1. **PURPOSE**
   To document the review and approval process for clinical trials.

2. **SCOPE**
   All clinical research groups in which clinical research involving human subjects is conducted.

3. **RESPONSIBILITIES**
   The Principal Investigator (PI), Study Coordinator (SC), or other delegated staff member is responsible for submitting all grant applications, study protocols, contracts, and budgets for Creighton University review and authorized signatures.

4. **BACKGROUND**
   The Office of Grants Administration for Creighton University must review all agreements, contracts, amendments, and any other legal documents requiring University signature for execution. Prior to signature, documents must be reviewed by appropriate university staff. Final documents must be accompanied by requisite routing forms for Division, Department, School, and University review and approval.

5. **PROCEDURE**
   **5.1. Review and Revision** - Clinical investigations offered by a sponsoring agency or contract research organization on behalf of a study sponsor should include the following review:
   5.1.1. Confidentiality/Nondisclosure Agreements should be routed to Grants Administration for legal review. Revisions should be returned to the study sponsor for review and acceptance prior to Creighton University signing the Agreement. The Agreement might be signed by both the PI and the Vice President for Administration and Finance.
   5.1.2. New projects should be evaluated according to CLN 2.00 Study Feasibility
   5.1.3. Request draft Clinical Trial Agreement and study budget from the sponsoring agency.
   5.1.4. Route the Clinical Trial Agreement to Grants Administration for legal review.
   5.1.5. Review the study budget alongside the study protocol to determine the accuracy of the budget, and revise budget as necessary to cover the study procedures, staff costs, and University fees.
   5.1.6. Return any revisions to the Agreement and budget to the sponsoring agency for review and approval.
5.2. Investigator Qualifications

5.2.1. All Investigators must have the following documentation and required training complete

5.2.1.1. The Human Subjects Research Education Program

5.2.1.2. Financial Conflict of Interest Disclosure

5.2.2. All Investigators must have a current curriculum vitae signed and dated within the past two years and a copy of their current medical license or certification as required by their occupation.

5.2.3. All Faculty Investigators must be available to sign the Creighton University Proposal Routing Form.

5.2.4. Non-faculty (staff) should be listed under Research Staff Disclosures on the Creighton University Proposal Routing Form.

5.2.5. University staff and hospital staff performing tasks normally required of their positions are not required to be listed as Investigators on the Routing Form, or listed under Research Staff Disclosures. Examples include Pathology staff performing routine laboratory assays, technicians performing a standard ECG, and phlebotomy technicians performing standard venipuncture.

5.3. Creighton University Proposal Routing Form

5.3.1. The Creighton University Proposal Routing Form is the required cover sheet for sponsored projects, including clinical trials.

5.3.2. The Routing Form must be completed accurately and reflect the correct indirect cost rate for the type of project.

5.3.3. Forms, instructions, and contact information are available on the Grants Administration web site.

5.3.4. Signature of the PI, followed by the additional Investigators, is required prior to submitting the Routing form for Department review and signature.

5.3.5. After Department approval, the Routing form, study Protocol, study Agreement, study Budget, and any other attachments are submitted to Grants Administration for review and final routing for required University signatures.

6. TERMS & ABBREVIATIONS

CDA  Confidential Disclosure Agreement
CTA  Clinical Trial Agreement
ECG  Electrocardiogram
IRB  Institutional Review Board
PI   Principal Investigator
SC   Study Coordinator.
7. REFERENCES
   7.1. Creighton University Office of Research and Compliance Services
   7.2. Creighton University Grants Administration
   7.3. Creighton University Institutional Review Board

8. ATTACHMENTS
   Grants Checklist