



Department of Statistics

Presents the

**Robert W. Makuch Distinguished
Lecture in Biostatistics**

Featuring

Andrea B. Troxel, Sc.D.
Division of Biostatistics
Dept. of Population Health
New York University School of Medicine

Statistical Issues in Pragmatic Behavioral Clinical Trials

ABSTRACT

Randomized clinical trials provide gold-standard evidence for the effectiveness of interventions. Explanatory trials, aimed at providing information on mechanisms of action, often involve highly selected populations. Pragmatic trials, aimed at generating information to enable decision-making, attempt to enroll a broader group of participants. We propose two innovations in pragmatic clinical trial design. The use of an opt-out framework for consent can increase the enrolled fraction of the target population, but brings with it new design challenges. Rapid-cycle adaptive testing offers a way to enhance the speed of evidence production while preserving the crucial benefits of randomization. We provide several examples of trials of behavioral interventions in which these ideas are implemented.

DATE: Wednesday, March 29, 2017

TIME: 4:00 p.m.

PLACE: Philip E. Austin Building – Room 105

Coffee will be served at 3:30 p.m. in the Noether Lounge (AUST 326)



Andrea B. Troxel, ScD, is professor of Population Health and director of the Division of Biostatistics, where she leads a growing group of 15 faculty and staff. Dr. Troxel's research aims to integrate the development of novel analytic approaches and their application to a wide range of areas in health and healthcare. She is an expert in statistical methods for longitudinal and missing data and the design and analysis of randomized clinical trials. In particular, she has developed novel approaches to pragmatic trials and rapid-cycle innovation. Her collaborative research focus is in oncology and behavioral economics.

Dr. Troxel's research has garnered substantial extramural funding. She is a fellow of the American Statistical Association and has served on numerous National Institutes of Health study sections. She has co-authored more than 200 peer-reviewed publications and is highly regarded nationally and internationally for her contributions to biostatistics and biomedical collaborations.

Dr. Troxel earned her BS in applied mathematics from Yale University and her doctorate in biostatistics from Harvard University. She was a faculty member in biostatistics at Columbia's Mailman School of Public Health and the University of Pennsylvania's Perelman School of Medicine before joining NYU School of Medicine in 2016.



Robert Makuch is a professor in the Department of Biostatistics at the Yale School of Public Health and Director of the Regulatory Affairs Track. A graduate of the University of Connecticut (BA), University of Washington (MA – mathematics), and Yale University (MPhil, PhD), Professor Makuch worked at the National Cancer Institute (NCI) and the World Health Organization's International Agency for Research on Cancer early in his career. He also was heavily involved in HIV research from the mid 80's through the early-mid 90's. He participated on the data monitoring committee for the original AZT vs. placebo randomized clinical trial in AIDS patients, and served on numerous committees for the NCI and the National Institute of Allergy and Infectious Diseases. He also worked closely with the Food and Drug Administration (FDA), developing and implementing more than 100 HIV studies. He also served as a Special

Government Employee (SGE) to the FDA. He returned to Yale in 1986, and has worked extensively on methodologic issues in clinical trials and large population-based studies since. Another area of interest involves detection of rare adverse drug events, especially in the post-marketing environment. These areas of methodologic research evolved as a result of his continued interest (since the mid 80s) in regulatory affairs science. In addition, Makuch developed a regulatory affairs track at YSPH for its students, and over the past 6 years has been the leader of numerous training programs for senior delegations of the Chinese Food and Drug Agency. His areas of medical application include cancer, HIV, arthritis, and cardiovascular disease.

In 2003, Makuch received the American Statistical Association Fellow Award for his numerous contributions to the field. In 2008, Makuch was received a Distinguished Alumni Award from the University of Connecticut. In 2012, Makuch was nominated to serve on the University of Connecticut Dean's Advisory Board for the College of Liberal Arts and Sciences. He also developed a 5-year biostatistics training program in Japan, in collaboration with the Japanese government. His primary research interests continue to be methodologic issues in the design, conduct, and analysis of clinical and large-population/epidemiologic studies. Design and sample size considerations for Phase IV studies is another active research area, in which a new class of hybrid designs has been proposed for scientific and regulatory purposes to detect rare adverse events.

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