**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 12 weekly presentations by faculty from the Departments of Preventative Medicine & Community Health and Internal Medicine. 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 epidemiological and statistical methods pertinent to clinical research.
2. Discuss methodological concepts using clinical examples.

**Registration**

You may complete registration electronically by visiting: https://redcap.utmb.edu

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)

**FAX OR MAIL REGISTRATION TO:**
Institute for Translational Sciences
Education Office (ITS - EO)
Research Building 6 (Children’s Hospital)
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**THIS COURSE IS 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).**
03/02/15  Descriptive Epidemiology and Measures of Morbidity & Mortality
Christine M. Arcari, Ph.D., M.P.H.
Define epidemiology, understand the historic development of epidemiology, and list the key features and uses of descriptive epidemiology. Define and calculate measures of incidence, prevalence, mortality rates, case-fatality rates, and proportionate mortality, explain the purpose of adjustment, and identify data sources and potential errors in measures of morbidity and mortality.

03/09/15  Validity and Reliability of Diagnostic & Screening Tests
Christine M. Arcari, Ph.D., M.P.H.
Define and calculate sensitivity, specificity, positive predictive value and negative predictive value, and describe the common risks associated with false positives and false negatives, differentiate between validity and reliability, and discuss intra- and inter-subject variation and the kappa statistic.

03/16/15  Healthcare Epidemiology
C. Glen Mayhall, M.D.
Describe healthcare epidemiology and discuss the role of the population-based perspective in the delivery of healthcare services.

03/23/15  Descriptive Statistics & Data Visualization
Heidi Spratt, Ph.D.
Define and describe the use of descriptive statistics, and discuss and interpret various statistical visualization methods.

04/06/15  Introduction to Study Design & Causality
Christine M. Arcari, Ph.D., M.P.H.
Differentiate descriptive and analytic and hypothesis generating and testing studies, define essential components of an epidemiologic study, and describe the guidelines for assessing causality.

04/13/15  Case-Control Studies
Christine M. Arcari, Ph.D., M.P.H.
Describe the distinguishing features of the case-control study design and the strengths and weaknesses of conducting a case-control study, emphasize the importance of proper control selection, identify possible biases, and describe and calculate the odds ratio.

04/20/15  Cohort Studies
Christine M. Arcari, Ph.D., M.P.H.
Describe the distinguishing features of the cohort study design and the strengths and weaknesses of conducting a cohort study, differentiate between prospective and retrospective cohort designs, identify possible biases, and describe and calculate the relative risk.

04/27/15  Clinical Trials
Christine M. Arcari, Ph.D., M.P.H.
Describe the distinguishing features of the clinical trial study design and the strengths and weaknesses of conducting a clinical trial, explain the purpose of randomization, explain the importance of written protocols, describe intention to treat analysis, distinguish between efficacy and effectiveness, describe common ethical issues, and differentiate between internal and external validity.

05/04/15  Estimation and Hypothesis Testing
Heidi Spratt, Ph.D.
Explain the purpose of estimation, describe how to make estimations based on sample data, explain hypothesis testing including how to formulate and test a proper hypothesis, and describe some commonly used analyses for hypothesis testing.

05/11/15  Confidence Intervals, Sample Size and Power
Heidi Spratt, Ph.D.
Calculate and explain the use of confidence intervals, differentiate power and sample size and describe power and sample size analyses.

05/18/15  Regression
Heidi Spratt, Ph.D.
Describe the method and purpose of basic linear regression, interpret linear regression results, describe the method and purpose of logistic regression, and interpret logistic regression results.