PI: NAAR, SYLVIE	Title: Transforming Health Equity Research in Integrated Primary Care: Antiracism as a Disruptive Innovation			
Received: 09/30/2020	Opportunity: RFA-RM-20-013	Council: 05/2021		
Competition ID: FORMS-F	FOA Title: NIH Directors Transformative Research Awards (R01 Clinical Trial Optional)			
1R01MD017404-01	Dual: OD,RM	Accession Number: 4495997		
IPF: 513804	Organization: FLORIDA STATE UNIVERSITY			
Former Number: 1R01OD031694-01	Department: Ctr. Transl. Behavioral Sci.			
IRG/SRG: ZRG1 BST-J (70)R	AIDS: N	Expedited: N		
Subtotal Direct Costs (excludes consortium F&A) Year 1: Year 2: Year 3: Year 4: Year 5:	Animals: N Humans: Y Clinical Trial: N Current HS Code: 30 HESC: N HFT: N	New Investigator: N Early Stage Investigator: N		
Senior/Key Personnel:	Organization:	Role Category:		
SYLVIE NAAR	FLORIDA STATE UNIVERSITY	PD/PI		
DOUGLAS LUKE	Washington University	Other (Specify)-Lead Consortium Investigator		
Ellis Ballard	Washington University	Co-Investigator		
Todd Combs	Washington University	Co-Investigator		
HEATHER FLYNN	FLORIDA STATE UNIVERSITY	Co-Investigator		
Norman Anderson	Florida State University	MPI		
Penny Ralston	Florida State University	Co-Investigator		
CHRIS SCHATSCHNEIDER	Florida State University	Co-Investigator		
Carrie Pettus-Davis	s Florida State University MPI			

OMB Number: 4040-0010 Expiration Date: 12/31/2022

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1. TYPE OF SUBI	MISSION*			4.a. Federal Id	entifier		
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Tracking Number: GRANT13212400

14. PROJECT DIRECTOR/PRINCI				
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Position/Title: Professor				
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15. ESTIMATED PROJECT FUND	ING		N SUBJECT TO REVIEW BY S	TATE
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Contact PD/PI: NAAR, SYLVIE

OMB Number: 4040-0010 Expiration Date: 12/31/2022

# **Project/Performance Site Location(s)**

#### **Project/Performance Site Primary Location**

O I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: FLORIDA STATE UNIVERSITY

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Street1\*:
Street2:
City\*:
County:
State\*:
Province:

Country\*:
Zip / Postal Code\*:

Project/Performance Site Congressional District\*:

FL-002

#### **Project/Performance Site Location 1**

O I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: Washington University
DUNS Number:

Street1\*:

City\*:
County:

State\*:

Province:

Country\*:
Zip / Postal Code\*:

Project/Performance Site Congressional District\*: Me

MO-001

Additional Location(s)

File Name:

OMB Number: 4040-0010 Expiration Date: 12/31/2022

# RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● `	Yes O No
1.a. If YES to Human Subjects	
Is the Project Exempt from Federal re	egulations?
If YES, check appropriate exe	emption number: 1 2 3 4 5 6 7 8
If NO, is the IRB review Pend	ing? ● Yes ⊃ No
IRB Approval Date:	
Human Subject Assura	ance Number
2. Are Vertebrate Animals Used?* O	Yes ● No
2.a. If YES to Vertebrate Animals	
Is the IACUC review Pending?	⊃ Yes ⊃ No
IACUC Approval Date:	
Animal Welfare Assurance Nu	umber
3. Is proprietary/privileged information in	ncluded in the application?* ○ Yes ● No
4.a. Does this project have an actual or p	otential impact - positive or negative - on the environment?* O Yes • No
4.b. If yes, please explain:	
4.c. If this project has an actual or potential	impact on the environment, has an exemption been authorized or an 🔾 Yes 🔾 No
environmental assessment (EA) or environr	nental impact statement (EIS) been performed?
4.d. If yes, please explain:	
5. Is the research performance site design	gnated, or eligible to be designated, as a historic place?*   ○ Yes   No
5.a. If yes, please explain:	
6. Does this project involve activities ou	tside the United States or partnership with international O Yes • No
collaborators?*	
6.a. If yes, identify countries:	
6.b. Optional Explanation:	
	name
7. Project Summary/Abstract* Tr01	_Project_Summary-Abstract_Naar_Pettus.pdf
8. Project Narrative* Tr01	_Narrative_Naar_Pettus.pdf
9. Bibliography & References Cited Tr01	_Refs_Final.pdf
10.Facilities & Other Resources Naa	r_TR01_Facilities_and_Other_Resources_FSU.pdf
11.Equipment EQU	JIPMENT.pdf

Increased media attention regarding COVID-related health disparities combined with horrific institutionalized violence against Black Americans have revitalized the call to action to address systemic racism in health care. Among the consequences of systemic racism in health care are significant health disparities in prevalence, diagnosis, and treatment of comorbid physical and mental health conditions. Despite decades of studies acknowledging health disparities based on race and an increased awareness of the social determinants of health, we seem to be lightvears away from significant change. There are shockingly few evidence-based interventions to change racism attitudes, behaviors, and practices at the provider and organizational-systems level. New paradigms are needed to intervene on, and not just document, racism in health care systems. We propose to develop and test a transformative paradigm for translating basic behavioral and social science into new anti-racism interventions for primary care settings. The paradigm is the first of its kind to integrate community-based participatory research, systems science, diffusion of innovation theory, and item response theory, leveraging an established framework of early phase translational behavioral and social science to rigorously define new anti-racism interventions within complex health systems and rigorously develop measures to assess impact. Anti-racism is a disruptive innovation in integrated primary care systems in the United States, one that can be rigorously mapped using community-engaged systems science methods. This map identifies "inflection points" likely to result in the most impactful intervention targets, and then established pathways can be used to translate fundamental behavioral and social science discoveries into new interventions at these points. Systems science modeling can then simulate potential interventions and produce mathematical standards for intervention efficacy in future trials. This transformative paradigm will also detail innovative methods to develop efficient and effective measurement tools to rigorously monitor outcomes. This transformative paradigm of antiracism as a disruptive innovation will not only revolutionize health equity interventions in integrated primary care systems but will provide a foundation for improving health care racism in other systems.

Contact PD/PI: NAAR, SYLVIE

## Narrative:

The current project proposes a transformative approach to improving health equity by engaging communities to develop a systems map of racism in integrated primary care and establishing a process for developing, simulating, and measuring effects of new antiracism interventions in health care.

Project Narrative Page 7

#### **FACILITIES AND OTHER RESOURCES**

#### FLORIDA STATE UNIVERSITY

## **MPI CENTERS AND INSTITUTES**

# The Center for Translational Behavioral Science (CTBScience)

Dr. Sylvie Naar is the Director of the Center for Translational Behavioral Science (CTBScience). CTBScience is a university center, affiliated with the FSU College of Medicine. This facility provides 6 faculty offices, 4 research core offices, a program manager office, two shared postdoc offices, offices for a research coordinator and research assistants, and a shared space for students and staff working with faculty. The center also houses 4 multifunctional participant spaces, 2 of which have the ability to function as working sleep laboratories equipped with state-of-the-art sleep diagnostic equipment, video monitoring / recording capability and 2 of which have the ability to be used as both assessment rooms and therapy rooms. Further, the center houses a conference room with video conferencing capabilities and a community space that functions as a group meeting room and/or classroom. Within its three cores (Management Core, Methods Core, and Tech Core), the Center has a dedicated clinical trials coordinator, administrative coordinator, grants contracts administrator, data manager, biostatisticians, and a communications expert as well as access to FSU's IT, library, and other administrative resources. The center also has a dedicated phlebotomy lab space, equipped with the necessary sample collection and sample storage equipment for human biological specimens. This facility hosts multiple research initiatives related to translational behavioral science including:

<u>The Adolescent and Emerging Adult Health Equity</u> program led by Dr. Sylvie Naar, focuses on developing and testing behavioral interventions to promote health equity among adolescents and emerging adults. The program includes several projects across the continuum of translation including early phase trials, clinical trials, effectiveness trials, and implementation trials. Studies are centered around improving health equity with behavioral interventions targeting the management of HIV, obesity, asthma, and diabetes.

