

## **Completed Research Projects by BERD Faculty and Staff**

**Multiple PI: Ning/Rahbar**

### **Statistical Methodology Development in Blood Transfusion Protocol Research**

The overall objective of this project is to address issues in blood transfusion research by developing latent class analysis and recurrent event data analysis methodology to apply to this field.

**PI: Reveille/DMSC PI: Rahbar**

### **Genetics and Ankylosing Spondylitis Pathogenesis**

The goal of this program is to further characterize the genetic basis of ankylosing spondylitis, as it affects disease susceptibility, severity, phenotype penetrance in family members and how these disease-related genetic polymorphisms relate to animal models and human disease. The Data Management and Statistical Core (DSMC) will collaborate with investigators on this project by leveraging resources to provide study design, data management, and statistical support.

**PI: Marian**

### **Hypertrophy Regression with N-Acetylcysteine in Hypertrophic Cardiomyopathy (HALT-HCM)**

The primary objective is to perform a pilot study in patients with hypertrophic cardiomyopathy (HCM) to establish safety and gather the prerequisite data for subsequent robust randomized placebo controlled efficacy studies with N-acetylcysteine (NAC). We will gather data on the recruitment, accrual, retention, and compliance rates of HCM patients randomized to treatment with a placebo or two escalating doses of NAC. Likewise, we will determine any potential side effects and estimate the effect size of NAC on indices of cardiac hypertrophy.

**PI: Reininger**

### **Salud y Vida 2.0: Enhancing Integrated Behavioral Health for Individuals with Diabetes in the Rio Grande Valley**

University of Texas School of Public Health, Houston Health Science Center, Brownsville Regional Campus (UTSPH). The SyV 2.0 program will be implemented and led by the UTSPH-Brownsville Regional Campus and its partners. The evaluation of this new 2.0 program will be tested in a randomized behavioral intervention trial.

**PI: Rhoads**

### **Safety of L. Reuteri and Effect on Microbiota and Biomarkers of Intestinal Health in Healthy Infants with Colic**

This project is focused on a population of healthy infants with colic to show safety of a probiotic that has been shown to reduce crying time in infants with colic. The primary aim is to demonstrate (in a 2-year trial) the safety of L. reuteri in healthy newborns with colic (n=30), by administering 5 x 10<sup>8</sup> c.f.u. by mouth once daily for 6 weeks. The secondary aims are to determine the effect of L. reuteri on (a) regulating gastrointestinal inflammation as assessed by fecal calprotectin; (b) serum cytokines; (c) circulating regulatory T-cells; and (d) fecal microbiota.

**PI: Kim**

**Mitral Value Dynamic Analysis and Potential Clinical Applications**

Mitral valve (MV) repair is the preferred treatment in patients with MV insufficiency. The unsolved problem in MV repair surgery is predicting which repair is optimal for each patient. The principal aim of this project is to develop a novel computational technique combining 3-D echocardiography with finite element and fluid-structure interaction analyses to evaluate the effects of MV morphology (normal vs. diseased valves, and pre- vs. post-repair) on MV function.

**PI: Savitz**

**The University of Texas Houston Regional Stroke Center**

The goal of this proposal is for UTHealth to serve as a regional clinical coordinating center for the NINDS Stroke Trials Network to conduct multi-site clinical trials focusing on stroke prevention, intervention, and recovery.

**PI: Suarez-Almazor**

**Methods Training in Patient-Centered Cancer Outcomes Research**

The overall goal of this application is to increase the U.S. workforce of cancer researchers conducting Comparative Effectiveness Research/Patient Centered Outcomes Research by providing a comprehensive learning and training program that will be innovative, accessible, and tailored to the needs and expertise of individual participants. CERC offers training in CER/PCOR methodology, provides guidance on promoting stakeholder involvement, assists researchers in obtaining external funding, and fosters collaborations between researchers and established CER/PCOR methodologists.

**PI: Nils Johnson**

**Distal Evaluation of Functional performance with Intravascular sensors to assess the Narrowing Effect – Combined pressure and Doppler FLOW velocity measurements (DEFINE-FLOW)**

The goal of this proposal is for the Division of Cardiology, Department of Medicine, The University of Texas Medical School at Houston, Memorial Hermann Hospital, Texas Medical Center to conduct multi-site focusing on Define independent prognostic value of coronary flow reserve and fractional flow reserve for lesions in patients undergoing physiologic assessment for percutaneous coronary intervention.

**PI: Barreto Andrew (Director of DCC: Rahbar)**

**A Pilot, Phase IIb, Randomized, Multi-center Safety and Activity Trial of Argatroban in Combination with TPA Stroke Study (ARTSS-2)**

This project is a supplement to the study The University of Texas Specialized Program in Acute Stroke (UT SPOTRIAS), University of Texas Medical School at Houston, University of Texas Health Science Center at Houston. Dr. Rahbar serves as PI of the Data Coordinating Center.

