# Eastern Association for the Surgery of Trauma

Advancing Science, Fostering Relationships, and Building Careers

## EAST MULTICENTER STUDY PROPOSAL

**Data Collection and Statistical Analysis:**

*Outline the data collection plan and statistical analysis plan succinctly here*

*An example might include:*

- *Standardized data will be collected for each patient (see data sheet, Appendix A). Risk factors for failure to achieve primary closure of the open abdomen will be assessed using univariate and multivariate analysis.*
- *Continuous variables will be compared using Student's t-test and the Mann Whitney U test. The Chi-squared tests or Fisher's exact test will be used to compare categorical variables. All variables with a p value <0.2 on univariate analysis will be entered into a multivariable logistic regression analysis to identify independent risk factors for failure to achieve primary fascial closure and development of complications. Data will be reported as adjusted odds ratios with 95 % confidence intervals. Statistical significance will be set at a p<0.05.*

**Consent Procedures:**

*Outline consent procedures here, if applicable. As an example for a prospective study where waiver of consent will be sought, verbiage might include:*

*"This is a prospective observational study, designed to prospectively record data on patients who are managed according to institutional patient management protocols. Thus, waiver of informed consent is requested. Data will be recorded on a data sheet and transferred to a secured database that is devoid of patient identifiers."*

**Risk/ Benefit Analysis:**

*Succinctly outline a risk / benefit analysis. An example of this might include:*

*"The incidence and natural history **DISEASE PROCCESS TO BE STUDIED** is unknown. If the optimal timing for and type of intervention can be identified to optimize outcomes in these patients, then significant benefit will result."*