



Department of Statistics

Presents the

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

Featuring

Thomas A. Louis, PhD
Department of Biostatistics
Johns Hopkins Bloomberg School of Public Health

Perils and potentials of self-selected entry to epidemiological studies and surveys

ABSTRACT

High-quality surveys and epidemiological or clinical studies are internally valid (valid inferences for the sample at hand). Traditional surveys directly address external validity (generalization of within-sample estimates to target a population) by designed sampling from a frame. The sample is 'representative' in that weights are available to transport it to a reference population. Analytical epidemiology and clinical trials have paid little explicit attention to external validity, but web-based enrollment with its low front-end cost, rapid accrual, and possible self-selection has amplified the importance of representation. I provide background and examples of these issues, the most central being whether conditional effects in the sample (the study population) can be transported to a desired target population or populations. Success depends on compatibility of causal structures, and taking of information from observational studies and administrative databases can be helpful. Statisticians, epidemiologists and survey researchers should collaborate on clarifying goals, calling for the design of transportable studies, and developing analytic approaches. Increased cross-fertilization among the domains will benefit science and policy.

DATE: Wednesday, March 30, 2016

TIME: 4:00 p.m.

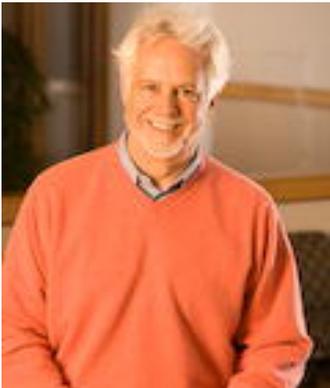
PLACE: Philip E. Austin Building – Room 105

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



Thomas A. Louis, PhD (Mathematical Statistics, Columbia University): Professor of Biostatistics, Johns Hopkins Bloomberg School of Public Health (2013-2015 also Associate Director for Research & Methodology/Chief Scientist, U.S. Census Bureau). Formerly, Assistant Professor of Mathematics at Boston University; Associate Professor of Biostatistics at the Harvard SPH; Professor and Head of Biostatistics, University of Minnesota SPH; Senior Statistical Scientist at Rand. Research includes Bayesian methods; clinical and field studies; health services research, environmental risk assessment, genomics, and survey methods. He is an elected member of the International Statistical Institute, a Fellow of the American Statistical Association and of the American Association for the Advancement of Science. He served as coordinating editor of *The Journal of the American Statistical Association*, co-editor of *Biometrics*, and president of the

International Biometric Society. He chaired the ASA section on Bayesian Statistical Science and the AAAS Statistics Section. Other service includes the Health Review Committee of the Health Effects Institute, the NIH/NIEHS Board of Scientific Counselors, chair of the COPSS-CMS committee on assessing hospital performance. Service via the National Academies includes the Committee on National Statistics, the Committee on Applied and Theoretical Statistics, the Panel on Estimates of Poverty for Small Geographic Areas, the Panel on Formula Allocation of Federal and State Program Funds, the Board of the Medical Follow-up Agency, the Panel to Assess the Health Consequences of Service in the Persian Gulf War, the Committee on the use of Third Party Toxicity Research, and the Standing Committee on Risk Assessment.



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 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 area 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 4 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.