**PI: Ayala**

**Comprehensive Tumor Microenvironment Based Prediction Models in Prostate Cancer**

Prostate cancer continues to have a significant health care impact due to its high incidence and mortality. Despite advancements in understanding the clinical spectrum of this disease, there are still limits in the ability to identify the patients who present with localized disease but are likely to fail standard treatment and progress to fatal disease. The overall goal of this project is to model a rigorous quantitative and reproducible tumor microenvironment-based test. Based on the hypothesis that such a test will improve predictability of currently used algorithms, the goal is to select those patients who can benefit from combined modality treatments or adjuvant/neoadjuvant approaches, or more intense follow-up.

**PI: Ayala**

**Predicting Prostate Cancer Aggressiveness**

**PI: Hwang**

**Text Messaging for Weight Loss**

**PI: Mansi Jhaveri**

**Telemedicine Guided Education on Fall Prevention and Secondary Stroke Prevention Following Inpatient Rehabilitation: A Feasibility Pilot Study**

The goal of this project is to determine the feasibility of weekly telephone contact using the FaceTime application to educate and monitor stroke patients after discharge from inpatient rehabilitation to home and collect preliminary data on the use of this strategy to prevent falls, recurrent strokes, and 30-day hospital readmission.

**PI: Hebert**

**Twice Daily Altabax Application for the Treatment of Uncomplicated Soft Tissue Infection**

The purpose of this study is to document the clinical and bacteriological efficacy of retapamulin in the treatment of subjects with bacterial infections, including impetigo, folliculitis, and minor soft tissue infections including secondarily infected eczema presumed to be caused by methicillin resistant Staph aureus.

**PI: Ifejika**

**Swipe Out Stroke (SOS)**

Feasibility of Using a Consumer Based Electronic Application to Improve Compliance with Weight Loss in Obese Minority Stroke Patients.

**PI: Rahbar**

**PROspective Observational Multi-center Massive Transfusion sTudy (PROMMTT-DCC)**

The purpose of this \$9.2 million project was for the Center for Clinical and Translational Sciences (CCTS) at The University of Texas Health Science Center at Houston (UTHealth) to serve as the Data Coordination Center for Prospective, Observational, Multi-center Massive Transfusion Trial (PROMMTT) which involves 10 major trauma research centers in the United States. PROMMTT-DCC will provide comprehensive administration including the establishment and management of a Consortium of at least 10 clinical sites and the coordination of data collection, data management and statistical analysis activities to achieve the overall objectives of this project.

**PI: Grotta (PI of Data Core: Rahbar)**

**The University of Texas Specialized Program in Acute Stroke (UT SPOTRIAS) Data Core**

This program is a renewal of The University of Texas Health Science Center at Houston Specialized Program in Translational Research in Acute Stroke. This program includes implementation of two clinical trials in stroke patients. This program also includes 3 Cores (Clinical, Data, and Tissue) to support these clinical and translational studies as well as a Career Development Program to train new investigators to carry out future translational studies.

**PI: Lindsey**

**Epstein-Barr Virus and Multiple Sclerosis: Correlation of Activity National Multiple Sclerosis Society**

Multiple sclerosis (MS) is an immune-mediated, demyelinating disease affecting the central nervous system. The etiology of MS is currently not known, but many features of the disease are consistent with an infectious cause. There are several lines of evidence associating MS with Epstein-Barr virus (EBV). Essentially all adults with MS are infected with EBV, EBV infection occurs before the clinical manifestations of MS, and high titers of antibodies against EBV or a history of symptomatic EBV infection predict a higher risk of developing MS. Despite these associations, the relation between the virus and the disease is not clear. The specific aim is to determine whether reactivation of EBV and changes in the anti-EBV immune response correlate with disease activity in relapsing-remitting MS.

**PI: Reininger**

**Tu Salud, ¡Si Cuenta!: Promotora Training and Community Education for Cancer Prevention Cancer Prevention and Research Institute of Texas (CPRIT)**

Tu Salud, ¡Si Cuenta! (Your Health Matters!) community-wide campaign was designed and implemented to reach adults aged 20-64 years and their families along the US/Mexico Border on the topics of physical activity and healthy food choice. It was hypothesized that individuals who reported exposure to multiple components of the CWC would also report greater physical activity and fruit and vegetable consumption. The purpose of this project is to implement community based cancer prevention using technology among the Mexican Americans.

**Transforming Texas in Cameron County: Healthy People in a Healthy Community Texas  
Department of State Health Services**

The purpose of this project is to implement policy and environmental change strategies to promote physical activity, healthful food choices, and smoking cessation.

