Introduction to Investigator-Initiated Research

Presentation to Division of Cardiology
January 26, 2011

Capital Health

Healthy People, Healthy Communities

Presentation Overview

- Clinical Trials
- Investigator as Sponsor
- IIR Research Studies and Agreements
- Budgets/Sources of Funds
- Recommendations

Clinical Trials:

- Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. (International Committee of Medical Journal Editors)*

- Clinical trials must be conducted in accordance with applicable Health Canada Regulations for: Drugs, Natural Health Products, Surgical Procedures,Medical Devices

- If it's a drug or NHP trial, it must also be conducted in accordance with ICH E6: Good Clinical Practice Guidelines http://www.ich.org

*Studies that are not clinical trials are referred to as "non-interventional studies at CH

Investigator as Sponsor

Sponsor: an individual, corporate body, institution or organization that conducts a clinical trial. [Food & Drug Regulations, Division 5 (Clinical Trials)]

- An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial. [ICH GCP 1.53]

Sponsor-Investigator: An individual who both initiates and conducts, alone or with others, a clinical trial… The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator. [ICH GCP 1.54]

Investigator as Sponsor

- The PI is a **sponsor-investigator** and must comply with all **sponsor** requirements *and* **investigator** requirements in the Regulations & ICH GCP (Sections 4 and 5)
- The PI is responsible for:
  - Filing CTA with Health Canada (required for Class 2-4 device trials and Phase 1-3 drug and NHP trials)
  - Registration of Study at www.clinicaltrials.gov
  - Monitoring Plan and Monitoring
  - SAE Reporting
  - Protocol Amendments
  - Complete the QIU and ensuring QIUs are in place for each PI involved.

** Warning **

Sponsor is not synonymous with **Funder**!

IIR Research Studies

- **Single Centre**
  - Agreements with funding source or award letter
  - Budget only for CH
  - Potential Agreements with third parties
  - PI/Sponsor obligations
  - No limits on IP Ownership and Publication
- **Multi centre**
  - Participating site
    - Sign site agreement with Lead Site/Investigator
  - Lead site/Lead Investigator
    - Participating site agreements with each site

CDHA Participating Site/ PI

- Institution
  - Sub-Institution, Participating Site
- Lead Investigator/Sponsor written Protocol
  - Principal Investigator at Local Institution
- Budget already provided
  - No overhead or mandatory fees included
- External Funder
  - Negotiated Agreement with Coordinating Site/Lead Investigator
- IP Ownership and Publication
- Administrative and Oversight Req's.
- Indemnity
  - Each sites accepts liability*

CH Lead Site/Investigator – Multi Centre Study

- Protocol written by Local Investigator / Sponsor (sometimes in collaboration with sites)
- Consult with participating sites re: budget expectations, resources, infrastructure, publication, data management
- Prepare and enter into Participating Site Agreements with each site
- External funder and/or provider
  - Budget development and terms
  - Funder agreement

Lead Site/Investigator – Multi Centre Study

- Administrative and Oversight requirements
  - Site visits/monitoring (Drugs and NHP only)
- Data management plan
  - Data entry
  - Analysis
- IP ownership and Publication
  - Site data,
  - Combined dataset
  - Publication terms (steering committee, enrollment,)
- Indemnity
  - Each site accepts liability*

Common Agreement/IIR Research Challenges

- Terminology
  - Sub-Investigator
  - Sponsor/Funder
- Requests for Indemnity
- Budget restrictions
- Sharing/Copying of Patient Medical Data
- Third Party Agreements
  - Fee for Service
- International sites/Regulations
- The **Funder** acting like the **Sponsor**
- Insurance

IIR Research Budgets

- All IIR Studies with costs above standard of care require a well defined and planned budget. This budget should itemize each cost.
- Specifically:
  - Laboratory/procedure/departmental costs – get a quote up front
  - Personnel and staffing costs- contact CH HR
  - Travel Costs – site investigators meeting, training,
  - Communication costs
  - Data entry and analysis costs*
  - Equipment costs *
  - Monitoring*
  - Drug purchasing, handling or storage, labelling

* Third party service or purchase agreements must go through CH purchasing

Funding Sources/Grant Applications

- Granting competitions –CIHR, NSHRF, Heart and Stroke
  - study budget
  - award letter
  - application
  - submission
  - “institution paid”
  - signatures
- An award received from CH/DAL Department or Division – study budget, award letter/account specifics

Funding Sources/Grant Applications

- Support received from Industry/External Funder at Investigator' or Institution's request
  - Requires funder agreement outlining terms of provision of funds.
  - Industry support - subject to 15% overhead on total budget.
  - Foundation or other agency support subject to allowable overhead as per agency's policy.
- Opening a Research Account

Recommendations

As a researcher, make sure you:

- Know which (if any) Regulations and standards apply to your trial
- Understand that you are also the Sponsor!
- Accurately and consistently identify the sponsor in all study documents
- Carefully consider logistics: randomization mechanisms, regulatory & essential documents, record keeping, training, archiving, PAPERWORK
- Budget ($$$, time, expertise) for the duties that come with being the sponsor of a regulated clinical trial

Recommendations

- Ask Research Services for advice
  - Research Quality - Mary Kate Needler
  - Research Education - Janet Gallant
  - Office of Contract/Grant Facilitation and Support
  - Research Finance – Denise Hatchette
- Familiarize yourself with the services available at CH and the relevant guidelines and processes
- Liaise with others who have been down the same path
- Share your experiences with your colleagues!

Further Questions or Requests for Assistance ???

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