned)

Document Date:
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## 1. Study Rationale and Objectives

This prospective observational study aims to evaluate and compare the predictive accuracy of perioperative risk scoring systems in patients undergoing gastrointestinal malignancy surgery. The primary objective is to assess the sensitivity of ASA, SAS, Portsmouth-POSSUM, ACS-NSQIP, and ARISCAT scores in predicting postoperative mortality. Secondary objectives include evaluating the ability of these scores to predict postoperative pulmonary and extrapulmonary complications, ICU admission, and length of hospital and ICU stay.

## 2. Study Design

This is a single-center, prospective observational study conducted at a tertiary referral hospital. No additional interventions beyond routine clinical care will be performed.

## 3. Study Population

Adult patients aged 18 years or older undergoing elective gastrointestinal malignancy surgery under general anesthesia who provide written informed consent will be included.

## 4. Outcome Measures

Primary outcome: postoperative mortality (30-day and 60-day). Secondary outcomes: postoperative pulmonary and extrapulmonary complications, ICU admission, length of hospital stay, and ICU stay.

## 5. Data Collection

Preoperative, intraoperative, and postoperative data will be collected prospectively. Mortality data will be assessed at 30 and 60 days using hospital records and telephone follow-up.

## 6. Statistical Analysis Plan

Statistical analyses will be performed using SPSS version 22.0. Continuous variables will be presented as mean $\pm$ standard deviation or median (interquartile range). Categorical variables will be presented as frequencies and percentages. Receiver operating characteristic (ROC) curve analysis will be used to assess the predictive performance of each scoring system. Sensitivity, specificity, and area under the curve (AUC) values will be calculated. A p-value $< 0.05$ will be considered statistically significant.

## 7. Ethical Considerations

The study was approved by the local ethics committee prior to patient enrollment. Written informed consent will be obtained from all participants. All data will be anonymized and handled confidentially.

Principal Investigator
Name and Signature: _____

Date: _____