Summer Institute 2017

Workshops In
Quantitative Research Methodology

Department of Public Health Sciences
Medical University of South Carolina
Charleston, South Carolina
May 1-12, 2017
www.musc.edu/dbe
The 2017 Summer Institute in the Department of Public Health Sciences in the College of Medicine at the Medical University of South Carolina (MUSC) offers several workshops that introduce current quantitative methods used in key areas of public health, population health, and biomedical and clinical research, and offer hands on experience with implementing these methods. The targeted audience includes public health professionals, biostatisticians, epidemiologists, biomedical and clinical researchers as well as residents, post docs, fellows and graduate students.

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Developing Your Clinical Trial Toolbox (May 1-2)

This workshop provides two sessions per day (8-12pm and 1-5pm each day) on aspects of clinical trial development and implementation for randomized clinical trials, and hands-on experience with the latest developments. Attendees have the opportunity to bring their specific trial questions to the course for discussion and feedback.

Day 1 Session I: Study Designs (aligning designs with objectives)
Day 1 Session II: Bayesian Trial Designs
Day 2 Session III: Interim Analysis and Data and Safety Monitoring
Day 2 Session IV: Practical Issues in Study Planning (budgets, form development, dissemination)

Who Should Attend:
Clinical researchers, biostatisticians and students having an interest in clinical trial design and methodology.

Valerie Durkalski is Professor of Biostatistics and Director of The Data Coordination Unit (DCU), a statistical and data management center housed in the Department. The DCU specializes in the design of clinical trials and analysis of their data and in establishing, implementing and maintaining data and project management systems for multicenter clinical trials. Dr. Durkalski collaborates on several large multicenter clinical trials in various therapeutic areas, serves on several Data and Safety Monitoring Boards (DSMBs) and NIH peer-review panels. She publishes and presents on various topics related to the design and conduct of clinical trials and teaches ‘Design & Conduct of Clinical Trials’ to graduate students and healthcare professionals.

Caitlyn Ellerbe is an Assistant Professor of Biostatistics and Senior Biostatistician with The Data Coordination Unit (DCU), a statistical and data management center housed in the Department of Public Health Sciences. The DCU specializes in the design of clinical trials and analysis of their data and in establishing, implementing and maintaining data and project management systems for multicenter clinical trials. Dr. Ellerbe collaborates on the design and implementation of several large multicenter clinical trials with a focus on rare diseases, stroke, and other neurological emergencies. She publishes and presents on various topics related to the design and conduct of clinical trials, with a special
**Subject Randomization: Design & Implementation in Clinical Trials (May 3)**

This workshop includes three sessions. The first session reviews the rationale of subject randomization in clinical trials and introduces a framework for the quantitative evaluation of treatment allocation randomness and treatment imbalance. Commonly used restricted randomization designs, including permuted block randomization, biased coin design, and urn design will be discussed and evaluated. For baseline covariate balancing, the stratified randomization and the minimization method will be introduced, and compared. The second session will present advanced randomization designs for specific trial scenarios, including trials with more than two arms, large number of baseline covariates, unequal allocations, and response adaptive randomization. Real trials will be used to illustrate the statistical and operational properties of these advanced randomization designs. The last session of this workshop will focus on the implementation of various randomization algorithms in clinical trial practice, including the integration of subject randomization with electronic data capture (EDC) system.

**Who Should Attend:**
Clinical researchers, biostatisticians and students having an interest in clinical trial randomization design and methodology.

**Wenle Zhao** is Professor of Biostatistics and Associate Director of IT with The Data Coordination Unit (DCU), a statistical and data management center housed in the Department of Public Health Sciences. The DCU specializes in the design and coordination of clinical trials and analysis of their data. Dr. Zhao has published several randomization designs, including the block urn design, the mass-weighted urn design for fixed unequal allocations and response adaptive randomization, the minimal sufficient balance design and the asymptotic maximal procedure ideal for small-medium trials expected to be analyzed with randomization tests. The contents of this workshop are based on his personal research achievements as well as his hands-on experience.
Bayesian Biostatistics I with SAS applications (May 2-3)

This course is aimed at those who wish to extend their knowledge and skill set within Bayesian data science using SAS. The focus of the workshop is on highly relevant topic areas which can be addressed using Bayesian analytic tools. The topics include linear models (LM, GLM, as GLMM), survival analysis, missing data analysis and Meta analysis. We will use appropriate data examples and SAS output to demonstrate the applications of Bayesian methods in the analysis of biomedical data using SAS. Example data sets and SAS code will be provided to participants. Participants are encouraged to come with SAS 9.3 or 9.4 loaded on their computers.