Intervention Research Advancing Care Equity (iRACE) program, led by Dr. Nicole Ennis, focuses on intervention research to improve patient care among medically underserved populations through evidence-based behavioral interventions in the context of learning healthcare systems. Guided by a dissemination and implementation science framework, the program aims to understand and intervene on factors that influence health outcomes among patients coping with substance misuse, depression, HIV infection and other chronic conditions. This program investigates the influence of individual, social, and structural barriers using an interdisciplinary team approach.

<u>The Sleep Trauma and Emotional Processing (STEP)</u> program led by Dr. Scott M. Pickett, examines the influence and interaction of vulnerabilities, such as maladaptive emotion regulation and sleep disruption, on negative mental and physical health outcomes. Primary vulnerabilities of interest are those associated with psychological trauma. Current projects utilize a variety of research designs from basic social and biomedical science to clinical trials.

The Community Health and Social Epidemiology (CHASE) program, led by Dr. Tyra Dark, investigates the impact of social conditions on community health. Social epidemiology assumes that the distribution of advantages and disadvantages in a society reflects the distribution of health and disease. As a social epidemiologist, Dr. Dark's research has focused on the unique health care needs and health economics of populations with complex chronic conditions (e.g., cardiometabolic syndrome in older adults and HIV/AIDS in young adults) and comorbid mental illness, and the role of race/ethnicity on delivery of care. The CHASE program focuses on identifying how care is delivered to this population to uncover potential contributors of racial/ethnic disparities that can inform future policy or other cost-effective health care delivery interventions to improve outcomes and reduce observed disparities.

<u>The Integrative Science for Healthy Aging (ISHA)</u> program, led by Dr. Julia Sheffler, broadly involves the development and assessment of interventions for mental-health problems and neurocognitive disorders

in older adults. Current projects involve the assessment of adverse childhood experiences on health and neurocognitive outcomes across the lifespan, implementing an intervention for emotion dysregulation in older age, and assessment of the implementation of dietary interventions and preventions for neurocognitive disorders.

The center also houses the CTSA KL2 program at FSU, a joint initiative with the University of Florida CTSI program focused on providing training and career development opportunities to junior investigators. Finally, the Tech Core of the center is supported by the Florida Center for Interactive Media. The Florida Center for Interactive Media (FCIM) has been a technology development center within FSU since 2004. FCIM services include website development, app development, and data platforms and storage. Services include facilitating the integration of appropriate technology solutions, website development and maintenance, mHealth application development, e-Learning opportunities for students and professionals, web-based tools for collecting data and generating meaningful reports, video production and editing, animation, and graphic arts. Lastly, CTBScience hosts the Adolescent Trials Network (ATN) Scale It Up Center's Analytic Core, Implementation Science Core, and Management Core, with dedicated faculty members assisting with protocol development, recruitment and retention, sustainment, study management, data management and analysis, and dissemination. There is a Youth Advisory Board nation-wide for the ATN as well as a Florida state-wide youth board for FLASH (Florida Adolescent/Young Adult Sexual Health network).

#### Institute for Justice Research and Development (IJRD)

Carrie Pettus-Davis (Contact PI), IJRD is located in Innovation Park nearby FSU, space provided and support by FSU Office of Research. IJRD has 17 faculty, staff, and student offices and is supported by full time personnel in the areas of data administration and management (2 FTEs); human resources (1 FTE); finances and budgeting (1 FTE); Training Coordinators (3 FTE); Operations Coordinator (1 FTE); Executive coordinator (1 FTE); Administrative Assistant (1 FTE); Project Directors (2 FTE); Director of Implementation and Administration (1 FTE); Director of Research Dissemination (1 FTE); Data Visualization and Communications (1 FTE); 3 faculty; 12 graduate students; and over 30 full time field staff located throughout the country conducting field based research.

The Institute for Justice Research and Development (IJRD) at Florida State University, College of Social Work was founded by MPI Pettus-Davis in June 2018. IJRD's approach is based on behavioral intervention research that uses rigorous methodology and strategies to advance science, policy, and practice to improve the well-being of individuals, families, and communities impacted by the criminal justice system. IJRD is dedicated to identifying data-driven solutions to criminal justice reform and changing conventional criminal justice outcomes, promoting racial and economic equality, behavioral health, and maximizing individual, family, and community well-being by working at all stages of the criminal justice system. Since IJRD's beginning, it has implemented several research projects and dissemination activities. Examples include:

Multi-site RCT on 5-Key Model for Reentry (PI: Pettus-Davis) – evidence driven behavioral health-focused supports for individuals leaving incarceration and coming back home. Unlike many models that help people during this transition time (often called the reentry period), the 5-Key Model can be adapted for use with all individuals leaving incarceration, including those experiencing mental health or substance use disorders and high-risk individuals convicted of serious crimes.

The 5-Key Model is undergoing 4 phases of research: (1) proof of concept, pilot, and refine; (2) simplify and optimize; (3) impact and potency; and (4) dissemination and scale. The research is currently in phases 1 and 2 and is occurring across 7 states, 90 prisons, and 24 rural and urban counties with over 3,000 individuals in the context of a multi-site randomized controlled trial.

The 5-Key Model was built by formerly incarcerated individuals, practitioners, and researchers and was grounded on a review of more than 100,000 program evaluations with criminal justice-involved and non-criminal justice-involved study samples. After closely examining these studies, the team identified the 5 Key Ingredients likely to best promote successful reentry. These 5 Key Ingredients include Healthy thinking patterns, Meaningful work trajectories, Effective coping strategies, Positive social engagement, and Positive interpersonal relationships. Drawing from comprehensive theoretical and empirical research, the team selected the most potent rehabilitative

interventions and combined them into one service model to both engage clients in reentry services and adequately respond to the complex needs of individuals. The resulting 5-Key Model is a package of evidence-driven reentry service approaches that addresses each of the 5 Key ingredients. The 5-Key Model is designed to begin reentry preparation work as early as possible during an individual's incarceration and continue the supports in the community after an individuals' release from incarceration.

Trauma Among Incarcerated Young Men (Co-PI: Pettus-Davis) - The majority of incarcerated men – hovering around 90% percent – have experienced at least one traumatic event in their lifetime prior to incarceration. These traumatic events include experiences of child abuse and neglect, physical and sexual assault, witnessing violence in the home and community, and having a loved one murdered, among others. Traumatic experiences may lead to mental health and substance use disorder symptoms and, when unaddressed, they are a potential driver of reincarceration after release, especially for young men (aged 18-24). Most trauma-based interventions, however, are provided only to incarcerated women.