**PI: McCormick**

**Collaboration with UT-Brownsville Campus: Center of Excellence for Diabetes in Americans of Mexican Descent**

This project will conduct research on the physiological progression of diabetes and its complications among Mexican Americans and develop diabetes prevention strategies and test innovative approaches to effective intervention in minorities. This Center of Excellence aims to 1) understand the changes proximal to the development of overt diabetes, 2) understand the mental health impact of diabetes and the potential for early intervention, 3) utilize the strong family unit in the Mexican American population to reduce the risk of obesity and diabetes in children through parental intervention, and 4) understand how to use the successful technique of behavioral journalism and the media to change diet and physical activity behavior at the population level.

**PI: Reininger**

**Collaboration with UT-Brownsville Campus: Social Cognitive Disaster Preparedness Communications for Mexican-Americans**

The purpose of this grant will be to identify the special needs population within Cameron, Hidalgo and Willacy Counties in South Texas who will need assistance in being evacuated in case of emergency. The specific aims of this project include: 1) needs assessment and to determine the number of persons with special needs requiring assistance with evacuation in case of emergency; by level of need, census tract, and county based on two stage community survey; 2) needs assessment and to determine the number of persons with special needs based in institutions providing care such as nursing homes, long-term care facilities, hospice, assisted living facilities, state schools and hospitals; requiring assistance with evacuation in case of emergency by level of need, census tract and county based on a self-reported questionnaire; and 3) experimental methods will be incorporated to evaluate and improve the effectiveness of our disaster preparedness guidelines in order to enable this population to better deal with a potential disaster in future in more scientific way.

**PI: Vernon**

**Initiation of Colorectal Cancer Screening in Veterans**

This is a nationwide, randomized, controlled intervention trial to increase the initiation of colorectal cancer screening in the population of male and female U.S. veterans between 50 and 64 years of age. The stepped intervention approach will use mailed intervention materials followed by telephone reminders comparing two different approaches: automated vs. live consultations that incorporate strategies from the field of motivational interviewing. This is a collaborative project with investigators at UTHealth, Duke University School of Medicine, the Durham VAMC, and Washington University (St. Louis) School of Medicine.

**PI: Cooper**

**Southwest Center for Agricultural Health, Injury Prevention and Education: Migrant Adolescent Health Research Study**

This is an epidemiologic study of the prevalence and incidence of early indicators of chronic disease (e.g., obesity and Type II diabetes) among farm worker adolescents (13-19 years of age) to support the prevention and comprehensive policy dimensions of NIOSH's WorkLife initiative. This project is part of the current research program of the Southwest Center for Agricultural Health, Injury Prevention, and Education at the University of Texas Health Science Center at Tyler that sponsors research, education/outreach programs.

**PI: Arnett**

**Center for Research Translation in Scleroderma**

This Center focuses on molecular approaches to understand the pathogenetic mechanisms (including genetic factors) and predictors of outcomes in systemic sclerosis. The study aims to identify the cellular pathways leading to disease and optimal targets for effective therapy and prevention. The patient population includes three major ethnic groups. There are 3 projects: 1. Functional Genomics Approach to Systemic Sclerosis Pathogenesis, 2. Gene Expression as Predictors of Outcomes in the GENISOS (Genetics versus Environment in Scleroderma Outcomes Study) Cohort, and 3. Role of TGF3 and CTGF Signaling in Transgenic Mouse Models of Scleroderma.

**PIs: Sdringola/Gould**

**Randomized Trial of Comprehensive Lifestyle Modification, Optimal Pharmacological Treatment and PET Imaging for Detection and Management of Stable Coronary Artery Disease (The Century Trial)**

The purpose of this randomized, controlled trial is to 1) evaluate the impact of stress perfusion imaging with SPECT or PET on post-test resource utilization and on risk stratification, and 2) assess whether a comprehensive program of lifestyle modification and lipid management, compared with standard therapy, reduces cardiovascular risk in patients with known disease or at high risk for coronary artery disease. Eligible patients are between 40 and 75 years of age and referred by their physicians to receive SPECT imaging. Participants are assigned randomly to receive either a comprehensive intervention program or standard follow-up care by their referring physician and are followed for five years to compare their post-intervention outcome scores on a standardized scale measuring cardiovascular risk factors and survival free of serious adverse cardiovascular disease events (e.g., myocardial infarction, stroke).

**PI: Dyer**

**Training Excellence in Aging Studies (TEXAS)**

TEXAS applies a competency-based approach to foster knowledge and skill acquisition in geriatrics at student, resident, faculty and practicing physician levels so that outcomes are realized at both organizational and individual levels. This program hopes to establish an innovative, high impact and sustainable geriatric education program for UTHealth students, residents and faculty and, ultimately, improve quality of care for the vulnerable elderly population.