I - Office of Human Research Protection
3rd Quarter, Fiscal Year 2017

<table>
<thead>
<tr>
<th>IRB Review Type and Funding Source</th>
<th>Active Studies per Review</th>
<th>Active Studies per Funding Source</th>
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IRB-A Categories: Cardiology, Vascular Surgery, Plastic Surgery, General Surgery, Orthopedics, Rehabilitation, Neurology, Nursing, Women’s, Internal Medicine, Pharmacy, Infectious Disease, General (non-pediatrics/non-oncology)

IRB-B Categories: Pediatrics (all), Women’s, Cardiology, Orthopedics, Internal Medicine, Infectious Diseases, Neurology, General (non-adult oncology)

IRB-C Category: Adult Oncology

Other: Chart reviews, questionnaires, pilot studies, feasibility studies, biology, Humanitarian Device Exempt (HDE) and Humanitarian Use Device (HUD) studies, specimen storage, Comparative Effectiveness Research, Social Behavioral Research, curriculum development, etc.
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<th>Categories of studies reviewed by committee</th>
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<td>Cardiology, Vascular Surgery, Plastic Surgery, General Surgery, Orthopedics, Rehabilitation, Neurology, Nursing, Women's, Internal Medicine; Pharmacy; Infectious Disease; General (non-pediatrics/non-oncology)</td>
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<tr>
<td>B</td>
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<td>Pediatrics (all), Women's, Cardiology, Orthopedics, Internal Medicine, Infectious Diseases, Neurology, General (non-adult oncology)</td>
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<tr>
<td>C</td>
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Clinical Trial: For the purpose of this report, a clinical trial is defined as a prospective, biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, biologics, treatments, devices, or new ways of using known drugs, biologics, treatments, or devices). This definition incorporates the major points of the term as defined by the NIH, DHHS, ICMJE, ICH GCP E6, FDA, WHO and the clinicaltrials.gov website.

Other types of clinical trials include prevention, treatment, vitamin, symptom management and radiation.

### Active Interventional Clinical Trials

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<th>Device</th>
<th>Other</th>
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### Interventional Clinical Trials by Department

- Cardiology: 2%
- ID / GI and Liver Center: 6%
- Endoc: 9%
- Oncology: 14%
- CIOS: 9%
- NeuroSciences: 71%
- GHS Orthopedics: 1%

### Interventional Clinical Trials by Study Type

- Drug: 77%
- Device: 14%
- Other: 9%
### Active Interventional Clinical Trials per Phase and Funding Source

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<th>Oncology</th>
<th>CIOS</th>
<th>NeuroSciences</th>
<th>GHS orthopedics</th>
<th>Hawkins Foundation</th>
<th>Sub-Total</th>
<th>Pediatrics</th>
<th>Hem/Onc</th>
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<th>Surgery</th>
<th>Womens</th>
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### Interventional Clinical Trials by Phase

- Phase I: 33%
- Phase II: 60%
- Phase III: 22%
- Phase IV: 2%

### Interventional Clinical Trials by Funding Source

- Industry: 37%
- Federal Funding: 59%
- Other: 4%

---

3. Other types of funding include foundation and departmental.
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<td><strong>Sub-Total</strong></td>
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NA: not Available.
III - Sponsored Programs Activity
3rd Quarter, Fiscal Year 2017

OVERALL SUMMARY

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<th>FY17 YTD</th>
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PROPOSAL SUMMARY

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Proposal Activity by Classification

- Research: 54%
- Other Sponsored Activity: 40%
- Instruction: 6%

Proposal Activity by Sponsor Type

- Federal Pass Through: 4%
- Federal: 25%
- State: 13%
- Foundation: 58%
- Industry: 5%
## AWARD SUMMARY

### Total Award Activity

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<th>Indirect Cost</th>
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<td>$241,918</td>
<td>$22,500</td>
<td>$3,293,302</td>
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### Sponsored Awards Classification

