Your Game
Deconstructing Multi-Component Research Grants

April 10, 2018
Multi-component Applications

Single submissions with multiple, interrelated components that share a common focus or objective

Additional Cores

Overall Component

Peggy Schachte, MBA

Thematic Focus

Admin Core

Research Projects

* Specific components WILL vary between PARs/RFAs
Multi-component Applications

Single submissions with multiple, **interrelated components** that **share a common focus or objective**

- Technology Core
- Research Support Core
- Community Engagement Core
- Management, Dissemination, and Training Core
- Genome Editing Testing Core
- Data Analysis Core
- Clinical Translation and Validation Core
- Database and Biorepository Core

*Specific components WILL vary between PARs/RFAs*
Collaborative Proposal Development

- Promote collaborative grants and publications

Submit Multi-Component Grants

ORD Services
- Provide templates/examples for scientific and non-scientific sections
- Draft timelines
- Identify potential team members/collaborators
- Comprehensive review of ALL application components
  - Clear
  - Concise
  - Consistent
  - COMPLETE

Develop Strategic Plans

Build Collaborative Team

- Identify funding opportunity
- Develop central theme
- Implement Timeline
Program Project/Center Grants (P series)

Large, multi-project efforts that include a diverse array of research activities

- Besim Ogretmen, PhD (P01)
- Teresa Kelechi, PhD (P20)
- Steven Kautz, PhD (COBRE)
- Stephen Duncan, DPhil (recently submitted COBRE)
Cooperative Agreements (U series)

Support mechanisms used for high-priority research areas that require a level of NIH involvement

- Marvella Ford, PhD (U54)
- Chanita Hughes Halbert, PhD (U54)
Besim Ogretmen, PhD

Professor, Biochemistry & Molecular Biology

P01: Development of Novel Cancer Therapeutics by Targeted Sphingolipid Signaling
Program Project Grant (PPG)
Development of Novel Cancer Therapeutics by Targeting Sphingolipid Signaling

PI: Besim Ogretmen, PhD
http://www.hollingscancercenter.org/research/membership-opportunities/ppg/index.html
Core A
Lipidomics and MALDI Imaging

Core B
Animal Models and Pathology

Core C
Biostatistics

Core D
Administration

Project 1
AC/S1P Signaling & Resistance to IR-mediated apoptosis

Targeting nuclear SK-2/S1P using ABC294640

Targeting AC/S1P using LCL521

Development of Novel Anti-Cancer Therapeutics

Project 2
Systemic S1P Signaling & Metastasis

Targeting systemic S1P using Asonep or LCL351

Project 3
Nuclear SK-2/S1P Signaling & c-Myc Regulation

Targeting nuclear SK-2/S1P using ABC294640

Targeting systemic S1P using Asonep or LCL351

Targeting AC/S1P using LCL521

Targeting systemic S1P using Asonep or LCL351
PILOT PPG:

Regulation of tumor immunology and immunotherapy by sphingolipid signaling

PI: Ogretmen, Co-PI: Yu,
Project Leaders: Mehrotra and Guo

(Funded by Holling Cancer Center in 3.1.2017)
PI: Ogretmen, Co-PI: Yu, Project Leaders: Mehrotra and Guo (Funded by Holling Cancer Center in 2017)

Targeting Ceramide/S1P Metabolism & Signaling

Core A Lipidomics

Core B Administration & Biostatistics

Core C Cell Isolation & Immuno monitoring

Project 1
SphK1/S1P in T cell Bioenergetics

Project 2
SphK1/S1P in Macrophages & Inflammosome

Project 3
SphK2/S1P in MDSC & HDACi

Project 4
Ceramide & S1P in T cell-based Immunotherapy

Development of Novel Strategies for anti-Cancer Immunotherapy
Teresa J. Kelechi, PhD

Professor, Nursing

P20: Technology Enhanced Self-Management Interventions for Fatigue & Pain:
The Symptoms Self Management Center
Centers in Self-Management of Symptoms: Building Research Teams for the Future (P20)

College of Nursing, MUSC
Technology Enhanced Self-Management Interventions for Fatigue and Pain: The Symptoms Self-Management Center

Co-Directors:
Teresa Kelechi PhD, RN
Ron Acierno, PhD

$1,864,510 (2016 - 2021)
Center Overview

• P20 is a mechanism used to:
  • Support planning for new programs, expansion or modification of existing resources, and feasibility studies to explore various approaches to the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of NIH.
  • Leads to center sustainability and/or the ability to be funded through other specialized or comprehensive grants.
    • **Build new research teams** in interdisciplinary, biobehavioral research for scientists conducting self-management of symptoms
    • Plan and build new research **infrastructures** and centralized **resources** in support of self-management of symptoms research.
- Develop **technologies** to facilitate early identification of symptoms
- Design **culturally appropriate** symptom self-management strategies or programs that promote health lifestyle choices
- Identify cost effective strategies for symptom self-management and promotion of personal health among long-term survivors of **chronic disease**.
- Study the multiple factors that influence **behavioral** self-management of symptoms and applications for the **design** of personalized interventions.
- Develop strategies to improve **self-management** of symptoms related to chronic illness across the lifespan.
“Deconstructed” into 3 major cores – leveraged resources

• Technology enhanced self management interventions – TACHL (Technology Applications Center for Healthful Lifestyles) to build apps, move interventions to web-based platforms, adapt existing technology (e.g., Bluetooth)
  ➢ Frank Treiber’s group (on executive committee)

• Biomedical informatics
  ➢ Les Lenert’s group (on executive committee)

• Community engaged research partnerships
  ➢ Carolyn Jenkins’s group (on executive committee)
Organizational chart
Staff

• 30% effort - program manager
  • overall pilot projects management including pre- and post-award oversight
  • IRB
  • REDCap for data storage
  • data coordination, performance metrics, progress reports, budget reconciliation

