BENEFICENCE, RISK/BENEFIT ANALYSIS, AND THE THERAPEUTIC MISCONCEPTION  
October 15  
Michele A. Carter, Ph.D.  
Discuss ethical axioms related to the principle of beneficence in clinical research studies, including risk-benefit appraisals, typologies of harm, and common problems such as the therapeutic misconception.

PRINCIPLES OF THE BELMONT REPORT: INFORMED CONSENT  
October 22  
Jason E. Glenn, Ph.D.  
Discuss the ethical principle of respect for persons in human subjects research. Describe respect for persons in terms of a requirement for informed consent, emerging technologies and new research paradigms.

ROLES AND RESPONSIBILITIES OF THE PI  
October 29  
Erin L. Pennington  
Describe the responsibilities one assumes when taking on the role of Principle Investigator in both sponsored and FDA regulated research. Identify several responsibilities one assumes when taking on the FDA defined role of “Sponsor”

OVERSIGHT AT THE FEDERAL LEVEL: MOST COMMON PI PITFALLS AND MISTAKES  
November 5  
Erin L. Pennington  
Discuss the current regulatory landscape regarding federal and local oversight of human subject research. Describe common deficiencies from recent GCP Good Clinical Practice audit findings from Clinical Investigators (sites) and how to prepare, identify, prevent and mitigate problems in clinical research studies.

RESEARCH IN FOREIGN COUNTRIES  
November 26  
Alexandra (Lexi) Nolen, M.P.H., Ph.D.  
Discuss recent trends in drug testing in foreign countries, and causes of the trends. Describe several challenges of ethical research in low and middle-income countries. Describe some of the responses to these ethical challenges.

CONFLICTS OF INTEREST IN PHARMACEUTICALS RESEARCH  
December 3  
Howard Brody, M.D., Ph.D.  
Discuss the ethical implications of conflicts of interest, including its impact on trust. Give examples of recent pharmaceutical research where conflicts of interest have threatened public health. Discuss the possible role of IRBs in policing commercial conflicts of interest in pharmaceutical research.

HOT TOPICS IN HUMAN SUBJECT RESEARCH: ETHICS OF RESEARCH ON PRISONERS  
December 10  
Jason E. Glenn, Ph.D.  
Discuss the history of prisoner research including its expansion post Nuremberg. Describe proposals to revise prisoner research guidelines including irresolvable ethical conflicts.
# REGULATIONS AND ETHICS IN CLINICAL RESEARCH 2012-2013

## REGISTRATION FORM

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIRST NAME</td>
<td>LAST NAME, DEGREE</td>
</tr>
<tr>
<td>EMPLOYEE #</td>
<td></td>
</tr>
<tr>
<td>DEPARTMENT/SCHOOL</td>
<td></td>
</tr>
<tr>
<td>JOB TITLE (Eg. Professor, PGY-6, Research Fellow)</td>
<td></td>
</tr>
<tr>
<td>PHONE AND CAMPUS MAIL ROUTE</td>
<td></td>
</tr>
<tr>
<td>COURSE FEE: $55</td>
<td></td>
</tr>
<tr>
<td>Method of payment:</td>
<td>Check enclosed, made payable to: &quot;UTMB – ITS-EO&quot;</td>
</tr>
<tr>
<td></td>
<td>Internal UTMB Billing: ITS-EO will initiate billing process</td>
</tr>
<tr>
<td>YOUR DEPARTMENT SPEED CHART NUMBERS</td>
<td></td>
</tr>
<tr>
<td>YOUR BILLING CONTACT PERSON</td>
<td></td>
</tr>
<tr>
<td>YOUR BILLING CONTACT PERSON'S PHONE NUMBER</td>
<td></td>
</tr>
</tbody>
</table>

**FAX OR MAIL REGISTRATION TO:**
Institute for Translational Sciences Education Office (ITS - EO)
Research Building 6 (Children's Hosp), Room 6.174; Route 0342
301 University Blvd.
Galveston, TX 77555-0342
FAX (409) 772-1968
PHONE (409) 772-1484

---

This overview course is designed for faculty, fellows, graduate students, and others interested in the regulations and ethics of research involving human subjects.

**DESCRIPTION**
“Regulations and Ethics in Clinical Research” is a modular component of the clinical research course, Clinical Research: Tools and Techniques. This module consists of 10 weekly presentations by faculty from the Institute for the Medical Humanities, ITS Clinical Research Center Sponsored Programs and other experts. These one-hour lecture/discussion sessions occur on Monday evenings beginning at 5:15 p.m., Children’s Hospital, Room 2.312.

**OBJECTIVES**
Upon completion of this course, participants will be able to: (1) Describe regulatory and ethical issues important to clinical investigators and others involved in clinical research, and (2) Discuss important dimensions of research such as the history of federal regulations, federal oversight, and conflicts of interest.

**TO REGISTER**
Complete and submit the registration form located on this brochure and at “Education & Career Development” on www.ITS.UTMB.EDU or contact the Institute for Translational Sciences - Education Office by e-mail CTSA@utmb.edu or phone (409)772-1484. Those who have already registered for this year’s course, “Clinical Research: Tools and Techniques” do not need to register again for this module.

**EARN CREDIT**
IRB This course is designated by UTMB-Research Services as providing a preparatory framework for the required UTMB Internet-based training for human subject protections - CITI training module.

---

**This Course is Part of the Institute for Translational Sciences Educational Program, Support Ed in Part by a Clinical & Translational Science Award from the National Institutes of Health (UL1TR000071)**