ANATOMY OF A CLINICAL TRIAL

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PEOPLE, COMPONENTS, and ACTIVITIES

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PEOPLE – Roles and Responsibilities

- Principal Investigator
- Project Manager
- Study Monitor
- Coordinator
- Clinical Staff
- Regulatory Staff
- Pharmacists
- Laboratory Scientists
PEOPLE – Service Organizations

• University of Minnesota
  • Clinical Trials Office
  • CTSI Clinical Research Services
  • Bionet
  • TTL – Translational Therapeutic Laboratory
  • MCT – Molecular Cell Therapy Services

• M Health (Fairview and UMP)
  • Medical Staff
  • Radiologists
  • Investigational Drug Services
  • Lab Services
LOCATIONS

- CTSI Research Services
- Delaware Clinical Research Unit (DCRU)
- Masonic Clinical Research Unit (MCRU)
- Clinics and Surgery Center (CSC)
- M Health Clinics
- Fairview Hospital System
Predefined written procedural method in the design and implementation of experiments

• General Information
  • PI
  • Title
  • Phase (I – IV)
  • Regulatory sponsor

• Rationale – Why does the PI think this will work?

• Study Objectives – What are they testing?
PROTOCOL

• Study Design
  • Population
  • Screening – Inclusion and exclusion criteria
  • Schedule of treatment and procedures
  • Methods to collect data
    • Blood test
    • Biopsy
    • Subject questionnaire

• Study Analysis
  • Data to be analyzed
  • Primary outcome measure
PROTOCOL

• Essential Documents
  • Informed Consent
  • Investigator’s Brochure
  • Record Retention
  • Study Monitoring
  • Adverse Events
    • Definition of Adverse Event vs. Serious Adverse Event
    • Responsibility to report
INFORMED CONSENT - Elements

- **Disclosure of information**
  - Purpose
  - Participation requirements or restrictions
  - Schedule of treatment and procedures
  - Side effects
  - Benefits
  - Cost (Co-pays, travel, stipend)
  - Confidentiality
INFORMED CONSENT - Elements

- **Capacity** of the subject to understand and ability to make a judgement
- Subject can **freely consent** without being subjected to external pressure such as coercion, manipulation, or undue influence
The IRB reviews research projects that involve human participants to ensure:

- Participants are not placed at undue risk
- Participants give uncoerced, informed consent to their participation.

The IRB is composed of approximately 60 members representing University faculty, staff, students, Fairview Health Services employees and the local community.
INSTITUTIONAL REVIEW BOARD

- Types of review
  - Full Committee
  - Expedited
  - Annual
  - Amendments (with or without Informed Consent change)
  - Closure
• Clinical Trial Management System
  • The CTMS maintains and manages planning, performing and reporting functions, along with participant contact information, tracking deadlines and milestones.
  • Legacy system TASCS
  • OnCore – Gradual implementation in process

• CTSI Portal
  • The Clinical Translational Research (CTR) Portal is an interactive, web-based system designed to provide targeted and secure access to research project information.
  • Time tracking and invoicing system
CLINICAL TRIAL SYSTEMS

- **EPIC**
  - Electronic health record software system for hospitals and clinics

- **Electronic Case Report Form**
  - Primary data collection tool for clinical trials
    - University created in TASCS or OnCore
    - Sponsor system
  - Record of treatment, procedures and outcomes
BUDGET – Cost Elements

• Start up costs
  • Clinical Staff Activities
    • Site initiation visit with sponsor
    • Create EPIC orders and review documents
    • Correspond with oversight committees
  • Regulatory Activities
    • Prepare and submit regulatory applications
    • Monitor IRB process and respond to stipulations
    • Create regulatory files,
    • Review study documents to insure Principal Investigator meets all compliance with regulations
  • Other Fees
BUDGET – Cost Elements

- **Subject Treatment and Care (Enrollment activity)**
  - Staff Labor
  - Clinic or hospital costs
  - Drugs and testing

- **Activities outside treatment schedule**
  - Subject Related (screen failure, unscheduled visit, additional tests, etc)
  - Study Related (regulatory requirements, monitor visits, amendments, re-consenting, etc)
BUDGET – Payment Terms

- Enrollment payments by sponsor
  - Lump sum per patient
  - Fixed fee based on activity
  - Program budget for large initiatives
- Services or treatment payable by SFR invoice
- Insurance payments for subject care
- Insurance co-pay by subjects
- University subsidy
STUDY ACTIVITY – Opening to Accrual

- Required prior to subject enrollment
  - IRB Approval
  - Clinical Trial Agreement and budget fully executed
  - Drug or Device received
  - EPIC and Lab orders established
  - Site initiation meeting has occurred
  - Training of study team
STUDY ACTIVITY – Ongoing Activity

- Subject Screening, Treatment, and Follow-up
- Safety Reporting (SAE/OSR)
- Monitor visits
- Protocol Amendments
- Budget Amendments
- Annual Review
- Audits
STUDY ACTIVITY – Closure

• Enrollment target met
• Abandoned for safety concerns
• Approval of device or drug for market release
CLOSE OUT PROCEDURE

- **Patient Information**
  - All Case Report Forms (CRFs) have been corrected, organized and filed
  - All serious events (SAEs) have been reported to the IRB, DSMB or Safety Monitor

- **Study Files are complete**
  - IRB approval letters (protocols, amendments, informed consent, annual reviews and advertisements)
  - IRB Membership list
  - All IRB correspondence
  - Site signature log
CLOSE OUT PROCEDURE

• Investigational Product
  • Clinical supplies, including any treatment intervention materials, have been shipped or disposed or according to protocol directions
  • Drug Accountability Records (shipping, receipt, dispensing, return or destruction) are up to date.

• Laboratory Records and Specimen Retention
  • Laboratory certifications, specimen tracking records, specimen storage records are complete and up to date.
  • Study specimens have been shipped to the analysis center
CLOSE OUT PROCEDURE

• Notifications and Equipment Removal
  • Final Report (study outcomes) has been prepared for the Institutional Review Board (IRB) and in conformance with institutional reporting requirements
  • Arrangements for the removal and shipment of any study specific equipment received by site (e.g. computers, diagnostics equipment, participant monitoring devices) have been made.

• Participant Rights and Notifications
  • A letter to thank each study participant has been prepared that includes relevant information (study findings, treatment assignment, explanation of close out, treatment options, transfer of care responsibilities, etc)
Resources

- Ctsi.umn.edu
- ctsi@umn.edu
- oncore@umn.edu