Study Start-Up & Essential Documents

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Objectives

Upon completion of this session, you will be able to describe the role of the site in:

- Pre-study contact
- Essential Documents
- FDA 1572
- Financial Compliance
- Investigator meeting
- Recruitment strategies
- Personnel responsibilities
- Organization of study files
- Source documentation
- Study drug & study supplies
- Site initiation visit
Pre-study Contact

- To confirm suitability of investigator & site to conduct research study
- To communicate sponsor expectations regarding general conduct of the study
- To ensure all regulatory, IRB and Good Clinical Practice (GCP) requirements have been met
- Confidentiality Agreement is sent by sponsor to site.
A Confidentiality Disclosure Agreement ("CDA") may also be referred to as a Nondisclosure Agreement (NDA) or Confidentiality Agreement.

The purpose of this type of agreement is to ensure that confidential information belonging to a party (or parties) to the agreement is protected.

The sponsor will not provide the site with any proprietary information (the protocol) until this is executed.

Although no longer required, Sponsored Programs can review and negotiate language if necessary.
Essential Start-up Documents from Sponsor

- Confidentiality Agreement
- Protocol
- Informed Consent Form (ICF) template
- Sample CRF’s
- Investigator’s Brochure
- Budget and Clinical Trial Agreement Template

- Advertising materials and brochures
- Financial Disclosure Forms (FDF’s)
- 1572 template
- Study operations manual
- Pharmacy Manual
Investigator Meeting

- Site training
- Key staff to attend
- The following items are reviewed:
  - Protocol objectives, rationale
  - Patient / subject selection criteria
  - Procedures & evaluations
  - Data collection
  - Clarification of questions
  - Recruitment strategies
FDA 1572

Signature on FDA 1572 obligates investigator as follows:

- compliance with protocol
- supervision by PI
- informed consent
- potential risks from study drug
- staff education

- IRB review & reports
- compliance with 21 CFR 312
- adverse experiences
- adequate records
Essential IRB Documents

Send to IRB:
- Protocol / amendments
- Investigator Brochure
- Sponsor Approved Consent forms
- Advertisements & Brochures

After Approval Obtain from IRB:
- IRB Approval letter
- IRB Approved ICF
- IRB membership list

IRB forms and guidance can be found at the following website:
http://research.ucdavis.edu/home.cfm?id=OVC,1
Contract & Budget

- Contract also known as CTA for a clinical trial agreement.
- Budget
- 700U state required financial form - only use if private sponsor
- Form 800 (federal form required for all human subjects studies private sponsor or otherwise)
- Exhibit B (university budget template)

Most of these forms can be found at the Sponsored Programs website
http://research.ucdavis.edu/home.cfm?id=OVC,3
Financial Disclosure Form (FDF)

- Financial disclosure is required by:
  - “Primary investigator, Sub-Investigator and/or Research Coordinator who is directly involved in the treatment or evaluation of research subjects”.

- Disclosure information includes:
  - A financial arrangement to include a grant to fund for ongoing research, compensation in form of equipment or ongoing consultation honoraria exceeding $25,000.
  - Equity interest exceeding $50,000 questionnaire
  - Compensation affected by outcome of study
  - Proprietary interest in study drug
**Documents Required by Sponsor for Initial Drug/Device Shipment**

- Original signed/dated protocol agreement page
- Copy of IRB approval letter, informed consent form, any patient education materials and advertisements
- Copy of IRB Membership List
- Original signed and dated Form FDA 1572
- CVs and medical license of principal, sub-investigators & study coordinator
- Original signed and dated Financial disclosure Forms (FDF)
- Fully Executed CTA and budget
Study Supplies

Supplies shipped to site include:

- Case Report Forms/ workbooks
- Laboratory supplies/Sample Collection Kits
- Study specific equipment (EKG machine)
- Regulatory binder
- Protocol Required Questionnaires
- Protocol-specific equipment
- Operations Manuals
- Study drug or Device
Recruitment Strategies

- Chart Audits
- ICD-9/CPT code EMR searches
- Health Screenings
- Advertising
- Referrals
- In-service Presentations
- Advocacy groups
Site Personnel Responsibilities

- Delegated by principal investigator
- Recorded in Delegation of Responsibilities Log
- Include appropriate education, training & experience
Prepare Study Files

- Use sponsor-designated sections
- File documents immediately
- Ensure documents filed consistently
Source Documentation

- A source document is the first recording of a study observation
- Use single line with date & initials to correct erroneous information
- Verify all data points on CRF in source documents
- Sign & date all source documents in black ink
- Record what is source document
- Use source identifiers
Study Drug Accountability

- Inventory drug
- Check for discrepancies
- Acknowledge receipt of drug
- Ensure appropriate storage conditions
- Prepare drug accountability log
- Understand randomization system
- Clarify unblinding procedures

Completed and managed by the
Investigational Drug Service (IDS)
Initiation Visit

Takes place after site has received first shipment of clinical supplies, & usually prior to any subject enrollment

- The following topics will be reviewed:
  - Drug inventory
  - Study protocol
  - Administrative binder
  - Adverse event reporting procedures
  - Good Clinical Practice
  - Source documentation
  - Record Retention
  - Procedures for completion of workbooks
  - Recruitment strategies
  - Monitoring procedures
Time to enroll:
Summary

During the study start-up phase, the Investigative site should:

- Review the protocol
- Attend the Pre-study visit and investigator’s meeting
- Obtain Essential Documents
- Organize study files and supplies
- Determine site personnel responsibilities
- Plan for subject recruitment
- Participate in the site initiation visit
Questions?

THANK YOU!