• 70% - project coordinator
  • Schedules participants, collects data, uploads common data elements, consents, recruits, prepares participant compensation
Best practices
• Requested colleagues’ P20s and P30s and took note of the strengths/weaknesses from their summary statements
• Talked to the PIs about lessons learned
• Reviewed P20s that were available from Carla’s shop
• Talked to the program officer
• Conducted mock review
• Sent the application out for review by PIs who had P20s in the past (not currently funded ones)
• Reviewed by Carla’s shop
Building a collaborative team
Build synergy

- The core directors – leveraged the expertise within the CON and University
- Diversity and health disparities
- Two nationally recognized external nurse scientists with expertise in pain and fatigue; pain expert internally
- Dean (sat on NINR council)
Pearls

- Address the “hot” topics and make them relevant to the P20 (self management)
  - Translational science
  - Implementation science
- Have more than one person with expertise in an area
  - Interdisciplinary but also had nurse scientists in the fields (bioinformatics)
  - Basic scientists – pain and fatigue mechanisms
- Connect the administration core with the pilot projects core
In the end, the deconstruction needs to provide some level of unique value or it’s not worth doing.

Lee Odden
Marvella E. Ford, PhD

Professor, Public Health Sciences

U54: SC Cancer Disparities Research Center (SC CADRE)
UP Your Game: Deconstructing Multi-Component Research Grants

Marvella E. Ford, PhD
Dept. of Public Health Sciences and Hollings Cancer Center
Medical University of South Carolina and SmartState Endowed Chair
South Carolina State University
April 6, 2018
If I have seen further, it is by standing on the shoulders of giants.

- Isaac Newton
It All Began with Project EXPORT

- Center of Excellence in Partnership for Community Outreach, Research on Health Disparities and Training
- Dr. Sabra Slaughter (MUSC), Dr. David Rivers (MUSC), and Dr. Judith Salley (SCSU) were previously funded for a Project EXPORT grant from the NIH/NIMHD
- Funded Years: 2002-2007
- Focused on metabolic syndrome research, with emphasis on community engagement
- $5.9M in total costs
Applications were submitted from both MUSC & SCSU in 2010

The revised applications were funded on September 22, 2011

4 years of funding
Five Main Goals of the P20:

- Establish and implement a Center governance structure
- Identify, conduct, and complete 3 pilot research projects
  - Each project was co-led by SCSU and MUSC investigators
- Employ a multi-level research mentoring strategy
  (undergraduates and junior faculty)
- Expand an existing undergraduate research training curriculum
- Obtain peer-review funding for new projects
Organizational Structure

Presidental Leadership at SCSU and MUSC
- G. Cooper (SCSU)
- R. Greenberg (MUSC)

SC CaDRe Principal Investigators
- J. Salley (SCSU)
- M. Ford (MUSC)

Administrative Leadership Group (ALG)
Prinicipal Investigators
- J. Salley (SCSU) and M. Ford (MUSC)
Community Representative
- L. Davis (Chair, SC CaDRE CAC)
Project Coordinators
- J. McLeod (SCSU) and M. Jefferson (MUSC)

External Scientific Advisory Committee (ESAC)
P20 Partnership Grant
- D. Louden (Lincoln University)
- J. R. Beck (Fox Chase Cancer Center)
P20 Partnership Grant
- M. Smith (NC A&T State University)
- S. Akman (Wake Forest University)

Community Advisory Committee (CAC)
- L. Davis, Chair (HCC Cancer Disp. Adv. Board)
- D. Foster (SCSU 1890 Research and Extension)*
- G. Good (Director, SC Rural Advancement Fund)
- B. Mitchell (HCC Cancer Disp. Adv. Board)*
- C. Mitchell (HCC Cancer Disp. Adv. Board)*
- E. Rutledge (Director, Sea Island Comprehensive Family Health Center)
- C. Seabrook (HCC Cancer Disp. Adv. Board)
- L. Whitesides (SCSU 1890 Research and Extension)*

Internal Scientific Advisory Committee (ISAC)
- D. Watson, ISAC Chair (MUSC)
- A. Alberg (MUSC)
- L. Bozinovska (SCSU)
- R. Kramer (MUSC)
- E. Malone * (SCSU)
- E. Rutledge (Community/CAC)
- W. Simpson (SCSU)
- I. Spruill (MUSC)
- J. Stukes (SCSU)
P20 Results:

• Dr. Ahmed from SCSU was awarded a $500,000 USDA grant for his next study following his P20-funded project: Investigations on Food-Derived Advanced Glycation Endproducts (AGEs) in Relation to Obesity and Breast Cancer

• Drs. Ashley-Evans Knowell and Shanora Brown from SCSU were awarded a $500,000 USDA grant for their next study following the P20-funded project: Analyzing the Role of High Pro-Inflammatory Diets and Childhood Obesity in the Risk of Adult Carcinogenesis in South Carolinian Children
P20 Results:

• Dr. David Turner (MUSC) was awarded two NIH/NCI R21 grants:
  • R21CA194469: AGEs and Race-Specific Tumor Immune Response in Prostate Cancer
  • R21CA176135: Glycation as a Mechanism Promoting cancer Disparity
P20 Results:

- Drs. Ford and Watson co-edited a 2017 *Advances in Cancer Research* volume focusing on cancer disparities
  - Several P20 investigators contributed papers
  - The journal has an impact factor of 6.27
Cancer Disparities

Edited by
Marvella E. Ford
Dennis K. Watson

MARVELLA E. FORD
Department of Public Health Sciences and Hollings Cancer Center, Medical University of South Carolina, Charleston, SC, USA

Dennis K. Watson
Department of Pathology and Laboratory Medicine and Hollings Cancer Center, Medical University of South Carolina, Charleston, SC, USA

Praise for the Serial
"This classic and essential series presents critical overviews on select aspects of both cancer research and the basic underlying sciences."
—AMERICAN SCIENTIST

