Course Overview
This overview course, presented by the Institute for Translational Sciences, Education Office (ITS-EO), is designed for UTMB faculty, fellows, residents and others interested in translational or patient-oriented research may attend.

DESCRIPTION “Regulations and Ethics in Translational Research” is a modular component of the course, Translational Research: Tools & Techniques. This module consists of 9 weekly presentations by faculty from the Institute for the Medical Humanities, ITS Clinical Research Center, Office of Sponsored Programs and other experts. One hour lecture/discussion sessions occur Monday evenings beginning at 5:15 pm, Research Building 6 (formerly 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 translational research.
2. Discuss important dimensions of research; such as, the history of federal regulations, federal oversight, and conflicts of interest.

Registration
You may complete registration electronically by visiting: https://redcapproject.utmb.edu/surveys/?s=nWEta6

Additional options include completing the form on the back of the brochure and submitting it to the Institute for Translational Sciences Education Office. If you are registered for “Translational Research: Tools & Techniques, you will not be required to register again.

Graduate Students must also register through the GSBS during regular fall and/or spring registration (Course ID: PHS 6135)

THESE COURSES ARE PART OF THE INSTITUTE FOR TRANSLATIONAL SCIENCES EDUCATIONAL PROGRAM, SUPPORTED IN PART BY A CLINICAL & TRANSLATIONAL SCIENCE AWARD FROM THE NATIONAL INSTITUTES OF HEALTH (UL1TR000071).
CLASS DESCRIPTIONS

10/06/14  Why Research Became Regulated\textsuperscript{d} \textcircled{\textdagger}
Jason E. Glenn, PhD
Explains the history of human subject research in relationship to the abuses of subject respect and dignity that led to reform in human subject research ethics and the code of federal regulations that now govern human research practices.

10/20/14  Research in International Settings\textsuperscript{c,d,k,m} \textcircled{\textdagger}
Matthew M. Dacso, MD
Examines the process for creating successful research-based collaborations in low to middle income countries. Recognize the influence of culture and power on conducting research, including unintended consequences. Outline key ethical challenges in research-limited settings. Discuss challenges on implementing international research projects or programs.

11/03/14  Principles of the Belmont Report: Informed Consent\textsuperscript{g} \textcircled{\textdagger}
Andrew M. Childress, PhD
Discuss the ethical principle of respect for persons in human subject’s research. Describe informed consent as means for showing respect for human research subjects as persons.

11/10/14  Beneficence, Risk/Benefit Analysis, and the Therapeutic Misconception\textsuperscript{g} \textcircled{\textdagger}
Michele Carter, PhD
Discusses 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.

11/17/14  Rethinking Culture Competency\textsuperscript{k,m,n} \textcircled{\textdagger}
Rebecca Hester, PhD
Explain various approaches to cultural competency, discuss, the relationship between culture, cultural competency and health inequities and provide a framework for re-thinking cultural competency.

11/24/14  Legal Perspectives on Human Subjects Protections: Court Interpretations\textsuperscript{g,h} \textcircled{\textdagger}
E. “Bernadette” McKinney, JD, PhD
Discuss the dynamic nature of legal and ethical interpretations of obligations, rights, and social values in biomedical research as illustrated by how the courts have interpreted key human subjects regulations.

12/01/14  Roles and Responsibilities of the PI\textsuperscript{h} \textcircled{\textdagger}
Michael Loeffelholz, PhD
Describes 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.”

12/08/14  Hot Topics in Human Subject Research – “Ethics of Research on Prisoners”\textsuperscript{d} \textcircled{\textdagger}
Jason E. Glenn, PhD
Discusses the history of prisoner research including its expansion post Nuremberg. Describes proposals to revise prisoner research guidelines including irresolvable ethical conflicts.

12/15/14  Oversight at the Federal Level: Most Common PI Pitfalls and Mistakes\textsuperscript{g} \textcircled{\textdagger}
Aristides Koutrouvelis, MD
Discuss the current regulatory landscape regarding federal and local oversight of human subject research. Describe common deficiencies from recent Good Clinical Practice (GCP) audit findings from Clinical Investigators (sites) and how to prepare, identify, prevent, and mitigate problems in clinical research studies.

Risk Management Education (\textcircled{\textdagger}) credit is required for all UTMB faculty, fellows, and house staff under the Medical Liability requirements. (\textcircled{\textdagger}) Sessions are approved by UTMB Risk Management to meet the annual requirement of up to 5.0 hours of Risk Management Education.

Core Competencies in Clinical & Translational Research
This activity is part of the ITS Educational Program and contributes to achieving the following competencies:

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\begin{itemize}
  \item Research Implementation
  \item Sources of Error
  \item Clinical Research Interactions / Responsible Conduct of Research
  \item Cultural Diversity
  \item Community Engagement
\end{itemize}