Graphic Flow Chart of the Clinical Trial Process: Identifying Legal Elements

Intellectual Property

- Patents
- Trade Secrets
- Trademarks
- Copyrights

Contracts

- Contracts between sponsor and sites
- FDA Form 1571 - INVESTIGATIONAL NEW DRUG APPLICATION (IND)
- FDA Form 1572 - STATEMENT OF INVESTIGATOR
- FDA Form 3454 - CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS
- FDA Form 3674 – CERTIFICATION OF COMPLIANCE
- Investigational Device Exemption Application

Clinical Trials

- HIPPA/Privacy
- Informed Consent
- Standard of Care Vs. Research
- Adverse Events
- Data/Safety Monitoring Committees
- Responsibilities to Participants

Post Product Approval/ Rejection

- Risk Evaluation and Mitigation Strategy
- Responsibility to Participants/Consumers
- Publications

USC School of Pharmacy
International Center for Regulatory Science

SC CTSI

USC Resources

Study Navigation Tool: This Study Navigation tool will help you determine where to go to activate your clinical research study at USC, including contracting offices, review committees, and ancillary services. Based on your answers to basic questions (type of funding, study location), it displays the primary units and systems you can expect to interact with on the road to study activation. Note: there may be exceptions, depending on your specific circumstances.
Link: https://sc-ctsi.org/resources/new-study-navigation-tool

FDA Form 1572 – Commitments (Legally Binding)

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.