Topics:
- What is Bayesian Biostatistics, and Bayesian Basics
- Hierarchical models; Posterior Sampling; MCMC
- Examples comparing conventional analysis and Bayesian analyses
- Survival analysis
- Meta analysis
- Missing data analysis

Who Should Attend:
Those interested in extending their toolbox on statistical modeling of data (continuous, discrete and time to event) using powerful Bayesian methodology.

Dr. Gebregziabher is Professor of Biostatistics in DPHS and a co-leader of the Biostatistics Core with the VA Health Services Research and Development funded Innovation Center for Health Equity and Rural Outreach. His research expertise is in longitudinal data, missing data, multiple outcomes research, and analysis of very large datasets. He collaborates in several areas of clinical & health services research related to T2DM, CKD, stroke, CVD, lung cancer and HIV/AIDS. He has over 100 peer-reviewed publications in top-tier biomedical journals and has developed/taught graduate courses on longitudinal data analysis, advanced regression, Bayesian analysis and Statistics in Epidemiology. He has served as President of Statistical Society of Ethiopians in North America, President of the South Carolina Chapter of the American Statistical Association and is currently Officer of the Statistics in Imaging Section.
Bayesian Biostatistics II:

This course will cover the use of OpenBUGS and INLA for Bayesian modeling and focus on specific application areas in more depth and is designed to be a continuation of the Part I course offered on May 2-3. The course fee includes the text, Lesaffre and Lawson (2012) *Bayesian Biostatistics*, Wiley, NY.

**Topics:**
- Review of Basic Bayesian methods and introduction to OpenBUGS and INLA
- Regression; LMMs and GLMMs
- Variable Selection
- Survival Analysis
- Meta Analysis
- Measurement error/SEMs and missing data
- Spatial applications: Imaging and disease mapping

**Who Should Attend:**
Those interested in extending their knowledge of statistics and modeling into hierarchical multi-level modeling using powerful Bayesian methodology.

Dr. Lawson is Professor of Biostatistics and has a wide experience of the development and application of Bayesian methods in Biostatistical problems. He has published a number of papers and books focused on Bayesian applications, in particular in spatial Biostatistics.
Longitudinal and Multilevel Modeling (May 4-5)

Frequently in medical research, data are collected longitudinally and/or in clusters. This workshop will focus on familiarizing the participants with the appropriate analyses for such data. Linear Mixed Models ANOVA (including random effects, fixed effects, nesting, repeated measures, missing data), Generalized Linear Mixed Models for analyzing categorical data and introduction to growth models will be presented. The workshop will be divided into three modules. Module I - multilevel data, Module II - longitudinal data, Module III—SAS software and hands-on experience in using SAS for topics covered in Modules I&II. Module II requires participants to have SAS installed on their laptops. The Modules I and II will be presented on Day 1 and the Module III will be presented on Day 2.

Who Should Attend: Clinical researchers, biostatisticians and students who have not been exposed to these topics.

Sharon Yeatts is an Associate Professor of Biostatistics in the Department. She collaborates with clinicians at MUSC and around the country in several health related topics, with a focus on neurological trials. She oversees design and biostatistical analyses of several multicenter longitudinal studies. She teaches regression and factorial analyses in the graduate program.

V. Ramakrishnan (Ramesh) is a Professor of Biostatistics in the Department. He has extensive experience in Multilevel and Longitudinal data methods. He has authored or coauthored methodological articles in several areas of biostatistics, including missing data, genetic epidemiology, longitudinal growth models, mixture normal models. He has developed and taught graduate courses on several topics including a course in longitudinal and
Geographic Information Systems (GIS) for Public Health (May 8-9)

Geographic information systems (GIS) are becoming increasingly popular in all areas of public health. The focus of this course is to teach practical GIS skills that can be applied in any public health setting. There are two goals for this course: 1) for students to develop a GIS toolkit by learning the most frequently used GIS skills (Day 1); and 2) for students to learn how to apply GIS in public health setting through the exploration of applicability of GIS to public health data (Day 2). The general teaching philosophy for the course is that hands-on training in GIS is the most effective approach for you to acquire this new skill. However, short lectures and selected readings will be used to reinforce critical concepts. Attendees should plan on bringing their laptops.