"Excellent, highly informative, in-depth reviews...expertly written, up-to-date, and well-referenced."
—JOURNAL OF MEDICINAL CHEMISTRY

"This is a series that has a long tradition of excellence in the field of cancer biology."—GOODY'S PUBLISHING REVIEWS

1. The Role of Advanced Glycation End-Products in Cancer Disparity
   D.P. Turner

2. Disparities in Obesity, Physical Activity Rates, and Breast Cancer Survival

3. MicroRNAs and Their Impact on Breast Cancer, the Tumor Microenvironment, and Disparities
   A. Evans-Kowalski, A.C. LeRice, and V.J. Findlay

4. Applying a Conceptual Framework to Maximize the Participation of Diverse Populations in Cancer Clinical Trials
   A. Napolais, E. Cook, T. Grissom, K.D. Knight, and M.E. Ford

5. Social Networks Across Common Cancer Types: The Evidence, Gaps, and Areas of Potential Impact
   L. Rice and C.M. Halbert

6. Disparities in Cervical Cancer Incidence and Mortality: Can Epigenetics Contribute to Eliminating Disparities?
   R.L. Miquel, A.C. Vidal, S.K. Murphy, and C. Hayo

Cover design: From Chapter 1, Figure 1. Through a series of condensation, rearrangement, fragmentation, and oxidation reactions driven by the Maillard reaction, sugars covalently attach to biological macromolecules such as proteins to form glycoxidation products.
Applications were submitted from both MUSC & SCSU on January 26, 2016

The grants were scored but not funded

The U54 leaders scheduled a teleconference with the NCI in the Spring of 2016 to obtain insight into preparing the resubmission
The revised applications were submitted from both MUSC & SCSU on January 29, 2017.

The grants were funded on September 21, 2017 and September 22, 2017, respectively.

- 5 years of funding
- $12.5M in total costs
SC CADRE Partnerships and Focal Areas
U54 SC CADRE
Team
Overarching Goals

1. Further elucidation of molecular mechanisms contributing to cancer disparities

2. An enhanced pipeline of diverse cancer researchers

3. An increased number of NIH research proposals led by SCSU faculty as independent investigator

4. Greater community engagement in cancer research.
Partnering Institutions

- SCSU
- MUSC-HCC
- Regional Medical Center of Orangeburg
Conceptual Framework

Social & Behavioral Factors:
- Obesity
- Diet
- Physical Activity
- Lifestyle Intervention
- Pharmacologic Intervention

Biological Factors:
- Inflammation
- Immune Response
- Genomics/Genetic Variants
- Epigenetics
- AGEs

SC CADRE
U54 SC CADRE

SC CADRE Organizational Chart

Program Steering Committee
- External

Linked PIs
- J. Salley (SCSU)
- M. Ford (MUSC-HCC)

Internal Scientific Advisory Committee

Research Education Core

Planning & Evaluation Core

Community Outreach Core

Administrative Core

Pilot Research Project 1
- Biostatistics and Quantitative Methods Shared Resource
- Office Shared Resource

Full Research Project
- Biorepository/Clinical Trials

Pilot Research Project 2
- AGE Analysis Shared Resource

Communication

Coordination

Determination
Community Engagement Core
(Co-Leaders: Dr. Audrey McCrary-Quarles (SCSU) and Dr. Gayenell Magwood (MUSC))

Specific Aims

1. Build and sustain a community outreach infrastructure to support and expand the outreach activities associated with SC CADRE-generated research
Community Engagement Core (Co-Leaders: Dr. Audrey McCrary-Quarles (SCSU) and Dr. Gayenell Magwood (MUSC))

Specific Aims (continued)

2. Engage community and academic stakeholders (SCSU students, staff, and faculty) in the:
   a. Development and deployment of evidence-based approaches to communicate, disseminate, and promote implementation of NCI recommendations for cancer prevention, early detection, and treatment, and in the
   b. Dissemination of SC CADRE research findings to SC’s communities
Specific Aims (continued)

3. Employing lay navigation, assist underserved patients in receiving timely interventions for cancer early detection and treatment as well as recruiting and retaining racially and ethnically diverse patients in research.