- Research: 11%
- Other Sponsored Activity: 10%
- Instruction: 79%

### Sponsored Awards by Sponsor Type

- Federal Pass Through: 5%
- Federal: 17%
- State: 12%
- Foundation: 5%
- Industry: 35%

### EXPENDITURE SUMMARY

<table>
<thead>
<tr>
<th>FY 17 Expenditures</th>
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<td>Q1</td>
<td>$1,997,630</td>
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<td>Q3</td>
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FY17Q3 Department of Research & Scholarship Activity Report
IV - Sponsored Programs Extramural Funding Requests
3rd Quarter, Fiscal Year 2017

The Office of Sponsored Programs reports that GHS faculty and staff members submitted the following 24 proposals, totaling $14,216,444, during the third quarter of fiscal year 2017.

Department of Obstetrics and Gynecology

Dr. Bruce Lessey: Elsa U. Pardee Foundation

 Activation of STAT3, KRAS and SIRTUIN-1 and Progesterone Resistance in Development of Endometriosis-Derived Ovarian Cancers

This study will compare central mediators of inflammation and progesterone resistance in endometrium, endometriosis and ovarian cancers thought to be derived from endometriosis, compared to non-endometriosis related tumors.

Project Dates: 10/01/2017 – 09/30/2018
Total: $261,219; Direct: $234,647; Indirect: $26,572

Dr. Bruce Lessey: National Institutes of Health

Inflammatory mediators of endometrial progesterone resistance

Inflammatory changes in the endometrium alter endometrial receptivity, leading to infertility and pregnancy loss. While much is known about normal hormone action, the mechanisms, etiology and physiological disruptions caused by endometriosis remain poorly understood. This application will utilize new genetic model systems to understand these critical mechanisms.

Project Dates: 04/01/2018 – 03/31/2023
Total: $3,564,087; Direct: $3,150,208; Indirect: $413,879

Dr. Amy Crockett: National Institutes of Health via NorthShore University HealthSystem

Psychosocial Intervention, Maternal Inflammation, Birth Outcomes: Centering vs. Routine Prenatal Care

This study will provide more understanding about how CenteringPregnancy group prenatal care reduces preterm birth by analyzing biomarkers of stress and inflammation, evaluating biologic pathways involving the HPA axis and glucocorticoid signaling pathways, and understanding more about the contribution of maternal psychosocial stress to adverse birth outcomes.

Project Dates: 04/01/2018 – 03/31/2023
Total: $1,166,248; Direct: $745,683; Indirect: $420,565

Health Sciences Center

Dr. Peggy Wagner: Patient-Centered Outcomes Research Institute (PCORI)

Engaging patients in diabetes-focused research to improve access, self-management, and service delivery

This project will engage patients reflective of the income and racial diversity differences of Laurens and Greenville Counties. This will clarify county context-specific areas of interest for diabetes-focused research. Establishing partnerships and enhancing research capacity in the vastly different rural/urban contexts will contribute to diabetes research essential to mitigating disparities in access, service delivery, and self-management of the chronic disease.

Project Dates: 10/01/2017 – 09/30/2018
Total: $50,000; Direct: $45,818; Indirect: $4,182
Department of Internal Medicine

**Dr. Melissa Bailey: National Institutes of Health**  
*Shifting the Paradigm of Detecting Cognitive Impairment*  
This project will reduce the economic, emotional, and medical burden of cognitive impairment by providing a validated and tested paradigm to improve detection of cognitive impairment in the general public and three health disparity communities in the US via focus groups, telemedicine, a multiple-discipline team, and provider training and education.  
Project Dates: 09/01/2017 – 08/31/2022  
Total: $3,149,316; Direct: $2,013,629; Indirect: $1,135,687

**Dr. Melissa Bailey: The Duke Endowment**  
*Memory Health Service Expansion - Anderson/Oconee/Pickens*  
This project will improve the health and quality of life for the 14,378+ persons with ADRD and their caregivers who live in Greenville, Anderson, Pickens and Oconee counties. Through the addition of a new location in Oconee County, GHS will be able to provide more accessible and increased diagnostic, healthcare and community services to these underserved populations.  
Project Dates: 01/01/2018 – 12/31/2020  
Total/Direct: $1,485,063; Cost Share: $424,764