Who Should Attend: Clinical researchers, biostatisticians and students having an interest in GIS.

John Pearce is an Assistant Professor of Environmental Health in the Department of Public Health Sciences. Dr. Pearce’s research seeks to investigate the nature of environmental risk factors and their impacts on human health. He has extensive experience in geographic information science for public health and has several ongoing studies that apply relevant methods. He currently teaches environmental health at MUSC and has taught courses on geographic information systems for public health.
Informatics and Data Management for Clinical Research (May 8-9)

This workshop is intended to introduce clinical researchers to research oriented data management and related topics in Informatics. Participants will learn about basic concepts in: relational databases, best practices in data management, data capture forms, data capture tools, clinical data warehousing, privacy issues in electronic data, data standards, self-service data navigation, regulatory requirements, security risks and mitigations. Participants get hands-on experience with using modern database tools, online systems such as REDCap (Research Electronic Data Capture), and navigating online clinical data query tools. The workshop includes three sessions provided over one and half days to cover the above topics.

Jihad Obeid, M.D. is the Co-director of the Biomedical Informatics Center, Associate Professor and Division Leader of Biomedical Informatics in the Department. He is a pediatrician who was formally trained in Medical Informatics at the Division of Health Sciences and Technology, a joint Harvard-MIT fellowship program. As co-director of the Biomedical Informatics Center, he oversees several academic and operational informatics initiatives including the Research Data Warehouse, i2b2, REDCap, Profiles research networking system, and many others. He is a co-investigator and informatics leader on several NIH funded projects. He is also responsible for the regulatory approval of the Research Data Warehouse. Dr. Obeid teaches a full course on the same topic in the Master’s program in Clinical Research.
Statistical Methods for Basic Scientists in Medical

Statistical Approaches for Laboratory Scientists Participants will learn appropriate and valid approaches for summary and graphical displays of data, hypothesis testing, and sample size justification. Both small and moderate size datasets will be discussed, with an emphasis on animal studies and studies of human tissue samples. Statistical software (SPSS and R) will be used to demonstrate implementation of methods. Valid interpretation and inference will be highlighted throughout the course, and published examples of correct and incorrect approaches will be used to illustrate concepts.

Who Should Attend: Basic scientists interested in improving their data analysis skills and understanding of experimental design.

Elizabeth Garrett-Mayer, Professor of Biostatistics, received her PhD in Biostatistics from Johns Hopkins University in 2000 and served as a Biostatistics faculty member at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University from 2000-2007. Since arriving at the Medical University of South Carolina in 2007, she has been the Biostatistics Core leader of two cancer-focused P01 projects and co-leader of an Administrative/Biostatistics Core of a third cancer-focused P01 in addition to serving as a co-investigator on numerous other grants. She has substantial experience in grant development and data analysis, as evidenced by the more than 200 articles in scholarly journals.

Elizabeth Hill received her PhD in Biostatistics from Emory University in 2002 and worked as a mathematical statistician at the Centers for Disease Control and Prevention from 2001 to 2003. She joined the faculty at the Medical University of South Carolina in 2003, and is currently an Associate Professor of Biostatistics and a long-standing member of the Hollings Cancer Center Biostatistics Shared Resource. She collaborates extensively with lab scientists across the university, and serves as co-investigator on numerous collaborative grants. Dr. Hill has expertise in proteomics and related experimental platforms, and has broad research interests in biomarker discovery.
Machine Learning (May 11-12)

Machine learning is growing in popularity among biomedical investigators due to the pressing need to systematize and extract the knowledge from multivariate datasets encountered in research application. This course will introduce key concepts in machine learning, descriptive unsupervised analysis, and supervised learning. Several popular machine learning frameworks, such as Support Vector Machines (SVMs), Random Forests, Neural Networks will be presented. Weka and RWeka will be introduced and applied to reanalysis of several biomedical datasets. Basic knowledge of R is a highly encouraged prerequisite.

Who Should Attend:
Biomedical investigators interested in applying machine learning to their research.

Alexander V. Alekseyenko is Associate Professor of Biomedical Informatics and the Founding Director for Program for Human Microbiome Research. He develops machine learning methods for personalize medicine applications in the human microbiome domain.