4. Establish an innovative, cancer-focused Community-Engaged Scholars Program to enable the capacity of community-academic partnerships to conduct cancer disparities research.
<table>
<thead>
<tr>
<th>Inputs</th>
<th>Activities</th>
<th>Outputs</th>
<th>Short-Term Outcomes</th>
<th>Long-Term Outcomes</th>
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</thead>
<tbody>
<tr>
<td>Aim 1: Community Engagement Panel</td>
<td>Guide the implementation and evaluation of the Community Outreach Core’s community engagement cancer outreach plan</td>
<td>Four CEP meetings will take place per year</td>
<td>Greater inclusion of community input into the Community Outreach Core’s planning and implementation activities</td>
<td>Reduced cancer disparities in SC</td>
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<td>Participate in the SC CADRE enrichment activities</td>
<td>The CEP will have representation in at least 50% of the SC CADRE enrichment activities</td>
<td>Increased scientific interaction between community members and SC CADRE’s research teams, junior faculty Scholars, and undergraduate student Scholars</td>
<td>Increased number of community member who are engaged in SC CADRE-sponsored research</td>
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<td>Aim 2: Continuing Medical Education</td>
<td>Develop a cancer disparities-focused professional medical education program for health care providers</td>
<td>The Community Outreach Core team will develop the program in Year 1. Two continuing medical education programs will be conducted, in Years 2 (Orangeburg) and 4 (Charleston).</td>
<td>Inaugural cancer disparities-focused continuing medical education program offered to health professionals in SC. Improved quality of cancer care provided to AAs in SC.</td>
<td>Improved cancer care outcomes for AAs in SC.</td>
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<td>Aim 2: MOVENUP</td>
<td>Disseminate the NCI’s new cancer prevention, early detection, and treatment initiatives. Conduct community-based cancer education training using a “Train the Trainer” approach.</td>
<td>New NCI initiatives will be disseminated to a minimum of 20 community partners. Four “Train the Trainer” sessions per year will be conducted, with at least 15 participants per session.</td>
<td>Increase in community members’ knowledge related to cancer prevention, early detection, and treatment.</td>
<td>Improved cancer prevention, early detection, and treatment outcomes in SC.</td>
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<td>Aim 2: Speaker’s Bureau</td>
<td>Develop a community-focused Speakers’ Bureau comprised of all of the U54 SC CADRE investigators, who will disseminate the results of their research projects.</td>
<td>The Speakers’ Bureau will conduct a minimum of three community sessions per year.</td>
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<td><strong>Aim 2:</strong> Community Compass</td>
<td>Develop a Community Compass forum to explain the relationship between obesity and prostate and breast cancer disparities</td>
<td>The Community Compass forum will take place in Orangeburg, SC in Year 2. It will include physical activities and cooking demonstrations with low-AGE foods. At least 100 community members will participate</td>
<td>Increase in knowledge related to the importance of maintaining a healthy weight, engaging in physical activities, and eating low-AGE foods for cancer risk reduction</td>
<td>Improved rates of physical activity and reductions in obesity in SC</td>
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<td><strong>Aim 2:</strong> Men Against Cancer</td>
<td>Share messaging related to cancer prevention, early detection, and treatment with AA men in SC</td>
<td>Quarterly messaging will be shared with Men Against Cancer</td>
<td>Increase in knowledge among AA men about evidence-based cancer prevention strategies, ways to reduce their risk of developing cancer, and available cancer treatment options</td>
<td>Improved rates of cancer screening and treatment adherence among AA men in SC</td>
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<td>Aim 2: Tri-County Health Network</td>
<td>Network members will be invited to participate in the Community Outreach Core’s continuing medical education activities</td>
<td>At least 10% of the Network’s members will participate in the Community Outreach Core’s continuing medical education activities</td>
<td>Improved quality of cancer care provided to AAS in SC by Network members</td>
<td>Improved cancer care outcomes for AAs in SC</td>
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<td>The Core will provide prostate and breast cancer education programs to the Network’s members and communities</td>
<td>At least 50% of the participants in the four planned MOVENUP sessions will be Network members/communities</td>
<td>Community members will gain knowledge related to cancer prevention, early detection, and treatment</td>
<td>Improved SC cancer prevention, early detection, and treatment outcomes</td>
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<td>Aim 2: NON-CHE</td>
<td>Establish a repository of SC-based community partners who are focused on outreach activities to reduce cancer disparities</td>
<td>The repository will include a minimum of 50 community partners</td>
<td>The repository will be shared with the community partners that comprise it</td>
<td>Increased shared/joint outreach activities among the partners in the repository</td>
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<td>The repository will also be shared with the MUSC-HCC’s Region 1 GMaP leaders to guide the dissemination of information through the GMaP network</td>
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<td>Increased dissemination of information to the partners in the repository</td>
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<td>Aim 2: Clinical Trials Awareness Campaign</td>
<td>Conduct a clinical trials awareness campaign at the RMC-MCC</td>
<td>Banners depicting the “Ask Me About Cancer Clinical Trials” will be created and displayed throughout the RMC-MCC</td>
<td>Increased number of RMC-MCC patients will inquire about participating in a cancer clinical trial</td>
<td>Increased number of RMC-MCC physicians who refer their patients to clinical trials</td>
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<td>Aim 2: Mobile Health Unit</td>
<td>Offer annual Mobile Health Unit services to the Orangeburg, SC area</td>
<td>Services provided by the Unit include breast, prostate, cervical, skin, and oral cancer screenings, as well as education services targeted to uninsured, poor, and minority men</td>
<td>Increased awareness regarding prevention and early detection strategies for patients in the Orangeburg community.</td>
<td>Improved SC cancer prevention, early detection, and treatment outcomes</td>
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<td>Aim 3: Lay Navigation for:</td>
<td>Implement a lay navigation program at RMC-MCC focusing on removing barriers to prostate and breast cancer treatment and clinical trial enrollment.</td>
<td>One lay navigator will be hired and trained at RMC-MCC. At least 40 breast and prostate cancer patients per year will be navigated to treatment completion at RMC-MCC.</td>
<td>RMC-MCC patients will be more adherent to cancer treatment, and more willing to enroll in a cancer clinical trial. MUSC-HCC patients will be more adherent to cancer treatment, and more willing to enroll in a cancer clinical trial.</td>
<td>Improved cancer treatment outcomes at RMC-MCC and MUSC-HCC.</td>
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<td>• Reducing barriers to cancer treatment adherence</td>
<td>Expand the breast cancer lay navigation program at MUSC-HCC to include a focus on prostate and breast cancer screening, treatment, and clinical trial enrollment.</td>
<td>One lay navigator will be hired and trained at MUSC-HCC. At least 40 breast and prostate cancer patients per year will be navigated to treatment completion at MUSC-HCC.</td>
<td>MUSC-HCC patients will be more adherent to cancer treatment, and more willing to enroll in a cancer clinical trial.</td>
<td>Increased clinical trial accruals at RMC-MCC and MUSC-HCC.</td>
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<tr>
<td>• Enhancing rates of participation in cancer clinical trials</td>
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<td>Aim 4: Community-Engaged Scholars Program</td>
<td>Enroll community-academic partner teams in the MUSC-HCC Community Engaged Scholars Program.</td>
<td>Two partner teams will be enrolled in the program. Each team will meet with assigned community and academic mentors monthly.</td>
<td>Each team will complete the program. At least one of the teams will apply for intra/extramural funding within one year of completing the program.</td>
<td>Increased number of subsequent grants awarded to community-academic partner teams at SCSU and at MUSC-HCC.</td>
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Initial Full and Pilot Research Projects

