



## UT-PHS JOINT LEADERSHIP MEETING

October 12, 2010

## PARTICIPATION IN CLINICAL TRIALS AND RESEARCH

**Debra E. Gmerek, Ph.D.**

Assoc Dean of Research COM, Dir Jacobson Center for Clinical & Translational Research

# Key Definitions

- **Research** - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
  - Based not on the Art of Medicine, but upon Scientific Investigation
- **Human Subject** - A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.
- **GCP** (Good Clinical Practice)- A standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials or studies



# Foundations for the ethical conduct of clinical research

- The Nuremberg Code (1947)
- The Declaration of Helsinki (1964)
- The Belmont Report (1979)
- International Conference on Harmonisation (ICH-GCP)
- Code of Federal Regulations (1997) 21 CFR



# Goals of Good Clinical Practice (GCP):

- To protect the rights, safety and welfare of humans participating in research
- To assure the quality, reliability and integrity of data collected
- To provide standards and guidelines for the conduct of clinical research
- GCP = Ethics + Quality Data



# Clinical Trials Research

- Industry-Sponsored
  - Phase 3 or Phase 4
  - Phase 2  $\Rightarrow$  key opinion leader
- Investigator-Initiated
  - Non-funded
  - Industry-funded
  - NIH-funded participant site
  - NIH-funded PI

# Primary Investigators are Responsible for:

- Ensuring that a clinical investigation is conducted according to the investigational plan, and applicable regulations;
- Protecting the rights, safety, and welfare of trial subjects;
- Control of drugs, biological products, and devices under investigation
- Obtaining and documenting the informed consent of each subject or each subject's legally authorized representative
- To personally conduct or supervise the investigation
- To comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR 312.

## **PHS Research Office (PHSRO) and UT Jacobson Center for Clinical & Translational Research (J-CCTR) will provide:**

- Clinical Research Administration
  - Legal and Financial
- Clinical Research Coordination
  - Regulatory Documents
  - Subject Recruitment Strategy
  - Subject Consent and Screening
  - Subject Visit Scheduling and Preparation
  - Subject Visit Procedures
  - Data Entry

# PHS Research Office (PHSRO) and UT Jacobson Center for Clinical & Translational Research (J-CCTR) will provide:

- Control of drugs, biologics or devices
  - In association with Pharmacy
- Audit Preparation
  - Sponsor monitor visits
  - FDA audit

Debra Gmerek 419-383-6960  
Janet Lyon 419-291-3498

# Investigator Responsibilities in Practice:

- Understand the protocol
- Complete required training
  - CITI
  - Protocol Specific
- Respond to requests for review and approval of documents
- Allow Clinical Research Coordinator access to patients for screening
- Work with Clinical Research Coordinator to consent subjects and operationalize the protocol

<https://www.citiprogram.org/Default.asp>

<http://ohrp-ed.od.nih.gov/CBTs/Assurance/default.asp>



# Academic Health Center Clinical Trial Collaboration Models

- “Single site” with PI and co-investigator(s) at UT and PHS
- Two site, with administrative efficiencies
  - Contract, budget
  - IRB, informed consent (reciprocity agreement)
  - Clinical Research Coordinator training
- Single site, single investigator

# Getting Started: Sponsor Contact

- Confidentiality
- Protocol Feasibility – enhanced through collaboration?
- Contract – through UT with subcontract to PHS if necessary
- Budget – meets both organization's fee structure and approval
- IRB – mutual recognition of PHS and UT IRB's, single informed consent template



# Getting Started: Patient Contact

- Availability of clinical trials
  - [clinicaltrials.gov](http://clinicaltrials.gov)
  - <http://utm.utoledo.edu/educationresearch/research/currentstudies.html>
  - <http://www.promedica.org/default.aspx?PageID=1470>
- Informed Consent before doing anything

# Compensation for Industry-Sponsored Clinical Trials

- PHS Investigators will be compensated for their participation in industry-sponsored clinical trials as before
- Overhead follows PI's institution on a per-subject basis



THE UNIVERSITY OF  
**TOLEDO**  
1872

## UT-PHS JOINT LEADERSHIP MEETING

*Questions - Comments*

**Better. Future. Together.**  
[www.betterfuturetogether.org](http://www.betterfuturetogether.org)

 THE UNIVERSITY OF  
**TOLEDO**  
1872

 **PROMEDICA**  
HEALTH SYSTEM

Jenn Kitzley, Medical Student

Bruce Barnett, MD