Lewis Frey, PhD develops novel algorithms and information systems for the purpose of discovery and data integration applicable to precision medicine. He applies novel machine learning approaches deployed through virtual machines in hospital networks and in big data technology within the Veterans Affairs for analysis over 20 million patients.
**Venue:**
The courses will take place on the campus of the Medical University of South Carolina, Department of Public Health Sciences, Room 301 and 305V, 135 Cannon Street, Charleston, South Carolina.

**Recommended Area Accommodations:**

- **Charleston Marriott Hotel**
  170 Lockwood Boulevard
  Charleston, SC  29403
  (843)723-3000/(800)968-3569
  www.marriott.com/chsmc

- **Springhill Suites/Charleston Riverview**
  90 Ripley Point Drive
  Charleston, SC 29407
  (843) 266-8081
  www.marriott.com/chssh

- **Comfort Inn**
  144 Bee Street
  Charleston, SC  29401
  (843)577-2224

- **The Courtyard by Marriott**
  35 Lockwood Drive
  Charleston, SC  29401
  (843) 722-7229
  www.marriott.com/chscy

Inquire about an MUSC discount when making reservations.
Additional information on Charleston and area hotel accommodations may be found at www.charlestoncvb.com. Download a campus map at www.musc.edu.

**General Daily Schedule (ask course instructor for a specific schedule):**

- 8:00 - 8:30am:
  Coffee/Registration

- 8:30 - 10:00 am:
  Workshop Session

- 10:00 - 10:30 am:
  Break

- 10:30 - 12:00 pm:
  Workshop Session (End of Day 2 for the 1 1/2day workshops)

- 12:00 - 1:00 pm:
  Lunch (provided)

- 1:00 - 3:00 pm:
  Workshop Session

- 3:00 - 3:30 pm:
  Break

- 3:30 - 5:00 pm:
  Workshop Session (End of Day 2 will be at 4pm)

- 5:00 - 6:00 pm:
  Network
Please register at [https://is.gd/summerinstitute2017](https://is.gd/summerinstitute2017)

**Paper Registration Form:**

Last Name: ___________________  First Name: ___________________

Institution: _______________________________________________

Mailing Address: _____________________________________

City: ____________________  State:____  Zip: __________

Phone: _______________  E-mail: __________________

- MUSC Student
- MUSC Employee
- Other Student
- Other Professional

**Workshop Registration & Fees:**

- **Clinical Trials Workshop**—$150 per session ($500 for all 4)
  - Session 1: Study Designs (May 1)
  - Session 2: Bayesian Trial Designs (May 1)
  - Session 3: Interim Analysis & Data & Safety Monitoring (May 2)
  - Session 4: Practical Issues in Study Planning (May 2)

- **Bayesian Workshop**—$600 each ($1000 for both)
  - Bayesian Biostatistics I—SAS (May 2-3)
  - Bayesian Biostatistics II—OpenBugs, INLA (May 4-5)

- **Other Workshops**
  - 2-day workshops—$500
  - 1.5-day workshops—$400
  - 1-day workshops—$300
    - Randomization (May 3) (1 day)
    - Longitudinal Analysis (May 4-5) (1.5 day)
    - Geographic Information Systems (May 8-9) (2 day)
    - Informatics and Data Management for Clinical Research (May 8-9) (1.5 day)
    - Stat Methods for Basic Scientists (May 10-11) (2 day)
    - Machine Learning (May 11-12) (2 day)

MUSC students and employees will receive a $100 discount* on any session, but must use their MUSC email address to register.

*$100 discount can only be applied to Clinical Trials Workshops if you sign up for all 4 sessions
Payment can be made by phone or mail. Contact information will be emailed to you upon completion of your online registration. Registration fees are payable in U.S. dollars only. Personal checks are acceptable if payable through a U.S. bank.

**Payment Method:**

- IIT (MUSC internal registrations only; send payment to watsonju@musc.edu)
- Check (make payable to MUSC, Dept. of Public Health Sciences)
- Visa
- Mastercard
- American Express

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<td>Please make checks payable to MUSC-DPHS.</td>
<td>We do not accept online credit card payments at this time. Please contact June Watson after submitting your online registration via email (<a href="mailto:watsonju@musc.edu">watsonju@musc.edu</a>) or phone (843-876-1578) to set up your credit card payment.</td>
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Department of Public Health Sciences  
Summer Institute 2017  
Medical University of South Carolina  
135 Cannon St., Suite 303  
MSC 835  
Charleston, SC 29425-8350

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Parking

Parking information will be uploaded shortly. Contract June Watson with questions in the meantime (843-876-1578) or watsonju@musc.edu.