• Full Research Project 1: Survivorship Care Physical Activity Initiative to Reduce Disparities in HRQoL for Prostate Cancer Survivors (RELate Study)
  Co-Leads: Mahtabuddin Ahmed, PhD (SCSU) and David P. Turner, PhD (MUSC)

• Pilot Research Project 1: A Phase 1b Trial of Oligomeric Procyanidin Complex in Combination with Metformin for Reduced AGE Levels in Racially Diverse Prostate Cancer Patients Receiving Androgen Deprivation Therapy
  Co-Leads: Shanora Brown, PhD (SCSU) and Michael Lilly, MD (MUSC)
Initial Full and Pilot Research Projects

• Pilot Research Project 2: Lifestyle-Associated Metabolites Drive Neuroendocrine Differentiation in Prostate Cancer Disparities
  • Co-Leads: Ashley Evans-Knowell, PhD (SCSU) and Victoria J. Findlay, PhD (MUSC)
Full Research Project
Ahmed/Turner
- Lifestyle Interventions
- Bio-behavioral Pathways

Pilot Research Project 1
Brown/Lilly
- Targeting AGE levels
- Pharmacological Interventions

Pilot Research Project 2
Evans-Knowles/Findlay
- Prevention of Progression
- MicroRNA Regulation

Tumor Biology
PBMCs
RCSs
OPC
AGEs
Metformin
OPC
mir204
PBMCs
RCSs
mir204

Translation
Professor, Psychiatry & Behavioral Sciences

U54: Transdisciplinary Collaborative Center in Precision Medicine & Minority Men’s Health
Transdisciplinary Teams for Precision Medicine and Minority Health

CHANITA HUGHES HALBERT, PHD
College of Medicine
Department of Psychiatry and Behavioral Sciences
Hollings Cancer Center
South Carolina Center for Translational Research
Medical University of South Carolina
Promote health equity through individualized approaches for early detection, prevention, and treatment.
All of Us℠ Research Program

**WHAT IS IT?**

**Precision medicine** is a groundbreaking approach to disease prevention and treatment based on people's individual differences in environment, genes and lifestyle.

The *All of Us* Research Program will lay the foundation for using this approach in **clinical practice**.
Community-based participatory research (in health) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings.

CBPR begins with a research topic of importance to the community with the aim of combining knowledge and action for social change to improve community (health).
Establish a Consortium that supports the active engagement of diverse stakeholders in precision medicine and health disparities research

Conduct translational research to understand the interaction between biological, social, psychological, behavioral, and clinical factors and health care and disease outcomes among minority men

Support the dissemination of evidence related to precision medicine and health disparities

Integrate data on biological, social, psychological, and clinical factors to validate findings from prospective TCC research
Minority men have poor health outcomes and lower life expectancy compared to non-minority men
- African American men 30% more likely to die from heart disease than white men
- African American men are 60% more likely to die from stroke than white men
- Hispanic men are twice as likely than white men to die from diabetes
- Hispanic men have a higher death rate from HIV compared to white men

Limited attention is given to minority men as part of health disparities research
Transdisciplinary Collaborative Center in Precision Medicine and Minority Men's Health

Multi-PIs/Admin
Hughes-Halbert, Lilly, & Ethier

Data Integration
Lenert, Obeid

Dissemination & Implementation
Melvin, Magwood
Minority men experience unique acute and chronic stressors.

Social and psychological stressors impact biological processes involved in the initiation and progression of disease.

Allostatic load is a marker of how much social and psychological stressors impact biological functioning.

Racial disparities in allostatic load exist.

Need to understand the effects of allostatic load on disease processes and outcomes.
PRECISION MEDICINE AND DISPARITIES

- Disease has a significant clinical and public health impact
- Priority condition for community residents and other stakeholders
- Biological, clinical, and public health relevance to other chronic conditions
Ever and Annual Use of Prostate Cancer Screening in African American Men

Chanita Hughes Halbert, PhD\textsuperscript{1,2}, Sebastiano Gattoni-Celli, MD\textsuperscript{1,2}, Stephen Savage, MD\textsuperscript{1,2}, Sandip M. Prasad, MD\textsuperscript{1,2}, Rick Kittles, PhD\textsuperscript{3}, Vanessa Briggs, MBA\textsuperscript{4}, Ernestine Delmoor, MPH\textsuperscript{5}, LaShanta J. Rice, PhD\textsuperscript{1}, Melanie Jefferson, MPH\textsuperscript{1}, and Jerry C. Johnson, MD\textsuperscript{6}

Triumphant Living Collaborative
West Philadelphia Consortium to Address Disparities
Racial Differences in Quality of Life Following Prostate Cancer Diagnosis

Chanita H. Halbert, James Coyne, Benita Weathers, Brandon Mahler, Ernestine Delmoor, David Vaughn, S. Bruce Malikowicz, David Lee, and Andrea Troxel

Sociocultural determinants of men’s reactions to prostate cancer diagnosis

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Biobank Intentions

McDonald et al., Public Health Genomics, 2014

Participate in Precision Medicine

Halbert et al. PLOS One, 2016,
OVERVIEW OF CENTER PROJECTS

- **Project 1:** Sociobiological Responses to Stress in Prostate Cancer Survivors (M. Lilly, C. Hughes-Halbert, Co-Leads).
  - Examine the effects of stress reactions and allostatic load on immune responses to a prostate cancer vaccine among survivors at high risk for recurrence.

- **Project 2:** Defining an Integrated Allostatic Load Index with Immune and Tumor Microenvironment Factors (R. Drake and J. Wu, Co-Leads)
  - Identify novel biomarkers for prostate cancer based on metabolites, glycans, and immune modulators in clinical prostate cancer biopsy samples, prostatectomy tissues, tissue microarrays.
  - Characterize the distribution of these biomarkers based on allostatic load, racial background, social factors, and psychological characteristics.

