Essential Elements of a Protocol

STUDY SCHEMA
STUDY SUMMARY
BACKGROUND AND RATIONALE
STUDY OBJECTIVES
- Primary Objectives
- Secondary Objectives
- Exploratory Objectives
- Endpoints

PATIENT ELIGIBILITY
TREATMENT PLAN
- Dosage and Administration
- Toxicities and Dosing Delays/Modifications
- Duration of Therapy
- Duration of Followup
- Removal of Patients from Therapy
- Patient Replacement

STUDY PROCEDURES
- Procedures at Screening/Baseline, During Treatment, and Followup
- Time and Events Table
- Removal of Subjects

MEASUREMENT OF EFFECT
ADVERSE EVENTS
- Monitoring
- Definitions
- Reporting Requirements
- Unblinding Procedures
- Stopping Rules

DRUG INFORMATION
CORRELATIVES/SPECIAL STUDIES
STATISTICAL CONSIDERATIONS
- Study Design/Study Endpoints
- Sample Size and Accrual
- Data Analyses Plans

STUDY MANAGEMENT
DATA MANAGEMENT AND MONITORING/AUDITING
- Data Management Plan
- Data and Safety Monitoring Plan
- Data Monitoring Committee/Data Safety Monitoring Board

REFERENCES
APPENDICES

All protocols must list an initial version date (should be the final version approved by the DFG) and list the amended date with each new amendment.