**Dr. Mahmoud Rayes: National Institutes of Health via MUSC**  
*Program to Avoid Cerebrovascular Events through Systematic Electronic Tracking and Tailoring of Eminent Risk-factors (PACESETTER)*  
The objective of this study is to demonstrate that a theoretical-model-based, mHealth technology-centered, multi-level integrated approach is effective in improving sustained BP control among 200 recent SC stroke patients within one month of symptom onset.  
Project Dates: 12/01/2017 – 11/30/2022  
Total: $294,245; Direct: $188,136; Indirect: $106,109

**Dr. Mahmoud Rayes: National Institutes of Health via Clemson University**  
*Does Telestroke Participation Reduce the Weekend Effect on Stroke Mortality*  
This project intends to demonstrate that a hospital’s stroke care center status (being a stroke center) is linked with the reduction of excess mortality among weekend-admitted ischemic stroke patients and that a non-stroke-center hospital’s participation in a telestroke network is associated with a decrease in the deleterious “weekend effect” of ischemic stroke mortality.  
Project Dates: 04/01/2018 – 03/31/2021  
Total: $23,460; Direct: $15,000; Indirect: $8,460

Roger C. Peace Rehabilitation Hospital

**Dr. Kevin Kopera: Department of Veterans Affairs**  
*GHS/RCP Adaptive Sports Outreach*  
This funding will help provide recreational opportunities for veterans and services members. The program will engage veterans in sports they once loved, have never tried or want to continue to progress in.  
Project Dates: 09/01/2017 – 09/30/2018  
Total: $109,752; Direct: $104,265; Indirect: $5,487

Department of Orthopaedic Surgery
**Dr. John Millon – American Society for Surgery of the Hand**  
*Buried Intramedullary Fixation vs Plate Fixation for Metacarpal Fractures*  
This study aims to compare clinical outcomes and cost associated with two different surgical  
techniques for extra-articular unstable metacarpal fractures; buried intramedullary k-wire fixation and  
plate and screw fixation.  
Project Dates: 10/01/2017 – 09/30/2019  
Total/Direct: $39,946

**Dr. Scott Porter: Zimmer Biomet**  
*42nd Annual Greenville Orthopaedic Day*  
This proposal requested support for the 42nd Annual Greenville Orthopaedic Day.  
Project Dates: 04/21/2017 – 05/19/2017  
Total/Direct: $5,000

**Dr. Kyle Jeray: Patient-Centered Outcomes Research Institute via University of Maryland**  
*High Periodic Loading Doses versus Low Daily Doses of Vitamin D to Optimize Fracture Healing*  
This trial will enroll tibia fracture patients to compare two high loading doses of vitamin D3 versus a  
standard recommended daily dose of vitamin D3 taken for 3 months in patients with these fractures and  
the effect on re-operation rates and fracture healing.  
Project Dates: 01/01/2018 – 12/31/2022  
Total: $165,060; Direct: $117,900; Indirect: $47,160

**Dr. Kyle Jeray: Orthopaedic Trauma Association via Carolinas HealthCare System**  
*Use of a Self-Directed Exercise Program (SDEP) Following Selected Lower Extremity Fractures: A randomized clinical trial*  
The purpose of this study is to compare the effectiveness and value of clinic-based PT and a home-  
based, self-directed exercise program (SDEP). The home exercise program will be developed by a  
team of physical therapists, orthopaedic trauma surgeons and experts in rehabilitation engagement in  
collaboration with patients recovering from traumatic lower-extremity injuries. The study will also  
determine which subgroups of individuals based on patient and injury characteristics are the best  
candidates for a home exercise program.  
Project Dates: 01/01/2018 – 12/31/2019  
Total/Direct: $33,000