- **Project 3:** Integrating Genomic and Sociobiological Data to Inform the Development of Prostate Cancer Treatment (S. Gattoni-Celli, Lead)
  - Evaluate the effects of Vitamin D supplementation on molecular changes in prostate cancer tissue.
  - Examine the effects of Vitamin D on HPA axis functioning and allostatic load biomarkers to determine individual response to supplementation.
CONSORTIUM CORE

- Form a multi-regional infrastructure to provide the direction, priorities and governance of the TCC to promote health equity among minority men through precision medicine

- Identify priorities for research in precision medicine and minority men among diverse academic, community, clinical, and public health stakeholders

- Implement and monitor pilot project research to address minority men’s health in precision medicine

- Translate findings from TCC research into clinic and community-based practices to address racial disparities among minority men
IMPLEMENTATION CORE

- Develop materials and methods to determine the needs, readiness, and capacity of stakeholders across multiple regions to implement and adopt precision medicine approaches into clinical care and public health practice.

- Identify ethical, legal, and social issues related to linking and integrating data on biological, social, psychological, behavioral, and clinical factors and develop recommendations to address these issues.

- Deliver Evidence Academies across the regions in the MUSC TCC Consortium to actively engage diverse stakeholders in the development of best practices for implementing precision medicine interventions into practice.
- Create a standards-based resource using nationally-recognized tools including REDCap and Informatics for Integrating Bench to Bedside (i2b2), for integration of data on the tumor microenvironments derived from proteoglycan analyses of prostate tissue and clinical studies of impacts of glucocorticoids on pathways for vitamin D effects.

- Develop natural language processing-based tools to extract discrete details on social stressors from clinicians’ notes and merge these data with clinical data within the i2b2 environment.

- Integrate clinical and experimental data into longitudinal patient records to expand data sets to represent the chronological order of significant clinical and social events surrounding the timing of a critical cancer diagnosis.

- Use data mining strategies to determine the temporal links between allostatic load and disease risk and outcomes.
How do you integrate these activities to facilitate effective academic and community engagement?
FIGURE 1—A framework for multidisciplinary research in genomics and health beyond bench to bedside, with green representing the first phase of translation (T1) and blue representing the second phase of translation (T2–T4), with a feedback loop to basic science discoveries (T0).

Source. Adapted from Khoury et al.²
Precision medicine is an emerging approach for preventing and treating diseases that uses biological, environmental, and lifestyle information to help develop personalized treatments and procedures. By combining this information, the delivery of medical care will be more personalized as doctors and patients will be able to co-develop targeted plans for prevention, detection and treatment. The goal for precision medicine is to provide the right medical care in the right dose to the right patient at the right time.
ESTABLISH GOALS FOR COMMUNITY ENGAGEMENT

The MUSC TCC in Precision Medicine and Minority Men’s Health will engage diverse stakeholders in activities to ensure that groups, organizations, and individuals:

- Are knowledgeable, aware, and informed about precision medicine
- Have the capacity and resources to apply and/or use precision medicine as part of their health care or clinical practice
- Have sufficient information to make informed decisions about participating in precision medicine research and/or referring patients/members for participation in studies
- Understand how to assure that the use of precision medicine does not exacerbate racial and ethnic disparities in health care and outcomes
COMMUNITY ENGAGEMENT STRATEGIES

**Precision Medicine Survey:** Identify priorities, concerns, and preferences of patients about precision medicine

**Organizational Capacity for Precision Medicine:** Identify resources and readiness for precision medicine

**Evidence Academy:** Dissemination strategy that focuses on enhancing knowledge about a health-related topic and developing tailored implementation strategies
REGIONAL IMPLEMENTATION TEAMS

Composed of stakeholders in each region who are critical to promoting, implementing, and adopting precision medicine. Team members will represent individual patient, health care providers/teams, organizational, community, and policy groups.

• Stakeholder interviews and review of draft documents and processes in Year 2

• In-person regional meetings (Evidence Academies in Years 2 and 4)

• Development and implementation of regional plans during years 2 & 3 using knowledge gained through TCC research to inform decisions and actions to change policies, programs and/or practices affecting the uptake and use of these interventions in their region and particularly among minority men
ISSUES FOR ACADEMIC-COMMUNITY PARTNERSHIPS

- Determining who are the right stakeholders?
- Deciding on when to expand and limit partnerships?
- Precision medicine versus basic health care services?
- Administrative coordination and integration of groups and activities
MUSC TRANSDISCIPLINARY COLLABORATIVE CENTER IN PRECISION MEDICINE AND MINORITY MEN’S HEALTH

- Claudia Baquet, MD
- Bettina Beech, DrPH
- Kathleen Cartmell, PhD
- Ernestine Delmoor, MPH
- Richard Drake, PhD
- Stephen Ethier, PhD
- Chanita Hughes-Halbert, PhD
- Melanie Jefferson, PhD
- Les Lenert, MD
- Michael Lilly, MD
- Gaynell Magwood, PhD
- Cathy Melvin, PhD
- Stephen Savage, MD
Steven A. Kautz, PhD

Professor & Chair, Health Sciences & Research

P20: PI, SC Research Center for Recovery from Stroke (COBRE)
P2C: PI, National Center of Neuromodulation for Rehabilitation (NM4R)
U54: MUSC Site PI, Delaware CTR (ACCEL Program)
Three Multi-Component Grants

• P20: PI, Center of Biomedical Research Excellence (COBRE) in Stroke Recovery
• P2C: PI, National Center of Neuromodulation for Rehabilitation (NM4R)
• U54: MUSC Site PI, Delaware CTR (ACCEL Program)
Best Practices

• When writing the grant
  • Read the RFA several times
  • Understand what the program office envisions as success and demonstrate that your group can achieve the objectives
  • Write to the RFA
  • Finish early and get outside feedback
  • Have a common voice in all sections of the grant
Best Practices

