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.