KEY ELEMENTS OF A CLINICAL RESEARCH PROTOCOL

What is a clinical research protocol? It is the formal design or plan of an experiment or research activity. It is the plan submitted to an Institutional Review Board for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on collected data.

An NU clinical research protocol should include the following:

1. Cover Page
    a. Protocol title, version number and version date
    b. Name and address of principal investigator
    c. Site(s) where study will be performed
2. Background/Rationale/Literature Review - basis for doing the clinical research study
3. Hypothesis/Key Questions - the hypothesis being evaluated; the key questions being asked in the research study
4. Research Objectives and Purpose - an extension of the hypothesis/key questions--can be combined. **Describe what procedures and research interventions are is being conducted at NU.**
5. Research Methods
    - Study Design (includes some or all of the following)
        - Primary and secondary endpoints
        - Type/design of the study (double-blind, placebo-controlled, etc.)
        - Measures taken to avoid/minimize bias (randomization, blinding)
        - Study treatments or interventions
        - Expected duration of subject participation; what is done and when
        - Stopping rules or discontinuation criteria
6. Selection and Withdrawal of Subjects
        - Inclusion criteria (include age range when subjects are being enrolled/consented)
        - Exclusion criteria
        - Withdrawal criteria (if applicable)
        - Recruitment Plan (if subjects are enrolled/consented) [age range, number of subjects at NU and all sites, list of all projects sites where subjects will be recruited)
        - Consenting Procedure (location, who will consent subjects, etc.)
    - Subject Compensation
7. Efficacy Assessment
8. Risk
9. Benefit
10. Safety Assessment – including recording adverse events
11. Statistical Analysis
        - Statistical methods including interim analysis if appropriate
        - Number of subjects to be enrolled
        - Rationale for choice of sample size (power calculation and clinical justification)
        - Level of significance to be used
        - Criteria for terminating the study
        - Procedures for reporting deviations from the original plan
        - Selection of subjects for inclusion in the analysis
6. Anticipated Results and Potential Pitfalls
7. Discussion of Next Steps
8. Scientific References/Bibliography