Clinical Research Methods Short Course

Wednesday, October 5, 2016
Wednesday, October 19, 2016

Auditorium
Biotech Place
575 Patterson Avenue
Winston-Salem, NC
Background
The rich interdisciplinary interaction that occurs in the health sciences is a critical element of a learning health care system and often generates new ideas as gaps in knowledge are discussed and potential methodologic 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 of clinical research methods, with the intent of providing clearer communication across the research team.

Course Overview
The Biostatistics Epidemiology and Research Design Program of the Wake Forest School of Medicine Clinical and Translational Science Institute presents a short course in clinical research methods that 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. The instructional approach includes both lecture and discussion/application exercises led by experts in the field. Topics will include an introduction to translational science, design of medical research studies, standard statistical tests and data analyses, and publication in the medical literature. 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;
• Successfully disseminate results in the medical literature.

Target Audience
Research scientists in the health sciences including faculty, fellows, and research/technical staff.

Attendance Limits
Course is limited to 60 participants. Priority will be given to those who can commit to attend both sessions.

Registration
Registration is required by September 28, 2016. To register, please complete the online registration form.
Wednesday, October 5
1:00 pm to 5:00 pm

Welcome and Introductions
Walter Ambrosius, PhD, Professor
Division of Public Health Sciences (DPHS), Biostatistical Sciences

The Translational Science Spectrum
Robert P. Byington, PhD, Professor
DPHS, Epidemiology and Prevention

- 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.

Study Design I: Determining Study Objectives
Robert P. Byington, PhD, Professor, DPHS, Epidemiology and Prevention
Elizabeth T. Jensen, PhD, Assistant Professor, DPHS, Epidemiology and Prevention

- Develop a study question and primary hypothesis.
- Summarize the unique features of varied research study designs.
- Select an appropriate and efficient study design for the research question.

Break (15 minutes)

Methodological Issues
Elizabeth T. Jensen, PhD, Assistant Professor
DPHS, Epidemiology and Prevention

- Describe different measures of association.
- Explore threats to validity.
- Explain interaction and effect modification.

Basic Statistics
Haiying Chen, MD, PhD, Associate Professor
DPHS, Biostatistical Sciences

- 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.
Agenda

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Study Design II: Sample Size and Power
Walter Ambrosius, PhD, Professor
DPHS, Biostatistical Sciences

- Explain the relationship of sample size and power analysis on effective design.
- Calculate needed sample size and power for a simple study.
- Demonstrate ability to use power calculator tools.

Study Design III: Designing Pilot Studies
Lynne Wagenknecht, DrPH, Professor
DPHS, Epidemiology and Prevention

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

Break (15 minutes)

Data Synthesis
Brian J. Wells, MD, PhD, Associate Professor
Clinical and Translational Science Institute

- Formulate clinically meaningful research questions that link ‘omics’ data with the electronic health record.
- Choose appropriate methods for interrogating relevant databases.
- Identify challenges and pitfalls in complex data synthesis questions.

Panel: Literature Review and Manuscript Submission
Ronny Bell, PhD, Professor, DPHS, Epidemiology and Prevention
William Applegate, MD, Professor, Internal Medicine, Gerontology & Geriatric Medicine
Debra Diz, PhD, Professor, General Surgery and Physiology & Pharmacology
Ralph D’Agostino, PhD, Professor, DPHS, Biostatistical Sciences

- Discuss how to successfully prepare and submit a manuscript.
- Describe a process to appropriately and comprehensively review a manuscript.
- Develop a written response to a reviewer critique.

Questions
Please contact Anita Pulley, Director CTSI Education, at apulley@wakehealth.edu