To close this gap, we are researching the impact of a comprehensive trauma-based program for young men releasing from Florida state prisons. We are assessing whether treating trauma and providing other transitional supports – such as employment assistance – as young men return home will help to improve their community stability and enhance their psychological well-being, in turn, resulting in less likelihood that a person will become incarcerated in the future. The intervention approach focuses on reducing trauma symptoms such as impulsivity and aggression and increasing community stabilization factors such as coping, housing stability and employment — all factors critical to success after release.

A total of 400 men aged 18 to 24 will be enrolled in the study. We will follow participants for three years after their release from incarceration to examine their longer-term outcomes including well-being, trauma symptoms, coping, housing stability, employment, and return to incarceration.

Building Capacity for Substance Use Disorder Treatment in Prisons (Co-PI: Pettus-Davis) - seeks to bridge the gap between prisoners identified as needing substance use disorder treatment and those that receive treatment during incarceration and expand treatment capacity, we are comparing the long-term effectiveness of three different substance use disorder treatment models in prisons across the state of Florida. Our goal is to identify ways to build capacity for prisons to dramatically increase the reach of substance use disorder treatment, ideally providing services to every incarcerated person who needs them.

Most contemporary approaches for in-prison substance use disorder treatment include outpatient treatment, intensive inpatient treatment, and Therapeutic Communities. Outpatient and intensive inpatient treatment functions similarly in prisons as they do in the community. However, Therapeutic Communities are 'treatment environments,' where incarcerated individuals with substance use disorders live together in an organized and structured manner. Recovery from substance use disorders guides all daily activities and individuals are provided with counseling, encounter groups, positive peer pressure, role modeling, accountability, and a system of incentives and sanctions to catalyze recovery. There is evidence to suggest that Therapeutic Communities have a greater impact than either outpatient or inpatient services, however, based on the intensity and cost of services, very few individuals receive this treatment. And, outpatient and inpatient treatment approaches are still cost-intensive.

In collaboration with the Florida Department of Corrections, we are examining whether an Interactive Journaling approach -- which allows for more self-directed work with the assistance of a counselor – can reduce costs, but maintain the effectiveness of other program approaches. If Interactive Journaling maintains or enhances program impacts, then there it is likely departments of corrections could meet the treatment needs of a much greater number of incarcerated individuals.

Our study examines the effectiveness of the different substance abuse treatment models using a large sample of more than 3,600 men and women identified as having a high need for substance use disorder treatment in Florida state prisons. We will examine the feasibility of providing different substance abuse treatment approaches to incarcerated individuals as well as their perceived satisfaction with the intervention they received. We will also follow individuals as they release from incarceration and return home to explore how each of the three-substance use disorder treatment models influences their success in the community.

Examining Crisis Stabilization Units and Mobile and Technology-Enhanced Aftercare (PI: Pettus-Davis) - Crisis Stabilization Units are community-based, short-term residential treatment units that provide immediate care to individuals experiencing a mental health or substance use disorder crisis. The goal of the crisis stabilization units is to quickly stabilize the individual – often within 72 hours – and refer that individual to community resources when they are available. Although crisis stabilization units are most widely used as an alternative to emergency rooms, communities across the nation – and particularly urban communities – are increasingly examining crisis stabilization units as an alternative to incarceration for individuals in crisis who come into contact with law enforcement.

In Florida, there are already 40 crisis stabilization units in communities across the state. However, retaining individuals in treatment after they are released from a crisis stabilization unit may be a major barrier to their effectiveness. Community-based treatment programs do not exist in all communities and when they do an individual's access to treatment can be compromised by logistical factors like lack of transportation, lack of stable housing, and long waitlists.

Our study seeks to identify whether mobile and technology-assisted aftercare supports can help to overcome the barriers to community treatment receipt and engagement and whether it enhances the impact of crisis stabilization units. We will also examine outcomes among individuals in crisis who law enforcement officers took to jail rather than a crisis stabilization unit and who law enforcement officers did not detain at all.

Jails have been referred to as the "new asylums" as individuals with mental health or substance use disorders are more likely to reside in jails and prisons than in psychiatric hospitals or residential substance abuse treatment programs. Over 60% of incarcerated individuals meet the criteria for a substance use disorder and almost 21% of incarcerated individuals have been diagnosed with a serious mental illness. However, symptoms of these disorders worsen for most individuals during incarceration and, on average, fewer than 10% of individuals who need treatment receive it during their incarceration.

This project aims to establish an evidence base for effective strategies for diverting individuals in crisis away from incarceration and instead connect them to evidence-driven supports in their communities.

Behavioral Health Focused Prosecutor's Research Network (PI: Pettus-Davis) - launched a network of 20 prosecutors' offices representing all regions of the country. The purpose of this network is to identify common data elements and innovation opportunities across jurisdiction for alternatives for incarceration for those with behavioral health disorders. This project views prosecution as an opportunity to use prosecution as a prevention intercept in the criminal justice system –prevention of pushing people with behavioral health disorders further into the criminal justice system; and prevention of the exacerbation of behavioral health symptoms as prosecution may sometimes be the first time a behavioral health disorder has been identified. Identifying Cost-Effective Substance Use Disorder Treatment in prisons. This project aims to identify those substance abuse treatment approaches that can be the least costly and equally impactful as more expensive substance abuse treatment approaches. The aim is to identify low cost substance abuse treatment approaches that correctional facilities can expand their capacity to meet the treatment needs of those incarcerated. Nationally, only about 10% of incarcerated individuals who need treatment actually receive treatment.

Gender Responsive Trauma Treatment for Jailed Men and Women (PI: Pettus-Davis) - applies a reentry-informed trauma treatment conceptual framework to the implementation and delivery of an evidence-based trauma treatment to men and women releasing from a county jail. The phased intervention begins providing treatment to participants prior to their release from incarceration and concludes treatment after their release from incarceration in the community. IJRD will examine psychological well-being outcomes, reductions in behavioral health symptoms, and re-arrest over a two-year period.

Postmasters Fellows - is the first of its kind postmasters' fellow program to implement the research activities of the institute. Seventeen fellows are located across 4 states (South Carolina, Ohio, Indiana, and Arizona) and conduct a combination of data collection and direct behavioral health services intervention. These three-year positions are paving the way for the future workforce of data driven criminal justice reform and interventions.

Student / Talent Development –In the first year, we had 10 undergraduate and 5 graduate student research technicians. We also created and supervised 8 masters level internships. These internships are conducted in partnership with three FSU law clinics, the local county jail, the 5-Key Model for Reentry project, and prosecutors' offices. The internships provide our student team members educational and workforce training while also creating opportunities for future employment in the same locations.

Academy for Justice, Arizona State University, Sandra Day O'Connor College of Law Post-Masters Fellowship – was created in the Summer of 2019 and formalized a collaboration between the Academy for Justice and IJRD to develop a postmaster's social work fellowship designed to help translate legal scholarship into real world policy and practice implementation.

Dissemination of research – In the first year, we have published 54 academic papers, 6 white papers, and 4 research reports to inform evidence-based criminal justice reforms. Our team members have been featured over 100 times in the media including newspaper and magazine articles, podcasts and radio interviews, and have delivered speeches at press conferences in states across the nation.

