Contents of a Clinical Trial Protocol (Example)

(d) Study Drug Interruption
(e) Dose Modification for Toxicity
(f) Packaging and Labeling
(g) Study Drug Supply, Storage, and Handling
(h) Drug Accountability
(i) Disposal, Return, or Retention of Unused Drug
(j) Compliance
(k) Blinding and Unblinding
    i. Blinding
    ii. Unblinding

11. Assessments
    (a) Timing of Assessments
    (b) Informed Consent/Assent
    (c) Subject and Disease Characteristics
    (d) Efficacy
        i. Primary Endpoint Assessment
        ii. Assessment of Secondary Endpoints
        iii. Assessment of Other Endpoints
    (e) Safety
        i. Adverse Events
        ii. Assessment of Adverse Events
12. Statistical and Analytical Plans
    (a) Sample Size and Power
    (b) Analysis Sets
    (c) Statistical Analysis
        i. General Considerations
        ii. Descriptive Analysis
            A. Subjects
            B. Demographics and Baseline Characteristics
            C. Prior and Concomitant Medications
            D. Study Drug Exposure
            E. Study Drug Compliance
    (d) Efficacy Analysis
        i. Analysis of Primary Outcome
        ii. Analysis of Secondary Outcomes
        iii. Analysis of Other Outcomes
    (e) Safety Analysis
        i. Adverse Events Analysis
    (f) Interim and IDMC Analyses
        i. Interim Analysis
        ii. DSMB Analysis
13. Procedural, Ethical, Regulatory, and Administrative Considerations
    (a) Adverse Event and Serious Adverse Event Documentation, Severity Grading, and Reporting
        i. Adverse Events