# Statistical Analysis Plan (SAP)
## Official Title:
## Comparison of Complication Rates of Onlay vs Sublay Mesh Repair of Incisional Hernia
## Brief Title:
Complication Rate of Onlay vs Sublay Mesh Repair in Incisional Hernia

**ClinicalTrials.gov Identifier:**
NCT ID: Not Yet Assigned

**Organization's Unique Protocol ID:**
HMC-QAD-F No. IREB-1221

**Study Type:**
Interventional Study (Randomized Controlled Trial)

**Study Design:**
Parallel Assignment, Open Label

**Sponsor:**
Hayatabad Medical Complex, Peshawar, Pakistan

**Responsible Party:**
Principal Investigator

**Principal Investigator:**
Dr. Gohar Ali
Principal Investigator
Department of Surgery
Hayatabad Medical Complex, Peshawar, Pakistan

**Planned Statistical Analysis:**
Comparative analysis of postoperative complication rates between onlay and sublay mesh repair techniques using appropriate descriptive and inferential statistical methods.

**Ethics Approval:**
Approved by Ethical Committee, Hayatabad Medical Complex, Peshawar
Approval Number: HMC-QAD-F No. IREB-1221

**Analysis Population:**
- All randomized patients
- Per-protocol population for sensitivity analysis

**Descriptive Statistics:**
- Continuous variables: mean ± SD or median (IQR)
- Categorical variables: frequency (%)

**Primary Outcome Analysis:**
- Compare **postoperative complication rate** between onlay and sublay groups
- **Statistical Test:** Chi-square or Fisher's exact test
- Significance level: $\alpha = 0.05$

**Secondary Outcome Analysis:**
1. **Hernia recurrence:** Chi-square test; Kaplan-Meier curves for time-to-recurrence
2. **Length of hospital stay:** Independent t-test or Mann-Whitney U test
3. **Operative time:** Independent t-test or Mann-Whitney U test

**Subgroup Analysis (optional):**
- Stratified by age group (<40 vs ≥40)
- Stratified by BMI (<30 vs 30–40)

**Handling Missing Data:**
- Multiple imputation if missing >5%
- Sensitivity analysis comparing complete case vs imputed dataset

**Software:**
- Analysis performed using **SPSS version 23**

**Reporting:**
- Two-sided p-values
- 95% confidence intervals for effect estimates
- Tables and figures for primary and secondary outcomes