Scientific Environment. The Florida State University (FSU) scientific environment will contribute substantially to the proposed project's success through its ample institutional support, physical resources, intellectual productivity, and collaborative atmosphere. FSU is a "very high research intensive" institution. Founded in 1851, Florida State University (FSU) is one of the nation's elite universities. FSU, with the highest Carnegie Classification of "Doctoral Universities: Very high research activity," offers a distinctive academic environment built on its cherished values and unique heritage. Seventeen colleges comprise the academic organization of the University. Florida State, situated in Florida's capital city of Tallahassee, offers baccalaureate degrees in 104 programs, master's degrees in 111 programs, advanced master's/specialist degrees in 11 programs, doctorates in 67 programs and two professional degrees [1]. The university offers fully accredited programs in both law (J.D.) and medicine (M.D.). With nearly 42,000 students enrolled in fall 2018, the student body was comprised of 78% undergraduates, 19% graduates and 3% unclassified. Women accounted for 56.6% of the enrollment and minorities made up 34.3% of student enrollment [2]. During the fall 2018 semester, there were 29 freshmen and 97 total undergraduate National Merit Scholars enrolled at Florida State University. The middle 50% high school GPA for the summer/fall 2018 freshman class was 4.0-4.4 and middle 50% SAT scores were 1260-1360[3].

The Florida State University Office of National Fellowships has mentored and assisted some of our most talented students. Since its inception in the spring of 2005, our students have won over 300 nationally competitive awards, including 3 prestigious Rhodes scholarships, 4 Truman scholarships, 9 Goldwater scholarships, 20 Hollings scholarships, 5 Pickering fellowships, 3 Payne fellowships and 104 Fulbright student scholarships. Our students have traveled to over 60 countries, expanding FSU's influence around the globe. The University also ranks 18th among all public national universities in the U.S. News & World Report 2020 edition of "America's Best Colleges"[4] — evidence that Florida State combines an outstanding education with economic value.

A total of 830 graduate students have been awarded competitive national and prestigious awards since 2011, including the first ever fiction writer to win the Woodrow Wilson Dissertation Fellowship in Women Studies, 26 National Science Foundation Graduate Research Fellowships, 41 P.E.O. Scholar Awards and International Peace Scholarships, 15 National Institutes of Health Fellowships, 7 NASA Awards, 6 Presser Foundation Graduate Music Awards, 7 American Heart Association Fellowships, 11 Dwight D. Eisenhower Transportation Fellowships, 2 Ford Foundation Fellowships, 2 Boren Fellowships, 4 American Association of University Women Fellowships and 55 McKnight Doctoral Fellowships.

During FY19, the **Office of Research** received over \$233 million in external grant awards. Scale of sponsored research for FY 2019 is detailed below:

External award dollars: \$233,600,000

Number of awards: 1050Number of proposals: 1190

Number of patent applications: 114

Number of patents: 51Number of licenses: 9

Florida State University received more than \$30.7 million dollars in research funding from industry and other private sources in FY19. Florida State consistently ranks in the top 10 universities nationally in physical sciences grants awarded by the National Science Foundation, and FSU receives more in NSF funding than any other university in Florida. Industry-sponsored research funding provides educational and knowledge expansion opportunities at the University as well as giving industry access to the most up-to-date technology, cutting-edge research, and prospective employees. Industry partnerships many times lead to licensing of technology either developed as a result of the industry-sponsored research project or industry exposure to university technology. Also, technology-licensing relationships frequently result in the licensee sponsoring research in the laboratory that developed the licensed technology. Perhaps the best example of that at FSU was our synthesis and subsequent licensing of the anti-cancer drug Taxol. This has saved the lives of millions of women and also generated \$352 million in licensing revenue for FSU.

The research team will have access to all of FSU's physical resources (e.g., libraries, computer facilities, conference rooms) and human resources (e.g., computer support, librarians). The interdisciplinary nature of FSU's centers and institutes demonstrate its commitment to faculty mentorship and success. As such, the research team will benefit from the intellectual generosity of their successful colleagues through various disciplines, including hard sciences, liberal arts, and social sciences.

#### **College of Social Work**

The College of Social Work (CSW) at FSU is one of the nation's leading institutions for social work education, training, and research. In 2018, the FSU College of Social Work was ranked a top 25 social work program at a public university (US News &World Report). The FSU CSW prioritizes research and houses five institutes and centers including the Institute for Justice Research and Development; the Center for she Study and Promotion of Communities, Families, and Children; The Florida Institute for Child Welfare, the FSU Multidisciplinary Center, and the Institute for Family Violence Studies. The CSW has 38 tenured, tenure-track, and clinical faculty members actively engaged in research (including NIH research projects), teaching, and service. The collaborative working environment supports a synergistic environment for individuals to display and build upon their scholarship through innovative research.

# Center for the Study and Promotion of Communities, Families and Children

The Center for the Study and Promotion of Communities, Families, and Children ("CFC Center") was created by the Stoops Family Foundation, Inc. to generate and sustain transformational knowledge development for effective policies, services, and usable research for the promotion of communities, families, and the children of Florida, the nation, and across the globe.

#### The Louise R. Goldhagen Multidisciplinary Evaluation and Consulting Center

The Multidisciplinary Evaluation and Consulting Center (MDC) is a university-based diagnostic and training center that serves preschool and school-aged children presenting complex academic, medical, emotional and/or behavioral problems in school programs. Comprehensive diagnostic, consultation, and counseling services are provided to 20 school districts in the Florida Panhandle (including the research schools at FSU and Florida A&M University) and a number of medical and community agencies that primarily serve low-income families (e.g., Children's Medical Services). Children and their families in the school districts are ethnically diverse and many are low-income families living in rural areas. Thirteen of the counties served are classified by the Florida Department of Education as "small and rural" with limited resources for psychological services. All eighteen counties are considered Medically Underserved Areas and/or Medically Underserved Populations. All eighteen counties also meet criteria for Health Professional Shortage Areas in primary care and fifteen counties meet the criteria for Health Professions Shortage Areas for mental health.

The MDC staff includes professionals from clinical, school, and counseling psychology; counseling education; and, social work. The MDC frequently collaborates with several FSU entities to provide services, including: The Center for Autism and Related Disabilities, the School of Communication Science and Disorders, the Department of Psychology, the Department of Educational Psychology and Learning Systems, and the FSU College of Medicine. Pre-service training placements are also provided for graduate and undergraduate students from the FSU school, counseling, and clinical psychology programs; the College of Social Work; and the art and music therapy programs. In-service training for school personnel is provided through seminars, workshops, and conferences.

#### **Institute for Family Violence Studies**

The Institute for Family Violence Studies (IFVS) conducts cutting-edge research on community solutions that employ both law and social services to end family violence. Their goal is to guide practice and shape real-world decisions in both the public and private sectors to keep families safe. Specifically, the IFVS conducts research on family violence and related research domains such as homelessness, financial literacy, and poverty. Multidisciplinary team projects include *The Law Enforcement Families Partnership (funded by the Verizon Foundation) and Increasing Family Economic Self- Sufficiency* (funded by the Administration for Children and Families at the U.S. Department of Health and Human Services).

IFVS develops online curricula for supervised visitation providers, judges, faith-based groups, and child protective service workers and collaborates with community organizations, such as the *Clearinghouse on Supervised Visitation* (funded by the Florida Department of Children and Families) and the *Alliance for Faith-Based Efforts to End Domestic Violence*. IFVS supports innovative programs to reduce family violence. IFVS participates in state and local fatality review teams, evaluate the effectiveness of family violence interventions, and disseminate the findings of our research at the local, state, national, and international levels

#### The Florida Institute for Child Welfare

In 2014, the Florida legislature established the Florida Institute for Child Welfare (FICW) at the Florida State University College of Social Work under legislative mandate, Section 1004.615, Florida Statutes. Researchers from across the state who work with FICW are dedicated to improving the safety, permanency and well-being outcomes for the children in Florida's child welfare system have joined the affiliate network to become FICW Affiliates and help FICW achieve its goals.

