AN ACADEMIC HEALTH CARE CENTER’S RESPONSE TO CLINICAL TRIAL MANAGEMENT

Penn State Milton S. Hershey Medical Center, Penn State College of Medicine, Hershey, Pennsylvania

INTRODUCTION

An academic health center strives to balance the competing interests of industry, academic researchers, and the public in the development of drugs and devices leading to potential advancements in healthcare. At Penn State Milton S. Hershey Medical Center (PSHMC), we have developed an integrated Research Support Team that is a critical component for streamlining the regulatory, contractual, and financial aspects of clinical trial management at our Institution.

PROCESS

The PSHMC Research Support Team is comprised of the Office of Technology Development (OTD), Clinical Trials Office (CTO), Human Subjects Protection Office (HSPO), and Office of Research Affairs (ORA). The collaborative efforts of these departments have created a process that provides the framework to balance effectively and efficiently the needs of all parties involved.

DISCUSSION

The integrated PSHMC Research Support Team process will be evaluated periodically to judge its effectiveness, and adjust practices as needed, to improve the Institution’s clinical trial management. PSHMC is dedicated through its Research Mission to develop an environment to achieve excellence in research throughout our academic health center.

Clinical Trial Management: From CDA to Award

Each Office is responsible for a key component of this process.

Office of Technology Development

The Office of Technology Development negotiates and processes the Confidentiality Disclosure Agreement.

What is a Confidential Disclosure Agreement?

- A Confidential Disclosure Agreement (otherwise known as a CDA) is a binding legal contract
  - Institution and Sponsor
  - PI acts on behalf of Institution
  - A CDA binds the recipient to protecting the sponsors proprietary information
- CDAs must be reviewed, negotiated (if needed), and signed by Institutional officials (fully executed) before the Principal Investigator reviews a protocol
  - The CDA review
  - The primary reason for review is to protect the Institution and investigator from legal ramifications
  - A thorough review can help facilitate a successful contract negotiation process
  - OTD and ORA work hand in hand
  - OTD provides ORA with a monthly report of fully executed CDAs
  - The end GOAL is to put our Institution in a legally sound position for site selection

Clinical Trials Office

The Clinical Trials Office determines protocol feasibility, analyzes the research budget and may submit regulatory documents.

1. Full CTO Service Option

- Principal Investigator Staff
- Technology Development
- CTO
  - Protocol Feasibility
  - Standardized Budget Creation
  (includes price quote acquisition for clinical procedures & labs)
- Database Entry
- Recruitment/Advertising (optional)
- Regulatory process

2. Limited CTO Service Option

- Principal Investigator Staff
- Technology Development
- CTO
  - Protocol Feasibility
  - Standardized Budget Creation
  (includes price quote acquisition for clinical procedures & labs)
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- Regulatory process

Office of Research Affairs/Human Subjects Protection Office

The Human Subjects Protection Office reviews the research for quality purposes and compliance with applicable federal law and local policies. Concurrently, the Office of Research Affairs negotiates and executes the Clinical Trial Agreement.

Clinical Trial May Begin Site Initiation/Enrollment

PI/Dept. Research Staff

HSPO

ORA

PI/Dept. Research Staff

HSPO

ORA

PSHMC Research Support Team Members:
Kathleen Hay, PhD, CIP
Monali Patel, MBA
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Conflict of Interest?
Unmanaged
Managed?

Conflict Resolution Process

STOP

Statement of Award Issued by ORA
Statement of Award Packet Distributed to:
Principal Investigator, Study Coordinator, Department Budget Office, Controller’s Office, HMC Finance

Award Process Initiated Upon Receipt of Executed Contract and All Research Approvals

Contract/Budget Negotiations Complete
ORA Notifies CTO or Department

Statement of Award Letter

Contract Review Process for Industry Sponsored Clinical Trials

ORA Receives Draft Contract and Internal Documents From:
CTO or Department

ORA Reviews Draft Contract
(oral or written)

Contract/Budget Negotiations Initiated Between ORA and Sponsor
CTO and/or Department Provide Budget Revisions
ORA, CTO and/or Department Collaborate to Finalize Budget

Statement of Award

Statement of Award Issued to ORA
(Statement of Award Packet Distributed to:
Principal Investigator, Study Coordinator, Department Budget Office, Controller’s Office, HMC Finance)

Clinical Trial May Begin Site Initiation/Enrollment