AGENDA

8:30 AM       Registration

9:00          Welcome and Introduction
Kathleen T. Brady, MD. PhD, Distinguished University Professor, Associate Provost, Clinical and Translational Science, MUSC & Director, SCTR Institute

9:10          Keynote Speaker Introduction
Perry V. Halushka, PhD. MD, Distinguished University Professor, Dean Emeritus, College of Graduate Studies, MUSC & Co-Director, SCTR Institute

Keynote Address #1 – Medical Research: From Discovery to Patient Outcomes Research
Ann Bonham, PhD, Chief Scientific Officer, Association of American Medical Colleges

10:10         What IS Comparative Effectiveness Research and Who Funds It?
Patrick D. Mauldin, PhD, Professor and Director, Section of Health Systems Research and Policy, Division of General Internal Medicine and Geriatrics, MUSC & Director, SCTR CER Initiative
This presentation will discuss the concept of CER, and introduce the Patient Centered Outcomes Research Institute (PCORI) funding organization.

10:30        Coffee Break & Networking

Session 1: Moderator – Leonard E. Egede, MD. MS, Endowed Chair and Professor, General Internal Medicine & Geriatrics, MUSC

10:45         The Magic of Pseudo-Randomizing Observational Data
Annie N. Simpson, PhD, Assistant Professor, Department of Healthcare Leadership and Management, MUSC
One of the most significant challenges of using large observational data to answer CER questions is the lack of randomized control groups leading to potential selection bias and the inability to make causal inferences. We will report methodological results from a recent study where we used propensity score matching, to match publicly available data from a non-randomized medication treatment trial with data from a non-randomized device trial to treat patients with treatment resistant depression, in order to compare outcomes.

11:05         Implementation Science: The “How” of Moving Comparative Effectiveness Findings into Practice
Cathy L. Melvin, PhD, MPH, Associate Professor, Department of Public Health Sciences, MUSC & Associate Director, SCTR Community Engagement Program
Implementation science seeks to improve the quality and effectiveness of health services by identifying rigorous approaches to promote and facilitate the systematic uptake of research findings and other evidence-based approaches into routine practice. As a multidisciplinary approach, implementation science seeks to effect change by identifying factors affecting health care professional and organizational behavior while taking into account patient desires, cultures, values, and life conditions. We will via examples from several studies, present methods used by
implementation scientists to affect rapid-cycle improvements, set performance goals, design effective implementation strategies, and assure sustainability.

11:25 **Conducting a CER Clinical Trial: Pragmatic, but Simple?**
Valerie Durkalski-Mauldin, PhD. MPH, Associate Professor, Department of Public Health Sciences, MUSC
To generate the necessary evidence to inform medical care, we need to design later stage trials that generalize to the true patient care setting. We will present features of large CER trials and share our experience with conducting the RAMPART study - a large CER clinical trial that was a collaborative effort between clinical research, EMS agencies and communities across the country as well as industry and federal agencies. This presentation will highlight the various aspects of RAMPART which include: developing the right question, conducting community engagement/consultation and maintaining the patient-care setting in a clinical trial.

11:45 **When the Problem is the System: Comparative Health Systems Research**
William P. Moran, MD. MS, Professor and Director, General Internal Medicine & Geriatrics, MUSC
Health Systems Research is a field of study that examines the organization, financing, implementation, and delivery of quality health care services in an efficient manner within healthcare organizations and communities, and the impact of these services on the health of individuals. This presentation will use a proposed Low Country HealthCare Transitions Collaborative to demonstrate the opportunities for CER research within the context of health systems.

12:05PM **Working Lunch Break**

12:15 - 12:45PM **Working Lunch & Networking Session Targeting CER/PCOR Grant Development, Funding Opportunities, and Q/A Session**
Hosted by Ann Bonham, PhD, and Patrick D. Mauldin, PhD.
Bioengineering Building Auditorium, Room 110

1:00 **Keynote Speaker Introduction**
Cathy L. Melvin, PhD. MPH.