FICW seeks to promote safety, permanency, and well-being among the children and families of Florida that are involved with the child welfare system. To accomplish this mission, FICW sponsors and supports interdisciplinary research projects and program evaluation initiatives that contribute to a dynamic knowledge base relevant for enhancing Florida's child welfare outcomes. FICW collaborates with community agencies across all sectors and other important organizations in order to translate relevant knowledge generated through research, policy analysis, and program evaluation. This is achieved through the design and implementation of developmentally-targeted and trauma-informed strategies for children and families involved in the child welfare system.

## Center on Better Health and Life for Underserved Populations (BHL)

FSU established the Center on Better Health and Life for Underserved Populations (the Center) in 2006. The *mission of the Center is to improve health of underserved populations through developing and evaluating community-based interventions*. The goals of the Center are to: 1) conduct research on health disparities and underserved populations to inform the program development process; 2) develop, implement and evaluate community-based programs to address health disparities of underserved populations; and 3) develop, implement and evaluate mentoring programs to increase the number of qualified students for the health sciences. The Center has been recognized by the National Institutes of Health through two funded projects: 1) \$1.75M award (1R24 MD002807) received in 2008 for "Reducing Cardiovascular Risk in African Americans," and 2) \$1.4M award for the follow-on dissemination grant ((2R24 MD002807), "Health for Hearts United Leadership Institute." The Center is currently participating in the UF-FSU CTSI Community Engagement Core which is housed in the FSU College of Medicine. The Center also works in an advisory capacity with the NIH-funded FAMU Center for Health Disparities Research.

In addition to local research efforts, the Center, through the PI, was extensively involved in leading the effort to develop the *Health Disparities Research (HDR) Agenda for Florida* in 2011 (see the following link for a copy of the HDR Agenda: http://cancer.ufl.edu/files/2012/08/FL\_CURED.pdf). Specifically, working in collaboration with the Office of Minority Health in the Florida Department of Health, the Biomedical Research Advisory Council and the Florida Center on Universal Research to Eliminate Disease (FL CURED), a Health Disparities Summit, attended by 50 researchers, was held in 2010 to begin developing priorities for a research direction for the state which was followed by the formation of a 31-member HDR Advisory Committee that developed the *HDR Agenda* in 2011. Subsequently, the Center director worked in conjunction with several others to secure state funding for the Florida Health Equity Research Institute (FL HERI) that has the mission of improving health of medically underserved populations by implementing the *HDR Agenda for Florida* through proactive collaborations among academic institutions, health care providers, government organizations, community-based organizations, and funding organizations (for more

information, go to: flheri.org). FL HERI has received \$800,000 in Legislative funding. The Center now handles Finance & Operations for FL HERI.

In addition to research, the Center also serves as a training site for undergraduate and graduate students from FSU and other universities in the local area. In any given semester, students are affiliated with the Center as volunteers or paid staff. During the summer, high achieving high school students locally and undergraduate students nationally have recently sought out the Center for training. For example, students from the University of Notre Dame and former high school mentees enrolled at Wake Forest and Cornell have served as research interns. Thus far, the Center has helped facilitate degree completion of 50 students (19 bachelor's, 27 masters', 3 Ph.D.'s and 1 M.D.) and the placement of 35 students (20 in medical school, 5 in doctoral programs, one master's, one in dentistry school, 8 employed full-time, including two in higher education academic positions). These students also have served as lead authors or co-authors of published articles.

More broadly, the Center is affiliated with the Sullivan Alliance established by the Honorable Louis Sullivan, MD, former Secretary of the U.S. Department of Health and Human Services, as a result of the 2004 report, *Missing Persons: Minorities in the Health Professions*. Through this affiliation, the Center helped to launch the Florida Alliance for Health Professions Diversity (FAHPD) in 2007 by hosting the inaugural conference for the organization. Since then 18 universities and other stakeholder organizations in the state have joined FAHPD. FAHPD, which now partners with the Florida Health Equity Research Institute to implement the Education and Training Core, has two signature programs to increase diversity in the health workforce, including the Florida Alliance Scholars, a statewide summer research internship for high school through master level students, and the Student Symposium on Health Professions that rotates among different communities around the state. Seven students from the Center have served as Florida Alliance Scholars. For these activities as well as research, the Center has access to a strong infrastructure of computer hardware, software and technical support.

#### The FSU Center for Behavioral Health Integration (CBHI)

The FSU CBHI was established by Dr. Flynn in partnership with the Florida Council for Behavioral Health in 2016. The mission of the FSU Center for Behavioral Health Integration is to strengthen the capacity of FSU to serve as an innovation leader by leading and conducting research, clinical and policy programming and education/training related to behavioral health and prevention of poor behavioral health outcomes. Center activities emphasize community and medical setting research, clinical and policy enhancements aimed to improve behavioral health outcomes. The overall goal is to significantly improve outcome associated with under-addressed behavioral health disorders (i.e. mental health and substance use) in Florida and nationally. In order to achieve its mission, the Center enhances collaboration with other professions interested in integrated health care; identify and promote the use of best practices for integrating and improving health care services; improve clinician training; improve data integration and analytics; and provide assistance to Florida's health care providers in best practice behavioral health care. The Center currently has \$4.5 million in funding with Dr Flynn as PI for behavioral health integration projects.

The Center has a major focus on integration of evidence-based interventions in health care settings aimed to prevent poor mental health and functioning outcomes for childbearing women and children. Projects are aimed at integration of screening, training, and other aspects of mental health integration in both pediatric and obstetrics settings. Dr. Flynn also Co-Chairs the Florida Maternal Mental Health Collaborative, which is a statewide coalition of stakeholders (clinicians, advocates, payers, lawmakers, and researchers) devoted to addressing gaps in clinical care, research, policy and education related to women's health outcomes in Florida. Based on statewide recognition of the Center, Dr Flynn has been invited to serve on two statewide prevention related Task Forces, the Governor's Opioid Task Force (Dr. Flynn chairs the prevention subcommittee) and the statewide Suicide Prevention Task Force.

# The Florida Center for Reading Research

The Florida Center for Reading Research (FCRR) is a multidisciplinary organizational unit of Florida State University that was established in 2002 by the Governor's office and the Legislature. Ten faculty within FCRR hold tenure-earning appointments in an academic department within the University. In addition to tenure-track faculty, the Center includes ~35 senior professional staff (most with MAs or Ph.D.s), 3 postdoctoral fellows, and 14 support staff. FCRR also houses the Quantitative Methodology and Innovation Division, which includes four methodologists (two full professors, an associate professor. and two research faculty members) and a postdoctoral fellow, all of whom have expertise in statistics and methods. The center is housed in approximately 30,000 sq. feet of office space, including a suite of offices for all tenure-track faculty and research space in FCRR as well as the FSU Psychology Building. FCRR employs 3 full-time computer engineers who can provide support for computer set-up and troubleshooting, programming for web-based surveys and data collection, development of digitized video applications, and set up and execution of teleconferencing applications. FCRR has video production facilities, including equipment to digitize, edit, and produce high-quality video for training and other research purposes. FCRR has approximately 40 portable computers that can be used for data collection in the field, and FCRR has site licenses for all the major word processing, presentation, and data management and analysis applications (MS Word, Excel, PowerPoint, SPSS, SAS). All of FCRR's space has wired or wireless Internet access to support office and research activities, as well as conference rooms equipped for video-conferencing.