Cancer Institute

**Gina Franco: Prevent Cancer Foundation**  
*Controlling Racially Observed Screening Shortages (CROSS)*  
This grant will help increase cancer screening among the African American (AA) population by doubling  
referrals for lung, breast, cervical and colorectal screenings among the AA population. This outreach  
initiative will aid in controlling racially observed screening shortages with the ultimate goal of seeing a  
sustainable increase in the AA population utilizing the clinic’s screening programs, resulting in earlier  
and more curable cancer detection.  
Project Dates: 07/15/2017 – 07/15/2018  
Total/Direct: $25,000
Dr. Mark O’Rourke: National Institutes of Health via University of South Carolina

Self-Management of Symptom Clusters among Cancer Survivors Using Heart Rate Variability Biofeedback

This biobehavioral intervention trial will be the first major study to examine HRV-B for self-management of cancer symptom clusters. The research team will test the hypothesis that HRV-B improves HRV coherence and reduces fatigue, pain, stress, depression, and insomnia among cancer survivors.

Project Dates: 04/01/2018 – 03/31/2022
Total: $810,187; Direct: $572,846; Indirect: $237,341

Department of General Surgery

Dr. Jeremy Warren: American Hernia Society

Laparoscopic vs Robotic Paraesophageal Hernia Repair: A Randomized Controlled Pilot Study of Short Term Outcomes and Ergonomic Impact

The purpose of this project is to evaluate the potential advantages of the robotic platform compared to the standard of care (LPEH) on both the clinical outcomes and surgeon ergonomics.

Project Dates: 07/01/2017 – 06/30/2018
Total/Direct: $50,000

Mike Walls: Firehouse Subs Public Safety Foundation

Public Access Bleeding Control Stations

The grant requested support to purchase public access bleeding control stations, which would assist in the event of a mass casualty incident or an incident involving severe bleeding.

Project Dates: 07/01/2017 – 09/01/2017
Total/Direct: $14,799

Accountable Communities

Candice Hipp: The Duke Endowment

Accountable Communities / Health Extension Project

The expansion of the Health Extension program will address the lack of health education in underserved populations or for any resident of our communities who needs access to educational resources to improve their overall health.

Project Dates: 01/01/2018 – 12/31/2020
Total/Direct: $1,627,970; Cost Share: $42,352

Heather Goss: The Duke Endowment

Mountain Lakes AccessHealth

The goal of this program is to improve health outcomes for the uninsured and the impact on the community by shifting from acute, episodic care in the ED to prevention, early intervention and chronic disease management in a medical home.

Project Dates: 01/01/2018 – 12/31/2019
Total/Direct: $500,000; Cost Share: $223,497
Department of Pediatrics

**Dr. Bryce Nelson: National Institutes of Health via University of South Carolina**  
*Impact of disparities in food security on glycemic control and health care utilization among youth and young adults with diabetes*

GHS will recruit SEARCH 4 participants for the SFS protocol, work with USC staff to collect data, including for SFS follow-up 1 and follow-up 2, complete blood draw and height/weight measurement on SFS participants at follow-up 2, and ship blood to the central laboratory.

Project Dates: 04/01/2018 – 03/31/2023  
Total: $69,787; Direct: $44,620; Indirect: $25,167

**Dr. Desmond Kelly: National Institutes of Health via Clemson University**  
*Metabolic profiles that reflect utero exposure to gestational diabetes and predict future adiposity-related outcomes in children*

The project will test the hypothesis that exposure to GDM in utero will result in changes in metabolic profiles in the offspring in early childhood and that these metabolic changes will be associated with future risk of childhood obesity.

Project Dates: 06/01/2018 – 05/31/2023  
Total: $645,841; Direct: $412,942; Indirect: $232,899

Bradshaw Institute for Community Child Health and Advocacy

**Kerry McKenzie: The Graham Foundation**  
*Choosy Farm to Belly*

This project introduces children to fresh produce and encourages their family’s preparation of culturally diverse, child-focused recipes. The project will create a hands-on, sustainable learning experience for young children in the target Head Start Centers. Nutritionist-modified family recipe kits, including fresh local produce, are provided at no cost for 15 weeks.

