Atrium Health

Wake Forest University
School of Medicine

Clinical Research Methods Short Course

December 1st & 8th
1:00 to 3:30pm

Sessions will be held remotely

Please register here!

Please plan to attend both sessions. Registration is required by November 24, 2023. To register please complete the online registration form.

Offered by the WFUSM Biostatistics, Epidemiology, and Research Design (BERD) Team & Clinical and Translational Science Institute (CTSI)

Questions? Contact ctsieducation@wakehealth.edu

Background & Course Overview

Background

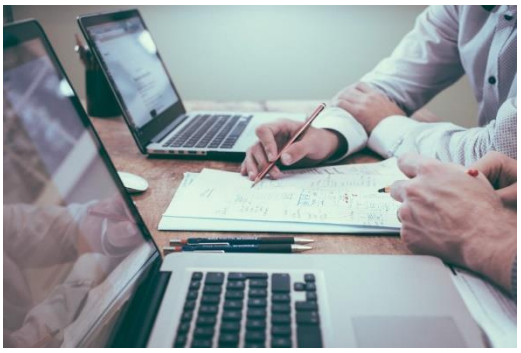
The rich interdisciplinary interaction that occurs in the health sciences is a critical element of an academic learning healthcare system and often generates new ideas as gaps in knowledge are discussed and potential methodological innovations are explored. Unfortunately, not all health researchers speak the same language, and are often slowed in their ability to translate innovations into the real world. This Clinical Research Methods short course seeks to overcome these challenges by providing an opportunity to learn the language and fundamental concepts of clinical research methods, with the intent of providing clearer communication across the research team.

Course Overview

The Biostatistics Epidemiology and Research Design (BERD) Program of the Wake Forest University School of Medicine Clinical and Translational Science Institute (CTSI) short course is designed especially for research scientists in the health sciences. The short course will introduce participants to both established and state-of-the-art methodology for biomedical studies across the translational spectrum. It consists of both lecture and discussion/application exercises led by experts in the field. Topics will include key aspects of study design for medical research studies, standard statistical tests and data analyses, and an overview of the translational science spectrum and resources available from our CTSI. Registrants should attend both sessions.

At the conclusion of this program, participants should be able to:

- Recognize common study designs and statistical methods used in medical research
- Identify and use basic statistical procedures under the guidance of a statistician, and interpret their results
- Communicate with biostatisticians and epidemiologists on study design and analysis topics
- Differentiate among the phases of the translational science spectrum



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.

Friday, December 1, 2023

1:00-1:05 pm **Welcome and Introductions**

Walter T. Ambrosius, PhD
Professor, Biostatistics and Data Science, Division of Public Health Sciences (DPHS)

1:05-1:45 pm **Study Design I: Determining Study Objectives**

Mike Bancks, PhD
Assistant 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

1:45-1:55 pm Break

1:55-2:35 pm **Study Design II: Sample Size and Power**

Walter T. 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

2:35-2:45 pm Break

2:45-3:25 pm **Study Design III: Methodological Issues**

Mike Bancks, PhD
Assistant Professor, Epidemiology and Prevention, DPHS

- Describe threats to validity
- Explain interaction and effect modification

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

Mike Bancks, PhD
Assistant Professor, Epidemiology and Prevention, DPHS

Friday, December 8, 2023

1:00-1:02 pm **Welcome and Introductions**

Mike Bancks, PhD
Assistant Professor, Epidemiology and Prevention, DPHS

1:02-1:42 pm **Basic Statistics**

Joseph Rigdon, PhD
Assistant 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

1:42-1:52 pm Break

1:52-2:32 pm **Methods for Pilot Studies**

Sean Simpson, 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

2:32-2:42 pm Break

2:42-3:12 pm **The Translational Science Spectrum**

Stephen B. Kritchevsky, PhD
Professor, Internal Medicine-Gerontology and Geriatric Medicine
Sticht Center on Aging and Rehabilitation

- 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

3:12-3:22pm **CTSI Research Resources**

Lindsay Trost, MHA
Director CTSI Administration, Clinical and Translational Science Institute

- Describe CTSA research programs and resources

3:22-3:30 pm **Conclusion**

Walter T. Ambrosius, PhD
Professor, Biostatistics and Data Science, DPHS