## Florida State University College of Medicine

The Florida State University College of Medicine (FSU COM), the first new medical school of the 21<sup>st</sup> Century, was established in June 2000 by the Florida Legislature with the mission of serving the unique needs of Floridians. The College of Medicine focuses on educating outstanding physicians for practice in community settings. It is located on the campus of one of the nation's elite research universities, Florida State University (FSU), a public institution that has the Carnegie Foundation's highest designation (Doctoral/Research University-Extensive) and offers a distinctive academic environment built on its cherished values and unique heritage. The college is designed as a community-based medical school, where students spend their first two years taking basic science courses on the FSU campus in Tallahassee and are then assigned to one of the regional medical school campuses for their third- and fourth-year clinical training. The 2+2 pre-clerkship/clerkship year's structure is distinguished by the extent and diversity of clinical training and experiences across the four-year continuum. Community engaged research and practice is at the forefront. FSU has strong connection with Florida Department of Health located within a few miles.

FSU COM has rich resources for research. The 300,000-square-foot COM complex includes scientific research and administrative buildings, 300-seat auditorium, and medical library. Each of the COM's five departments has faculty members involved in research. Florida Statute 1004.42 defined the purpose of the FSU COM to prepare "... physicians to practice primary care, geriatric, and rural medicine, to make appropriate use of emerging technologies, and to function successfully in a rapidly changing health care environment; advancing knowledge in the applied biomedical and behavioral sciences, geriatric research. autism, cancer, and chronic diseases; ..." The types of research include areas of mission orientation in aging-related disease areas such as neuroscience and cancer, health policy research, geriatric care and education, autism, rural health care, and others. The researchers are highly productive in funding, providing educational opportunities for medical, graduate and undergraduate students, and are actively publishing the outcomes of their work. Additionally, our researchers actively collaborate with others across the university, state, nation and world. Our foci in neuroscience and geriatrics have generated a lot of cross-disciplinary research with colleagues at FSU and elsewhere. Our founding research faculty members have been heavily engaged in the creation of our school, putting into place departments, degree programs, policies, procedures, oversight committees and serving on accreditation subcommittees, and planning committees for buildings and facilities. Having achieved so much in their research arenas at the same time is evidence of their commitment to our school's mission.

The research vision for the FSU COM is a collaborative, multidisciplinary research network of faculty and community-based healthcare professionals that supports clinical and translational research. This goal would enhance and promote research collaboration and strengthen partnerships through a formalized,

structured, and integrated network of professionals working with patients, students, faculty, and the community to improve health outcomes for all Floridians. Florida State University College of Medicine's community-based model of education provides an ideal foundation for the development of a community-based clinical research network. The existent infrastructure of six regional campuses across Florida (Daytona, Fort Pierce, Orlando, Pensacola, Sarasota, and Tallahassee), two rural training sites (Immokalee and Marianna) and over 1,900 physicians in private, group or hospital-based practices allows access to as many as two million Floridian patients from across the spectrum of health and illness, gender, age, and socioeconomic status, residing in rural, suburban, and urban communities. Such a network can build upon this collaborative infrastructure to provide clinical, translational, and behavioral research opportunities for clinicians, faculty and students in real world, community-based practice settings. Such linkages will empower therapeutic discoveries and enhance health care practice and delivery to improve the health of Florida's diverse population

## The Department of Behavioral Sciences and Social Medicine in the FSU College of Medicine

Within FSU COM, the Department of Behavioral Sciences and Social Medicine (BSSM) represents the psychosocial components of the biopsychosocial model integrated with Public Health in medical education, patient care, and research. BSSM's goal is to be a leader in the creation of new knowledge emphasizing multidisciplinary, applied research with health providers and patients. There are 20 BSSM faculty members including clinical and social psychologists, public health and health services researchers, an epidemiologist, an ethicist, and a historian. Faculty research interests are broad and include: Improving barriers to care, engagement and interventions for depression in health care settings; STD, HIV, and cervical cancer prevention, health communication, and risk perception; alternative health care delivery approaches, aging and disability, and health outcomes measurement; medical regimen adherence, psychosocial aspects of type 1 and 2 diabetes in children and of genetic testing on children and families; culturally appropriate delivery of health care to underserved populations; and history of medicine and addiction. Several senior faculty (Drs. Flynn, Johnson, Glueckauf) have a long-standing history of successful grant awards from foundations, the NIH and the US Department of Education. Junior faculty have received awards as well. BSSM faculty collaborates with faculty in epidemiology, biostatistics, psychology, nutrition and exercise, and with community physicians. All BSSM faculty have ample office space with computers, printers, software, and central back-up and storage of data. In addition, all researchers have their own laboratory designed to their specifications. Further. BSSM has a longstanding relationship with the Florida Department of Health, as Dr. Les Beitsch (Dept. Chair) is a former Deputy Secretary of Health, and Dr. Shamarial Roberson (current Deputy Secretary for Health) and Claudia Blackburn (Health Officer for the Leon County Department of Health) hold faculty appointments at Florida State University (Social Science Research and Nursing, respectively) and are both actively involved in collaborations with the Center for Translational Behavioral Science, the FSU College of Medicine and BSSM community health initiatives.

#### Information Technology in the FSU College of Medicine

The FSU College of Medicine has excellent Information Technology (IT) resources that support faculty research, teaching, and clinical services. The IT Department is divided into two sections: technical services and information services. The technical services section provides network and end-user support for faculty and staff, including the server maintenance, backups, the e-mail system, and the overall network infrastructure, as well as support and maintenance of faculty computer hardware and software. The responsibilities of the information services section are primarily database design and administration, including design of program interfaces for submission of data and data reports as well as training faculty in the use of graphic and presentation software. Various software programs are provided including, but not limited to: Outlook, Access, Excel, Word, SPSS, and SAS. Additional software is purchased to meet each faculty's teaching and research needs. The acquisition and support of unique/special purpose software and hardware is coordinated through the IT Department and the primary stakeholder(s).

Located on the main campus of the College are nearly 40 servers dedicated to supporting the College's academic, administrative and research functions. Six of these servers are dedicated to three separate two-node clusters. The network resources that are clustered include SQL Server 2000, Exchange Server

2003, file and print services. The College's network storage consists of an EMC/Dell Storage Area Network (SAN) that contains over one terabyte of storage space. Extensive additional computing capability including a 16 processor Linux server is available within the statistics department. Data residing in the SAN and on various servers are backed up at various intervals, including nightly, using tape and other media. The College is committed to expanding the network storage and back-up capacity to meet the teaching, database, and research needs of the College. The wired network infrastructure consists of 100 megabit and 1000-megabit connections to desktop computers, servers and wiring closets. A wireless network, utilizing the 802.11a (54 megabit) and 802.11b (11 megabit) standards, covers more than 90% of the college campus. All faculty members are provided with a desktop or laptop computer. The configuration includes at least a 1.0 GHz processor, 256 MB of RAM and a 20 GB hard drive. The lifecycle replacement for most computers is 4 years. A network administered antivirus client is installed on each computer. A firewall and other security measure are also in place to safeguard local and network resources. Access to resources is controlled through the implementation of Microsoft Windows Active Directory.

