Creighton UNIVERSITY

Creighton University Institutional Review Board
2500 California Plaza, Omaha, NE 68178 • Phone: 402-280-2126 • Fax: 402-280-4766
Campus Address: Criss I, Room 104
Email: irb@creighton.edu

Guidance

Writing a Research Protocol

Please submit a protocol that includes all of the following sections. Protocols must include a version number and/or date and all pages must be numbered.

1) Background and Significance (including progress report and preliminary studies)
   a) Historical background
   b) Previous pre-clinical or clinical studies leading up to and supporting the proposed research
   c) Rationale behind the proposed research and potential benefits to participants and/or society

2) Specific Aims (Research Objectives)
   a) Specify objectives and hypotheses to be tested in the research project

3) Subject Selection
   a) Inclusion/exclusion criteria
   b) Source of subjects and recruitment methods

4) Subject Enrollment
   a) Methods of enrollment, including procedures for participant registration and/or randomization
   b) Procedures for obtaining informed consent (including timing of consent process)
   c) Treatment assignment and randomization (if applicable)

5) Study Procedures
   a) Study visits and parameters to be measured (e.g., laboratory tests, x-rays, and other testing)
   b) Drugs to be used (dose, method, schedule of administration, dose modifications, toxicities, including Toxicity Grading Scale (if applicable))
   c) Devices to be used
   d) Procedures/interventions, etc.
   e) Data to be collected and when the data is to be collected

6) Biostatistical Analysis
   a) Specific data variables being collected for the study (e.g., data collection sheets)
   b) Study endpoints
   c) Statistical methods
   d) Sample size considerations and power analysis (e.g., evaluable participants, etc.)

7) Risks and Discomforts (stratify by common and uncommon)
   a) Complications of surgical and non-surgical procedures, etc.
   b) Drug side effects and toxicities
   c) Device complications/malfunctions
   d) Psychosocial (non-medical)
   e) Radiation risks (see the Radiation Safety Committee)

8) Potential Benefits
    a) Potential benefits to participating individuals
    b) Potential benefits to society (e.g., increased understanding of disease process, etc.)

9) Monitoring and Quality Assurance
    a) Independent monitoring of source data
    b) Safety monitoring (e.g., Data Safety Monitoring Board, etc.)
    c) Outcomes monitoring
    d) Adverse event reporting guidelines

10) References