Project Dates: 06/01/2017 – 05/31/2018  
Total/Direct: $80,000

**Jane Witowski: Trident United Way**  
*Read Rattle & Roll*

Read Rattle & Roll is a HMG SC community event offering families a free and fun opportunity to be introduced to developmental screening. It is designed for children from birth to 5 ½, and allows children to enjoy fun and interactive play areas focused on learning, behavior, communications, and problem solving. Parents will learn how these interactions stimulate their child’s development and complete a short questionnaire that will help to identify their child’s strengths or areas where extra support may be needed.

Project Dates: 07/01/2017 – 06/30/2018  
Total/Direct: $5,464

**Jane Witowski: Coastal Carolina Foundation**  
*Help Me Grow – South Carolina Low Country Expansion*

This grant will provide funding to build capacity and provide access to Help Me Grow’s services for an additional 16,000 families in the Lowcountry.

Project Dates: 11/01/2017 – 10/31/2018  
Total/Direct: $41,000
V - Sponsored Programs Award Activity
3rd Quarter, Fiscal Year 2017

The Office of Sponsored Programs reports that GHS faculty and staff members received the following 18 awards, totaling $3,293,302 during the third quarter of fiscal year 2017.

Department of Obstetrics and Gynecology

Dr. Amy Crockett: March of Dimes
*BOI Clinical Lead*
Dr. Crockett will serve as the clinical lead for the Birth Outcomes Initiative, a partnership focused on improving the health of newborns in the Medicaid program.
Project Dates: 1/1/2017 – 12/31/2017
Total/Direct: $45,000

Dr. Melisa Holmes: New Morning Foundation
*Choose Well Initiative*
Through participation in the Choose Well Initiative, Greenville Memorial Hospital (GMH), part of the Greenville Health System, seeks to meet its goal to optimize patient knowledge about contraceptive choices, improve accessibility for immediate post-partum patients, and improve clinician acceptance and use of LARCs specifically in the post-partum setting.
Project Dates: 1/1/2017 – 12/31/2017
Total: $133,386; Direct: $121,260; Indirect: $12,126

Department of Pediatrics

Tyner Lollis: Brave Beginnings
*Neonatal Resuscitation Grant*
Funding will support the purchase of neopuffs (t-piece resuscitators) which have been shown to decrease damage to the lungs incurred when resuscitating small neonates.
Project Dates: 04/01/2017 – 03/31/2018
Total/Direct: $57,900

Dr. Nicholas Kelley: Mary Black Foundation
*Healthy Families Initiative – Standard Triple P Implementation*
This grant will provide resources to implement the Triple P - Positive Parenting Program, which aims to: 1) Promote the independence and health of families through the enhancement of parents' knowledge, skills confidence, and self-sufficiency; 2) Promote the development of non-violent, protective, and nurturing environments for children; 3) Promote the development, growth, health, and social competence of young children; and, 4) Reduce the incidence of child maltreatment and behavioral/emotional problems in childhood and adolescence.
Project Dates: 04/01/2017 – 03/31/2022
Total/Direct: $25,000

Dr. Nicholas Kelley: South Carolina Asthma Alliance
*M & M’s for Asthma*
This grant will support an RN to gain Asthma Educator (AE) certification by providing funding to cover exam preparation and exam fees.
Project Dates: 03/01/2017 – 10/31/2017
Total/Direct: $500
Dr. Nicholas Kelley: HHS via Mary Black Foundation
*Replication of Evidence-Based TPP Programs to Scale in Communities with Greatest Need Tier IB*

The Triple P - Positive Parenting Program is a multi-tiered system of evidence-based education and support for parents and caregivers of children and adolescents and serves as both an early intervention and prevention model. Through this funding, GHS will be able to implement this model through collaboration with community partners and the GHS OB GNY Teen Center/Clinic.

Project Dates: 04/01/2017 – 03/31/2018
Total/Direct: $5,000

Dr. Nichole Bryant: KOA Care Camps
*Camp Courage*

Awarded funds will be used to support the BI-LO Charities Children's Cancer Center sponsored summer camp, Camp Courage, which is attended by children and teens with cancer or blood disorders from the Upstate of South Carolina, western North Carolina, and Northeast Georgia.