Core Values
- Multidisciplinary people and tools (engineers, PT, OT, neurology, neuroscience, etc.)
- We are a community (everybody participates regularly)
- Passion to build a great center (not just about getting the money, but using it to do something special)
- Intellectual curiosity (always looking for new ideas from other disciplines)

Core Purpose
- Enable the science that seeks to improve neural recovery from stroke

What you are deeply passionate about?
Performing research designed to provide clinicians with optimal tools for diagnosing and individualizing neuroplasticity based treatment of post-stroke deficits.
Fostering multidisciplinary understanding through outstanding cores
Building a theoretical framework for how and why interventions work/don’t work that specifically recognizes the heterogeneity of the post-stroke population

What you can be the best at?
Multidisciplinary translational human research targeting understanding the mechanisms of interventions and how to individualize them for the post-stroke population
Developing multidisciplinary outcome measures that are theory based (allow test of hypotheses of the underlying mechanism of action or serve as behavioral, neurophysiological or imaging biomarkers)
Neuromodulation for rehabilitation

What drives your success?
Total grant funding (function of total number of investigators, quality of cores, great science being done, success with funding and size of the awards)
Total and quality of publications

Not passionate about
Neuroprotection, medical management, assistive devices, policy/cost analysis

Can’t be best at
Large clinical trials, inpatient rehabilitation studies, basic science, bioengineering

Potentially misleading drivers
Efficiency measures (e.g., per investigator)
Best Practices

• Structure the Center so that there are benefits for all partners and minimal barriers or skewed incentives?
  • F&A sharing agreement between CHP and COM
• Monthly two-hour meeting (2\textsuperscript{nd} Thursday 8-10 AM)
• Collaborative leadership
• Effective Administrative Core (continually improving processes)
• Robust Evaluation Program
How We Built our Collaborative Team

• SCTR held a retreat on Neural Repair, Regeneration and Rehabilitation
  • We identified and invited all of the groups on campus working in the problem area (i.e., CHP, Neurology and Neuroscience) or with skills translatable to the problem area (i.e., Center for Biomedical Imaging, Brain Stimulation Lab, Comprehensive Stroke Center)

• Six months later we held a two-hour campus wide meeting in Stroke Recovery Research
  • Gave us an inventory of interested leaders and areas of strength

• When COBRE concept paper call occurred we had pretty good outline of who would be the leadership team
  • Outreach to as many departments as possible for Junior Investigator candidates
Stephen A. Duncan, DPhil

Professor & Chair, Regenerative Medicine & Cell Biology

P20: COBRE in Digestive & Liver Disease
(Submitted January 2018)
COBRE IN DIGESTIVE AND LIVER DISEASE

Director/PI: Stephen A. Duncan, D.Phil.
Co-Director: Don Rockey, M.D. Ph.D.
Aim of the proposed COBRE is to provide mentoring and core services that support the advancement of junior digestive disease researchers with the ultimate objective of establishing an NIDDK funded Silvio O. Conte Digestive Disease Research Core Center at MUSC.

- Focused theme, broad participation
- Inter–departmental and college wide initiative
- Basic – translational – clinical
- Leverages existing strengths and investments at MUSC
- Expansion of cores to broadly benefit MUSC research
The 2017 MUSC Digestive Disease Mini-Retreat will feature scientific presentations and posters highlighting digestive disease research and analysis, with focus on inflammation of the gut and liver, fibrosis, and metabolic disease. Cores and Enrichment Programs will be explored.

Event date: July 28, 2017
Event time: 9:00 a.m. - 3:00 p.m.
Location: Hollings Cancer Center

A new Pilot and Feasibility Program focusing on digestive disease projects will be announced.

- Retreat attracted 75 attendees
- 28 abstracts
- 20 poster presentations
- 12 platform presentations
- Established Enrichment Program
  - Medicine/Regenerative Medicine – seminar series, mentoring, and retreat
- Announced Pilot and Feasibility Program
  - Focused on junior investigators
  - $100,000 from MUSC College of Medicine
  - Received 9 applications
COBRE IN DIGESTIVE AND LIVER DISEASE – ADMINISTRATIVE STRUCTURE

MUSC President (D. Cole, MD)
Vice President for Research (R. Brady, MD, PhD)
Vice President for Academic Affairs & Provost (L. Saladin, PhD)

SC Clinical & Translational Research Inst (SCTR/CTSA)
Hollings Cancer Center
Other MUSC Research Centers

College Deans & Department Chairs
University Research Administration
University Cores Committee

NIH/ NIGMS
EXTERNAL ADVISORY BOARD
INTERNAL ADVISORY COMMITTEE

COBRE in Digestive & Liver Diseases
Stephen Duncan, DPhil, PD & Admin Core Ldr
Don C. Rockey, MD, Associate Director

EXECUTIVE COMMITTEE
Drs. Craig, Diehl, Howe, Lemasters,
Mulse-Helmericks, Traktman, Westwater

Administrative & Mentoring Core
Leadership, Mentoring, Biostatistics,
Pilot Projects & Program Evaluation

Animal Models Core
Project 1
Project 2
Cell Models Core
Project 3
Project 4
Advanced Imaging Core
• We established a leadership team in Dr. Duncan and Dr. Rockey who have international reputations as leaders of their respective fields

• We assembled an institution-wide team of mentors with unparalleled experience

• We created a comprehensive mentoring and training pipeline that maximizes the prospects of young investigators

• We identified several outstanding young investigators with well-developed research projects

• The commitment of both RMCB and Medicine to recruit liver and digestive disease researchers to MUSC and the fact that digestive disease research encompasses a broad range of research interests will ensure the availability of talented young investigators that will maintain the long-term success of this COBRE Center

• Funding this COBRE center will enhance the competitiveness of MUSC to become an NIDDK designated Silvio O. Conte Digestive Disease Research Core Center by increasing the pool of successful digestive disease researchers on campus and by expanding the funding base.
Peggy Schachte, MBA

Emeritus Director,
MUSC Office of Research Development
UP YOUR GAME!

