Syllabus
Navigating the IRB & Investigator Responsibilities
CTPS 6113

This course is designed for those with responsibilities in human subjects research. The course prepares researchers to:
- Identify the purpose, history and structure of the Institutional Review Board (IRB);
- Develop a framework for research with humans and human tissues, as well as vulnerable populations;
- Develop a protocol for submission to and review by the IRB;
- Report adverse events related to human research;
- Develop forms for obtaining informed consent from potential research subjects; and
- Develop acceptable methods for obtaining informed consent.

This program consists of three 90 minute sessions scheduled in Rebecca Sealy East 4.302/4.304.

Session 1: Tuesday, April 1, 9:30-11:00 am
Overview of the IRB
Links to handouts and PowerPoint presentation are below.

Topics:
- Governing Regulations
- Definitions
- The IRB at UTMB
- The IRB in Action
- Points for Investigators

Objectives:
- Define an IRB and discuss its role at UTMB
- Identify the regulatory agencies and regulations that govern IRBs
- List key best practices when working with protocols subject to IRB review

Speaker(s):
Research Services Staff

Links
Handouts for Session 1
PowerPoint Presentation Session 1
Class Recording Session 1

Session 2: Tuesday, April 8, 9:30-11:00 am
Getting Started - Initial Submissions & Ongoing Research Review
Links to handouts and PowerPoint presentation are below.

Topics:
- Overview of policies and requirements
- Initial Submissions and Reviews
- Continuing Review
- Study Closure
- Reporting Modifications, Deviations and Adverse Events

Objectives:
- Be able to explain the steps necessary to file an initial submission to the IRB
- Know the various steps and procedures involved in a protocol review
Understand when events need to be reported to the IRB

**Speaker(s):**
Research Services Staff

**Links**
Handouts for Session 2
PowerPoint Presentation Session 2
Class Recording Session 2
Video: InfoEd Tutorials

**Session 3:**  
**Tuesday, April 15, 9:30-11:00 am**
Obtaining Informed Consent
Links to handouts and PowerPoint presentation are below.

**Topics:**
- Definition of Informed Consent
- Regulatory and Ethical Foundation
- Informed Consent Process
- Best Practices and Tips

**Objectives:**
- Explain the informed consent process
- Identify the required elements of a consent form

**Video Presentation:**
"The Informed Consent Zone" (30 minutes - Optional)

**Speaker(s):**
Research Services Staff

**Links**
Handouts Session 3
PowerPoint Presentation Session 3
Class Recording Session 3
Video: Informed Consent Zone

**Prerequisites:** None

**Required Texts:** None

**Class Policies:**
**Grading**
This course is offered on a Satisfactory/Unsatisfactory basis. Grading is based on attendance and participation (70%); completion of the protocol model (15%), and completion of the informed consent form model (15%). 80% is required for a satisfactory grade.

**Disability/Special Accommodations Statement:** It is the policy of the University of Texas Medical Branch (UTMB) at Galveston to comply with the Americans with Disabilities Act, Section 504 of the Rehabilitation Act of 1973, and state and local requirements regarding students and applicants with disabilities. Under these laws, no otherwise qualified and competitive individual with a disability shall be denied access to or participation in services, programs, and activities of UTMB-Galveston solely on the basis of the disability. The University of Texas Medical Branch is committed to equal opportunity for students with disabilities. If you have a documented disability or would like to obtain information regarding services for students with disabilities, a complete copy of the “Student with Disabilities: Guidelines for Compliance” may be obtained from the Office of Equal Opportunity and Diversity.
UTMB Honor Pledge
On my honor, as a member of the UTMB community, I pledge to act with integrity, compassion and respect in all my academic and professional endeavors.

Student Conduct and Discipline
Student Conduct and Discipline policy in the Institutional Handbook of Policies and Procedures (IHOP), Section 7.1.3 (http://www.utmb.edu/policy/ihop/search/07-01-03.pdf). “General Responsibilities: It is the responsibility of every student, faculty member and administrative official to initiate a disciplinary complaint when scholastic dishonesty or other misconduct is involved” UTMB IHOP Section 7.1.3. Student Conduct and Discipline: General Responsibilities.