**Keynote Address #2 - Application of Community Engagement/CBPR Principles and Measures and Metrics to PCOR and Comparative Effectiveness Research**
Nina Wallerstein, DrPH, Professor Public Health Program, Department of Family and Community Medicine & Senior Fellow, Robert Wood Johnson Center for Health Policy, University of New Mexico

**Session 2: Moderator –Patrick D. Mauldin, PhD**

1:30 **Quality of Life and Quality-Adjusted Life Year Modeling: Essential CER Measures**
Kit N. Simpson, DrPH, Professor, Department of Health Science and Research, MUSC
CER studies must consider the outcomes that patients care about. These can be measured using three approaches: disease-specific or global measures of quality of life, or patient utility weights. Each approach has strengths and weaknesses. Data from a study of patients with treatment-resistant depression provides an example of how these measures are used in CER and how their impact can be linked with cost data to predict budget impact beyond the trial's time by using Markov modeling.

1:45 **Meta Analysis: A Versatile Tool for Conducting CER**
Paul J. Nietert, PhD, Professor, Department of Public Health Sciences, MUSC & Director, SCTR Biostatistics, Epidemiology & Research Design Program
This presentation will involve discussions of the benefits and limitations of meta analyses, especially in the context of comparative effectiveness research. Several relevant examples will be presented.
2:00 Infrastructure Development Program in Patient-Centered Outcomes Research (PCOR) (R24)
Steve M. Ornstein, MD, Professor, Department of Family Medicine, MUSC
Investigators from the Departments of Family Medicine, Internal Medicine, and Pediatrics are collaborating on
development of an application in response to the above Program Announcement. The proposed project will have
Core components and investigator research projects with the theme of implementing recommendations of the US
Preventive Services Task Force.

2:15 Coffee Break & Networking

Session 3: Moderator – Marc Chimowitz MB. ChB, Professor of Neurology, Associate Dean for Faculty
Development, MUSC

2:30 A Statewide Clinical Data Warehouse: From Vision to Reality to Research
Christine Turley, MD, Chief Medical Officer, Health Sciences South Carolina & Professor of Clinical
Pediatrics, University of South Carolina
The creation of a multi-institutional integrated Clinical Data Warehouse (CDW) has been the subject of much
collaborative effort in South Carolina for 3 years, and has become a reality in August 2013. We will present the
HSSC CDW and the associated tool, Informatics for integrating Biology and the Bedside (i2b2) webclient, along with
mechanisms for requesting data that maximize collaboration and use of these research resources as secure tools to
improve health and health care in the state.

2:45 Method to Translate Patient Reported Outcome Measures into Disability Indicators
Craig Velozo, PhD, Director and Professor, Division of Occupational Therapy, MUSC
The purpose of this presentation is to demonstrate the use of Item Response Theory (IRT) methods to convert
assessment measures to disability indices. Innovative outputs generated by IRT methods may facilitate the use of
Patient Centered Outcomes in clinical practice.

3:00 Adding Insight by Using CER Techniques when Examining Racial Disparities in Transplantation
David J. Taber, PharmD, Assistant Professor, Department of Surgery, MUSC
African-Americans experience a disproportionately higher rate of graft loss following kidney transplantation. Due to
the numerous and complex etiologies surrounding this disparity, the use of comparative effectiveness research
techniques are useful at adding detailed insight into this important public health issue.

3:15 Assessment of Pain after Cholecystectomy; Navigating a Minefield
Peter B. Cotton, MD, Professor, Department of Medicine, MUSC
One of the many challenges of patient centered care and research is how to measure patients pain (which is often
intermittent), and what decrease might constitute successful treatment. We report interesting results from our recent
multi-center randomized study (EPISOD) of patients who present with troublesome pain after gall bladder removal.

3:30 SCTR Pilot Project Program Funding Opportunities
Dayan Ranwala, PhD, Research Assistant Professor, SCTR Pilot Project Program
The SCTR Pilot Project Program supports the conduct of scientifically meritorious, new and innovative pilot projects
to support multidisciplinary translational research. We strongly encourage retreat participants to submit CER-
related pilot project applications that emanate from today’s retreat as special funds have been set aside for this
purpose.

3:45 Summary, Discussion & Next Steps
Patrick D. Mauldin, PhD

4:00 Meeting Adjourn