DE-CONSTRUCTING MULTI-COMPONENT RESEARCH GRANTS
BASIC INGREDIENTS

• ALL MULTI-COMPONENT RESEARCH GRANTS INCLUDE:
  • AN OVERALL COMPONENT DESCRIBING THE VISION, SYNERGY, STRATEGY, KEY PLAYERS AND SPECIAL STRENGTHS.
  • A MIX OF ADDITIONAL COMPONENTS IDENTIFIED IN THE FOA – RESEARCH PROJECTS, CORES, PILOT PROJECTS.
  • DATA SUMMARIES THAT ARE AUTOMATICALLY COMPILED BY GRANTS.GOV.
  • ADDITIONAL REQUIREMENTS, E.G., SPECIAL DATA TABLES, INSTITUTIONAL COMMITMENTS, MIN/MAX EFFORT LEVELS, AND SO FORTH.
THE MECHANICS ARE BORING BUT ESSENTIAL.

EVERY PROJECT/CORE LEADER SHOULD PRINT THE FOA AND MARK IT WITH A HIGHLIGHTER OR PEN.

AT LEAST TWO PEOPLE SHOULD BE DESIGNATED EXPERTS ON THE FOA AND HOLD EVERYONE ELSE ACCOUNTABLE.

A WORKING BUDGET SHOULD BE ASSEMBLED ABOUT HALFWAY THROUGH THE PROCESS TO DEMONSTRATE THAT YOU CAN AFFORD WHAT YOU PROPOSE AND PROPOSE WHAT YOU CAN AFFORD.
BASIC PRINCIPLES (PART 1)

• **COMMUNICATION IS KEY.** HAVE REGULARLY SCHEDULED PROGRAM PLANNING MEETINGS AND MAKE SURE THAT CRITICAL PEOPLE ATTEND – CRITICAL IN BOTH SENSES OF THE WORD.

• **TIMELINESS IS ESSENTIAL.** HAVE A TIMELINE, STICK TO IT YOURSELF, HOUND OTHERS TO STICK TO IT.

• **TEAMWORK IS REQUIRED.** REPLACE OR RE-DESIGN AROUND PEOPLE WHO DON’T DELIVER.

• **PROOF IS PARAMOUNT.** SHOW EVIDENCE OF COLLABORATION, PUBLISHED & PRELIMINARY DATA, CONCEPTUAL WORKING MODEL, ETC.
BASIC PRINCIPLES (PART 2)

- **GRANTSMAHSHIP TRUMPS Aces.** Good science is not enough.
  - Be totally responsive to the FOA. If the FOA contains inconsistencies, discuss and consider asking for clarification – especially if there is a webinar opportunity.
  - Use diagrams and tables to illustrate the plan and distill info (save space & provide eye relief).
  - Be legible, especially in figures that present data.

- **Be Consistent** – format, fonts, spacing, citations, nomenclature, dates, periodicity, etc.

- **Be Consistent Everywhere** – figures & captions, biosketches, facilities & resources, sharing plans, letters – especially if you copy material from other documents.
SYNERGY

• PROVIDE EVIDENCE IN THE OVERVIEW.

• SHOW HOW THE INDIVIDUAL COMPONENTS WILL BE COORDINATED AND WORK TOGETHER TO ADDRESS THE OVERALL GOALS AND AIMS OF THE PROGRAM.

• INCLUDE A SCHEMATIC OVERVIEW OF THE INTERACTIONS AND COLLABORATIONS AMONG THE COMPONENTS.

• HIGHLIGHT COLLABORATIONS AMONG TEAM MEMBERS AND RELEVANT PUBLICATIONS CO-AUTHORED BY MEMBERS OF THE PROGRAM.
SET YOURSELF APART

- WHAT MAKES THIS PROGRAM UNIQUE? WHY IS IT MORE SIGNIFICANT THAN ANY OTHER PROPOSAL?
- WHY IS THIS TEAM THE BEST TEAM IN THE WORLD TO CARRY OUT THE PROPOSED WORK?
- WHY IS MUSC (AND OTHER PERFORMANCE SITES) THE BEST PLACE(S) IN THE WORLD TO DO THIS WORK?
- VISION AND LEADERSHIP ARE NECESSARY BUT NOT SUFFICIENT. YOU HAVE TO HAVE TO BE SPECIAL.
DECONSTRUCTING THE REVIEW

• Usually reviewed by a special emphasis panel. Some institutes have standing study sections for PPGs (P01s).

• First they assess the merit of each project and core, then the overall application.

• Generally, only the research projects get individual criterion scores as well as an overall impact score. Cores receive an overall impact score.

• The overall program receives an overall impact score.

• The payline will vary depending on the FOA and the IC’s funding priorities and funds.
AN UNFINISHED SYMPHONY

- Constructing a P or U application can be like completing an unfinished symphony.
- Science and scholarship provide clues and context.
- The PD/PI is/are composer and conductor.
- Project and core leaders are the first chairs; key personnel are the instrumentalists.
- Success requires harmony, re-working, self-criticism and putting the team above the individual.
Questions?

For further information contact Kimberly Cannady, PhD: cannadyk@musc.edu or 843-792-0870
http://academicdepartments.musc.edu/research/ord/
Request for Applications for Collaborative Project Grants
SCTR sponsored

RFA Release Date: Late May

Grant period: 1 year

Total funding: $100,000 (direct costs only)

REQUIREMENTS:
• There should be at least 3 project leaders with proposed projects that are sufficiently interrelated that they could form the basis of a collaborative grant application.
• There should be clear milestones that are articulated in the application.
• The theme for the Collaborative Project Grant must be articulated in the application by the potential lead PI.