<u>Database specification and security.</u> We will ensure that all data file transfer methods are secure and HIPPA compliant and that all database connections are secure and are compliant with computing standards and guidelines. All participant data is de-identified, but "Moderate" security level for confidentiality, integrity, and availability derived using the Center for Medicaid Services Information Security Risk Assessment (RA) Methodology will be maintained. Administrative Safeguards supporting the HiTech Act will include replicated systems and daily backups to a secondary facility with an RPO (Recovery Point Objective) of a day. The managed databases are secure and protected by appropriate firewalls. Data is maintained centrally at the main campus. Over 80 servers are dedicated to supporting the College's academic, administrative and research functions. The network resources that are clustered include SQL Server 2000, Exchange Server 2003, file and print services. The College's network storage consists of a Storage Area Network (SAN) that contains over 30 terabytes of storage space.

#### **Medical Library in the FSU College of Medicine**

The Charlotte Edwards Maguire Medical Library (MML) supports the medical curriculum and research objectives of the Florida State University College of Medicine (FSUCOM). Close to 100% of the library's resources are electronic and available 24 hours a day, 7 days a week. FSUCOM students and over 2100 full-time and quarter-time clinical faculty located throughout the state of Florida have access to over 2,100 medical and biomedical journals, linking seamlessly to roughly 10.5 million full-text articles included in PubMed. Approximately 500 electronic medical reference and textbooks are licensed both for the College of Medicine and the University. The library's electronic collection is continually evaluated and updated by librarians, faculty curriculum leaders and researchers for relevancy to the curriculum and research interests of the college. New and emerging evidence-based medicine websites and mobile device products are especially suited to the electronic environment because they are continually updated and summarize the latest medical treatments and protocols. To name a few, the library licenses Essential Evidence Plus, Dynamed, ePocrates, Clinical Evidence, ACP Pier, PepID, and the Cochrane databases.

The MML is one of seven libraries at FSU, including the Dirac Science Library, open to FSUCOM researchers and students. The FSU University Library holdings are supported by an annual materials budget of \$10 million and include 700 databases and 70,000 full-text e-journals. Through participation in many cooperative licensing agreements, the FSUCOM has access to electronic journals packages that typically deliver entire collections of journals from Elsevier, Wiley, Blackwell, Lippincott Williams and Wilkins, Sage, Taylor and Francis, and other publishers in medicine, biomedicine, and the social sciences. All are available to FSU COM faculty, staff, and students for campus or remote access.

The Maguire Medical Library supports clinical faculty, researchers and students through personalized reference service both in person and via e-mail. In order for students and faculty to make the most productive use of electronic information, a strong and well-developed medical informatics curriculum is integrated into coursework throughout all four years of medical school and is also provided as part of faculty development programming at all campuses. Resources not licensed or parts of the vast print collections at FSU are borrowed through interlibrary loan with a typical turnaround time of less than 24

hours. In addition to interlibrary loan service, FSU participates fully in a universal book lending service which provides access to the print collections of all state university libraries in Florida. Reference support is provided to researchers and students using the bibliographic management software application EndNote, which stores references for ease of retrieval and formatting of reports and articles. The Maguire Medical Library supports open access initiatives and employs a Scholarly Communications Librarian who assists faculty in interpreting and complying with the NIH Public Access Policy and serves as curator for the newly acquired digital repository for Florida State University.

# Florida State University / University of Florida Clinical and Translational Science Award (CTSA)

Funded by the National Institutes of Health National Center for Advancing Translational Sciences, the UF-FSU Clinical and Translational Science Award (CTSA) Program hub is one of two hubs in Florida and is part of a national network of more than 50 hubs nationwide. The CTSA Program is designed to develop innovative solutions that will improve the efficiency, quality and impact of the process for turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public. A CTSA Program hub is an integrated research and training environment for translational and clinical science that catalyzes the development, demonstration and dissemination of methods and technologies that dramatically improve efficiency and quality across the translational research spectrum. The Florida State University (FSU), in partnership with the University of Florida Clinical and Translation Science Institute (UF CTSI) builds upon a successful nine-year record of accomplishment as an NIH-funded CTSA hub, which includes training team scientists, incorporating team science into tenure and promotion guidelines, supporting the full spectrum of translational research, developing and deploying new resources to support a wide range of clinical research, fostering stakeholder-engaged partnerships throughout the research process, and evaluating performance data for ongoing improvement. The UF/FSU CTSA hub has integrated a total of 23 colleges between both institutions and is geographically located amid three large urban areas (Jacksonville, Orlando, and Tampa), intersecting within expansive rural communities across 25 counties in North and Central Florida. FSU's CTSA hub team is based in the College of Medicine, established in 2000 as a community-based medical school emphasizing primary care and serving elder, rural, minority, and underserved populations. The FSU CTSA, in collaboration with the UF CTSI, continually collaborate toward evolvement in line the goals and mission of the partnership, as evidenced by many of the programs and activities it supports, which include:

#### The Biostatistics, Epidemiology, and Research Design (BERD) Program

The BERD Program provides a central location to access support services related to human health data and research including:

- Clinical research design
- Biomedical informatics database access (e.g., OneFlorida Data Trust)
- Quantitative and qualitative analysis
- Access to support services for health data collection (e.g., REDCap)

BERD links investigators with multidisciplinary faculty members and experts in various methodological techniques including biostatistics, epidemiology, biomedical informatics, artificial intelligence, qualitative research, and measurement and evaluation in health-related research. Investigators can consult with the BERD team for research design, data acquisition and management, and data analysis needs that are applicable across the entire spectrum of clinical and translational research.

#### The Health Data Sciences Institute

The Health Data Sciences Institute is a multidisciplinary, multi-college task force has been created to explore big data strategies in the biological, social, and health sciences to support extramural funding in these domains. Based on the task force's work to date, in the areas of biological, social, and health sciences:

- Big data capacities are required to significantly expand federal, foundation, and industry funding
- FSU is competing for external funding with other universities who have significant big data capacity and expertise already in place
- Advancing our knowledge will depend significantly on big data capacity and expertise.

 Attracting top faculty and students requires providing significant research and education opportunities using big data.

## **FSU Office for Human Subjects Protection**

The FSU Office of Research, through its Office for Human Subjects Protection, or OHSP, provides the requisite reviews and on-going oversight of all exempt research involving human subjects; provides the research community with consultation on and regulatory determinations for activities that may involve research or research involving human subjects but that may not require OHSP or IRB reviews under applicable law or FSU policy; performs pre-IRB review of non-exempt research involving human subjects; provides post-approval monitoring to ensure compliance with applicable laws; provides professional, technical and administrative support to the IRB, its business, meetings and documentation; maintains the electronic protocol management systems that serve to document and archive OHSP and IRB reviews and determinations; provides FSU leadership, the research community, and the IRB with applicable law and policy information and resources; and provides or makes available initial, renewing and continuing training regarding human research regulatory requirements and related guidance. The OHSP staff also serve as a resource for investigators and IRB members, and has delegated authority to determine the initial appropriate level of review required for each research proposal submitted for IRB review.

Institutional Review Board Established pursuant to federal statute and regulations, the IRB is a committee composed of scientists, non-scientists including other professionally trained and lay individuals, as well as unaffiliated members who review all proposed human subjects research to ensure that the safety and welfare of human subjects are protected. Non-exempt as well as select exempt research involving human subjects requires review and approval by an IRB prior to conducting any human subjects research, such as for example recruiting or consenting study subjects; collecting, using, analyzing or sharing any individual's identifiable information or biospecimen for any research purpose, including data or tissue banking or repository; or involving individuals in any interaction (e.g., interviews, focus groups or surveys, regardless of mode or medium) or intervention, for a research purpose. The FSU IRB is responsible for the review and on-going oversight of the above and other activities proposed or conducted by FSU employees (faculty, students, staff) and agents, regardless of the source of funding. FSU has significant experience as a single IRB of record for large scale projects such as the Adolescent Trials Network U19 (Naar PI) and ATN 162, an ATN-wide electronic health records protocol.

