Clinical Research Methods Short Course

December 5th & 12th 1:00 - 3:30 pm EST via Teams



If you have not registered, please complete the <u>online registration form</u>. Registration should be completed by November 28, 2025. Participants are expected to attend both days.

If you have any questions, contact ctsieducationAHWFB@advocatehealth.org.



Background & Course Overview

Background

Collaboration in health sciences is vital but often hindered by communication gaps among researchers. This Clinical Research Methods Short Course aims to teach key concepts and terminology to improve understanding and teamwork in clinical research.





Target Audience

- Introductory level research scientists and clinical investigators.
- Participants who want to expand their capacity to lead or collaborate in clinical, population-based, or basic science research will benefit most from this short course.

Course Overview

The Biostatistics Epidemiology and Research Design (BERD) Program at Wake Forest University School of Medicine, in partnership with the Clinical and Translational Science Institute (CTSI), offers the Clinical Research Methods Short Course aimed at health science research professionals. This course introduces both established and innovative techniques used in biomedical research across the translational spectrum. Topics covered include fundamental aspects of medical research study design, commonly used statistical tests and data analysis methods, and an overview of the translational science spectrum and available CTSI resources. Participants are expected to attend both sessions.

Upon completion of the short course, participants will be able to:

- Recognize common study designs and statistical methods typically used in medical research
- Utilize basic statistical techniques with guidance from statisticians and interpret results accurately
- Collaborate effectively with biostatisticians and epidemiologists on study design and analysis
- ◆ Differentiate the various stages within the translational science spectrum.



Friday, December 5, 2025

1:00-1:05 pm Welcome and Introduction

Joe Rigdon, PhD, Associate Professor, Biostatistics and Data Science, DPHS

1:05-1:45 pm Sample Size and Power Estimation

Walter Ambrosius. PhD

Professor, Biostatistics and Data Science, DPHS

- Explain the relationship of sample size and power analysis on effective design
- Calculate needed sample size and power for a simple study
- Demonstrate a power calculator tool

1:45-1:55 pm **Break**

1:55-2:35 pm Fundamental Study Designs and Measures of Association

Mike Bancks, PhD

Associate Professor, Epidemiology and Prevention, DPHS

- · Summarize the unique features of varied research study designs
- Select an efficient study design for your research question
- · Introduce different measures of association

2:35-2:45 pm **Break**

2:45-3:25 pm **Designing Pilot Studies**

Janet Tooze, PhD

Professor, Biostatistics and Data Science, DPHS

- Select measures of feasibility to assess in a pilot study. Determine appropriate pilot study sample sizes
- Make appropriate generalizations from pilot data

3:25-3:30 pm **Conclusion**

Mike Bancks, PhD

Associate Professor, Epidemiology and Prevention, DPHS



Friday, December 12, 2025

1:00-1:05 pm Introduction

Mike Bancks, PhD

Associate Professor, Epidemiology and Prevention, DPHS

1:05-1:45 pm Basic Statistics

Joe Rigdon, PhD

Associate Professor, Biostatistics and Data Science, DPHS

- Describe basic statistical principles of estimation and hypothesis testing
- Introduce basic statistical procedures used in the health sciences and biomedical research
- Explain continuous and discrete variables, and one-sample and two-sample tests

1:45-1:55pm **Break**

1:55-2:35 pm Methodological Issues

Michael Webster-Clark, PhD, PharmD

Assistant Professor, Epidemiology and Prevention, DPHS

- Describe threats to validity
- Explain interaction and effect modification

2:35-2:40 pm **Break**

2:40-3:10 pm The Translational Science Spectrum

Erica Hale, MS

Program Director, Department of Internal Medicine

- Define translational science and the role of bi-directionality
- Differentiate among the stages of translational science
- Identify common barriers in moving through the stages of the translational science spectrum

3:10-3:20pm CTSI Research Resources

Lindsay Trost, MHA

Director CTSI Administration, Clinical and Translational Science Institute

Describe CTSI research programs and resources

3:20-3:30 pm **Conclusion**

Joe Rigdon, PhD

Associate Professor, Biostatistics and Data Science, DPHS

