Overview of Investigator Initiated Trials (IIT)

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Objectives

• What are IITs?
• Review the responsibilities and role of PI in IITs
• General overview of timeline, funding, and next steps with these trials
• Brief overview of IDE and INDs
Investigator Initiated Trials (IIT)

• Clinical trials/studies/research
  • Investigator initiated study/research
    • “Individual” researcher
      • Team of experts and individuals involved: mentors (if applicable), program manager, grants manager, research coordinators and assistants, regulatory team, pharmacist, etc.

• Pharmaceutical companies
  • Also referred to as “industry”

• Contract Research Organizations (CROs)
  • Intermediary
Who is a “sponsor”?

• Oversees the clinical trial – takes responsibility for and conducts the trial

• Sponsor may be the pharmaceutical company
  • CRO is the “middle (wo)man”
  • There is an overall principal investigator (PI) and site PI at each site

• In IITs, the researcher with the idea for the study at the research site is both sponsor and investigator
Responsibilities of the investigator

• Design protocol
• Manage the investigational drug or product
  • Acquisition – from the manufacturer
  • Approvals
• Follow regulations
  • IRB, FDA
• Training team involved in the trial
• Financial disclosures
• Monitor progress
• Assure protection of human subjects, monitor safety
• Data collection, study visits
• Keep IRB and FDA updated
What is the process?

Before funding
• Study design
• Protocol
  • Statistics
  • Collaborations
  • Sites
• Funding application!
  • Budget
• Personnel
• Grants review

We will get all the grants.
For all the things
Process – study design, protocol

- Investigator’s idea
- Does the facility have the resources needed
  - Staff
  - Equipment
  - Space
- Is recruitment feasible
  - Inclusion/exclusion
- Collaborations
  - Single center or multicenter trial!
  - Contractual agreements between institutions
Process – funding and budgets

• Funding
  • Grant proposal with budget
  • Budget needs to be reviewed/approved by home institution
    • Grants administration department
    • Chair of the department
    • Funding for research assistant, coordinators, regulatory fees, etc.

• Sources of funding
  • Industry: pharma, device manufacturers
    • Remember: Industry is NOT the sponsor, the investigator is in IITs
    • Research support includes providing drug or device
    • Also have funding mechanisms for IITs
  • Foundations
    • National or institutional
  • Federal
    • [www.grants.gov](http://www.grants.gov)
    • NIH, DoD, etc.
Process

Received funding!

• OSRA number (office of sponsored research administration)
• Contracting
• IND/IDE if indicated
• IRB submission/approval
• NCT registration (national clinical trial) – www.clinicaltrials.gov
• CMS approval if indicated
Process – IDE or IND

• Investigational Device Exemption (IDE)
  • Approved by IRB +/- FDA approval if determined to be significant risk
  • Can ask for a risk assessment by the FDA to see if full application needed

• Investigational New Drug (IND) – research (non-commercial)
  • “Studying an unapproved drug, or an approved product for a new indication or in a new patient population”
  • Preclinical data and previous experience with the drug in humans (perhaps outside the US)
  • Manufacturing information
  • Clinical protocols

• New Drug Application (NDA)
• FDA – approved in 30 days unless FDA states otherwise
Process

- Contracting
  - Separate department at institution
  - Institutional language

- IRB submission
  - Consent forms
    - Languages
  - HIPAA
  - Data storage plan
    - For example, RedCAP
Process – CMS approval

• Medicare coverage related to IDE studies
• “The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) allowed Medicare payment of the routine costs of care furnished to Medicare beneficiaries in certain categories of Investigational Device Exemption (IDE) studies. Covering the costs in these IDE studies removes a financial barrier that could otherwise discourage beneficiaries from participating.”
• Will cover routine care aspects of the study but not the experimental aspect
• Request letter describing the IDE study
  • IDE approval
  • IRB approval
  • National Clinical Trial number (NCT)
Process

- ✔ Funding
- ✔ Contracts signed
- ✔ IDE/IND
- ✔ Database setup
- ✔ IRB approval
- ✔ CMS approval
- Start recruiting!
During and after the study

• Investigator responsibilities
  • Research coordinators, assistants, regulatory
  • Sub-investigators
• Tracking adverse events (AEs)
• Progress report to funding agency
• Updating IRB
• DSMB involved
  • Data and Safety Monitoring Board
• Study closeout
• Publications