Project Dates: 05/01/2017 – 09/30/2017
Total/Direct: $14,000

Dr. Carley Howard-Draddy: SC Children's Hospital Collaborative
*Pediatric Telehealth Network Agreement*

Through this funding, GHS will be able to develop out operations of the pediatric critical care, neonatology, and pediatric medical transport telehealth services and obtain telehealth equipment.

Project Dates: 03/30/2017 – 06/30/2018
Total/Direct: $234,000

Dr. Jonathan Markowitz: SC Telehealth Alliance via Clemson University
*Feasibility of Eosinophilic Esophagitis Follow-Up Care through Telemedicine: A Pilot Study on Patient's Perspective*

Funding to be used to purchase a computer processor and telemedicine equipment to support this project that investigates the use of telemedicine visits to provide follow up care in patients with eosinophilic esophagitis.

Project Dates: 06/01/2017 – 05/31/2017
Total: $2,152

Dr. Jennifer Hudson: SC Department of Health and Human Services
*Managing Abstinence in Newborns (MAiN) Model Expansion in SC Hospitals Providing Regular OB Services*

GHS through Dr. Hudson has pioneered a new model of care providing early methadone therapy to otherwise healthy newborns at highest risk for NAS. The MAiN model is a proven safe, lower cost, and more family-centered than the traditional model of prolonged NICU care. Through this award, the MAiN model will be implemented at 10 hospitals, with intensive in-person training, remote support and quality control, and program evaluation for each site.

Project Dates: 07/01/2017 – 06/30/2022
Total: $2,567,295 Direct: $2,346,443 Indirect: $220,852
Dr. Nancy Powers: HHS via SC Developmental Disabilities Council  
SC Medical Legal Partnership  
This award provides this year’s support for the Medical-Legal Partnership program at GHS.  
Project Dates: 07/01/2017 – 06/30/2018  
Total: $22,500 Direct: $19,068 Indirect: $3,432 Cost Share: $22,500

Jane Witowski: HHS via SC Department of Social Services via University of South Carolina  
Building a Statewide System for Inclusion 2015-16  
This amendment provides GHS with indirect costs associated with the previously awarded project.  
Project Dates: 10/01/2016 – 09/30/2017  
Total/Indirect: $5,508

General Surgery

Dr. Alfredo Carbonell: W. L. Gore and Associates  
MIS Fellowship  
This funding will support a Division of Minimal Access and Bariatric Surgery fellowship position in advanced laparoscopy and bariatric surgery in a one-year program based on patient care, continuing education, and clinical research.  
Project Dates: 08/01/2017 – 07/31/2018  
Total/Direct: $33,000

Dr. Alfredo Carbonell: Foundation for Surgical Fellowships  
MIS Fellowship  
This year's support for the Minimally Invasive Surgery Fellow.  
Project Dates: 08/01/2018 – 07/31/2019  
Total/Direct: $20,000

Department of Emergency Medicine

Dr. Eric Ossmann: Department of Homeland Security  
Assignment Agreement  
At the direction of the Director of the Office of Counterterrorism and Security Preparedness, Dr. Ossmann will support the PNP implementation, maintenance, and revision efforts related to the development of the Emergency Operation Planning Guides and assist in the development of an annual assessment/report of the Joint Counterterrorism Awareness Workshop Series.  
Project Dates: 06/15/2017 – 06/14/2018  
Total/Direct: $39,911
Department of Community Relations

**Melinda Gillispie: SC Department of Health and Environmental Control**  
*Diabetes Education, Prevention and Support*  
Funding awarded to support diabetes education offered in conjunction with the GHS Minority Health Summit.  
Project Dates: 03/27/2017 – 06/30/2017  
Total/Direct: $8,250

Health Sciences Center

**Dr. Bill Schmidt: Sanders Family Foundation**  
*USCSOMG Paladin Scholarship*  
Project Dates: 05/30/2017 – 05/31/2018  
Total/Direct: $50,000