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**Industry-Sponsored Clinical Research at
BUMC: An Introduction**

Clinical Research Seminar
November 19, 2008

Learning Objectives

- Finding sources of industry funding for clinical efforts
- Navigating from project concept to award
- Managing fiscal aspects of the clinical research project

Industry Agreements for Clinical Research at BUMC: Who's Who?

- Karen Mullin, Sr Research Attorney, ORA
 - Negotiates all industry agreements
- Emily Campbell, Research Administrator, ORA
 - Triages review of proposals
 - Negotiates budget
- Linda Davis, Research Administrator, Research Accounting Office
 - Manages accounts through close-out

What is Clinical Research?

Clinical Research $\neq$ Clinical Trial

Based on HHS definition:

- Any research project that involves human subjects (living persons) about whom an investigator conducting research obtains:
 - Data through intervention with the person (e.g., drug trial)
 - Data through interaction with the person (e.g., survey)
 - Identifiable private information
- When in doubt----ASK THE IRB!

Strategic Advantage for PI

- Potential expansion of menu of sponsors as funding climate becomes more difficult
 - NIH budget flat-lined since FY2003
 - Some sponsors reducing or rescinding awards
- Access to conduct research on drugs/devices
- Build new research directions with potential to impact on health care delivery

Strategic Advantage for Industry

- Access to good name of BUMCenter institution and investigators
- Access to patient population/database
- Potential payoff (e.g., new indication for approved drug) with less investment than in-house research

Finding Industry Funding

- Community of Science (www.cos.com)
- Colleagues/mentors
- Contacts at meetings

Agreements

- Institutional approval of contracts is required for:
 - Manufacturer of test article (if not currently marketed)
 - Entity providing support (cash or in-kind)

Agreement Types for Clinical Research Protocol

<u>Study</u>		
<u>Initiator:</u>	<u>Company</u>	<u>Investigator</u>
Develops protocol	X	X
Files IND/IDE	X	X
# of sites	may be multiple	usually single
Clinicaltrials.gov	X	X

Getting Started

Industry-initiated clinical research project

- Confidentiality Disclosure Agreement (CDA)
 - Company usually asks for CDA to be signed before sending protocol
 - PI, not BUMC, signs such CDAs
- Contact Karen Mullin before signing

Initiating Review of a Sponsored Research Agreement

Send the following to Emily Campbell, ORA:

- Hard copy:
 - Completed checklist (handout)
 - Proposal Summary Form
 - Project-specific COI Form
 - Approvals (IRB, IBC, etc)
 - Protocol
- Electronically:
 - Sponsor's Study Agreement
 - Preliminary Budget

Reminder: Financial COI

- Who Must Submit a Project-specific COI Form?

All principal investigators, co-investigators, and others (e.g., graduate students, post-doctoral fellows, technicians), who are responsible for designing, conducting, or reporting covered research.

- BU FCOI FAQs:

<http://www.bu.edu/research/compliance/financial-conflict/faqs/index.shtml>

- BU FCOI Power point:

<http://www.bu.edu/research/policies/ppt/conflict4.ppt>

- Dec. 20---Susan Frey will present on COIs

Investigator-initiated IND or IDE

- If IND or IDE is required, PI typically holds IND or IDE and must fulfill *substantial* FDA responsibilities as “Sponsor-Investigator”
- Office of Clinical Research Guidelines
<http://www.bu.edu/cms/www.bumc.bu.edu/ocr/files/PDFs/Sponsor-InvGuidelinesBU.pdf>
- When in doubt---ASK PAT BASS, Associate General Counsel, BMC!

Review & Negotiation of Agreement (budget)

- Include all relevant costs
 - Company may provide budget estimate or ceiling but need to estimate real cost of study
 - 30% F&A on Total Direct Cost
 - Include start-up costs (e.g., RB review, study advertising for patient recruitment, pharmacy fee)
- Determine payment terms & schedule
 - Up-front payment for up-front costs
 - More aggressive payment schedule for “riskier” companies

Review & Negotiation of Agreement (non-financial)

Key Issues:

- Intellectual Property
- Confidentiality
- Publication rights
- Indemnification

Account Set-up

Prerequisites:

- Agreement executed (signed by all parties)
- All applicable IRB, IACUC, IBC approvals in place
- Any COI issues resolved

THEN

- Source account is set up
- Study can begin

Account Management

- Periodically review account activities & charges
- Promptly invoice company
 - Research Accounting invoices for scheduled payments, and initial start up costs
 - Department invoices for payments based on patient accrual
- Ensure that compliances are current
- Notify ORA if terms of study change

Account Close-out

At end of study:

- Review account to reconcile expenditures
- Verify that all payments have been received
- Resolve any cost over-runs before the account can be closed out
- Work with Research Accounting to properly close out account



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