Research Administration Management Portal FSU is in the process of implementing software to modernize the University's research administration business processes and technologies, as well as improve research compliance and financial management. This multi-year, multi-phased project will provide FSU researchers and administrators with comprehensive tools to support the administration of research within one integrated system. The software includes electronic proposal development and routing as well as system-to-system proposal submission, where available by sponsor. It will also provide tools for the development and management of ACUC and IRB protocols and for the management of subcontracts, contract negotiations, and export controls. Five modules will be included as part of this project - ACUC, IRB, Grants, Agreements and Export Control.

#### **FSU Office of Clinical Research Advancement**

The Office of Clinical Research Advancement (OCRA) at Florida State University is a joint initiative between the FSU Office of the Vice President for Research and the College of Medicine. The intent of OCRA is to centrally coordinate and leverage resources to support clinical research across the FSU research enterprise. OCRA provides services to researchers related to informed guidance through feedback from FSU faculty, healthcare partners, and other university models. OCRA is guided by an interdisciplinary faculty advisory council from six health sciences colleges on the FSU campus and utilizes their own in-house Clinical Research Navigator to support investigators throughout the life cycle of research studies. Informed guidance includes topics related to regulatory compliance, centralized administration and assistance with ClinicalTrials.gov, and assistance with the Institutional Review Board RAMP system related to research agreements. Further, OCRA provides consultation on study design and

data management/analysis, hosts training and educational workshops, and serves as a point of connection between researchers both within FSU and between external research resources and collaborators.

## The Florida State University Research Computer Center

The Research Computing Center (RCC) operates within the university as an academic service unit of Information Technology Services (ITS). The RCC Director oversees 7.5 permanent professional staff and a variable number of term limited project staff and students. The RCC staff and students are responsible for maintaining core systems and are assigned to work in support of specific research domain projects. The RCC staff offices are located on the main campus of FSU in the first floor of the Dirac Science Library. Each RCC office is equipped with workstations, monitors, and essential software applications. The RCC also supports two conference rooms with projection and video conferencing capabilities.

<u>High performance computing</u>. The FSU HPC system is comprised of 6,484 x86 64-bit compute cores linked together by low-latency Infiniband networks for MPI communication. The aggregate peak performance of the system is 75.4 TFLOPS. Compute nodes support between 2 and 4 GBs of memory per core. A total of 13 login nodes serve as the user entry points to the system. The MOAB job manager and the Torque resource scheduler handle job submission and scheduling on the HPC system. A broad set of compilers, math and communication libraries, and software applications are made available on the HPC to maximize the utility of the system by users from diverse disciplines.

<u>High throughput computing</u>. A total of 1,200 x86 64-bit compute cores are available as part of the RCC Condor cluster. The system is specifically tailored to support large batches of serial jobs where overall throughput is preferred over performance. The aggregate peak performance of the system is 16.5 TFLOPS. Compute nodes support between 2 and 8 GBs of memory per core. Users submit jobs to the condor cluster by logging into a robust submission node and calling the Condor submission software.

Interactive computing and scientific visualization. Large datasets generated on RCC computing resources or by research instrumentation on or off FSU's campus can be interactively analyzed and explored using the Spear Cluster. The Spear Cluster is comprised of 288 x86 64-bit process cores linked together by a QDR Infiniband network. Eight of the Spear nodes also connect to a PCI chassis equipped with 16 Nvidia Tesla gpGPU cards (M2050) for a total of 7,168 GPU cores for a peak system performance of 19.8 TFLOPS. Users log directly into Spear nodes and run jobs interactively through a basic shell or X11based systems (NoMachine). An optional load balancing system for general access and owner-based Spear nodes can be used to spread usage evenly over Spear resources. FSU also supports a general access laboratory for scientific visualization in the Department of Scientific Computing (DSC). The laboratory is located in the center of the main FSU campus on the fourth floor of the Dirac Science Library (DSL). The Visualization Laboratory hosts five high-end visualization workstations each equipped with NVIDIA GPU video cards that are compatible with the CUDA SDK. The University visualization resources also include a high-resolution stereographic projection system, funded by the National Science Foundation, to support multidisciplinary scientific visualization. The system is located in an 80-person seminar room adjacent to the Visualization Lab. Four state of the art rear-mounted projectors illuminate an 18' x 8' screen. The system switches between 2D and 3D mode with a touch of a button and also supports numerous other input devices (e.g., a document camera, DVD/VHS player, cable TV, and two hookups for personal laptops) via a simple to use touch panel screen. The DSC also supports a state-ofthe-art classroom for 3D immersive visualization and game design courses. The classroom is equipped with 19 high-end workstations attached to 23" passive 3D monitors. A 62" passive 3D monitor is connected to the instructor workstation. Both the seminar room and classroom support a wide variety of remote collaboration technologies including Access Grid and EVO – The Collaboration Network.

<u>Cloud computing</u>. The RCC supports a cloud computing platform built on OpenStack to allow quick deployment of web, database, and other non-High-Performance Computing systems. Virtual instances are available in three sizes depending on the number of processors and the amount of memory and disk space required.

<u>Data storage</u>. Two high performance parallel file systems are available to facilitate data analysis pipelines and workflows. A 256 TB (usable capacity) Panasas file system is mounted on all of the HPC compute nodes over a dedicated 1 Gbps network. Our 344 TB (usable capacity) Lustre file system is available through a native interface on the interactive compute nodes and is available through a pair of load balanced NFS servers to select data acquisition instruments on FSU's campus.

<u>Data center facilities and network connectivity</u>. Computing and data storage resources managed by the RCC occupy two core data center facilities; one located on the main FSU campus in the Dirac Science Library and the other located at Innovation park in the Bernard Sliger Building. Both facilities are equipped with raised floors and HVAC cooling systems, extensive power distribution systems, large format UPS battery backup systems, and diesel-powered backup generators for prolonged outages. Each of the campus data centers is connected to the campus enterprise and research networks via multiple 10 Gbps connections. Data centers also connect directly to Florida's regional optical network, the Florida LambdaRail.

#### **WASHINGTON UNIVERSITY IN ST. LOUIS**

#### Resources

**Washington University in St. Louis**, founded in 1853, is a medium-sized, private research university with approximately 12,500 full-time students, fairly evenly divided between undergraduate and graduate/professional) independent, Research I university. Washington University's student body represents all 50 states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands and more than 80 countries around the world, with approximately ninety percent of undergraduates come from outside the state of Missouri. The academic units that comprise the University are Arts & Sciences and the schools of Architecture, Art, Business, Engineering & Applied Science, Law, Medicine, and Social Work.

Founded in 1925, the **George Warren Brown School of Social Work (the Brown School)** is one of the leading schools of social work in the country. The Brown School is ranked second in the nation by *U.S. News & World Report 2016*, and has established rich resources for its research and educational programs. Fully accredited by the Council on Social Work Education, the school has both an MSW and a PhD program, which is one of the oldest and strongest doctoral programs of social work in the nation. In 2009, the Brown School nearly doubled in size by further expanding its transdisciplinary work and launching a Master of Public Health (MPH) program, which was accredited by the Council on Education for Public Health in 2012. A new doctoral program in Public Health Sciences began in 2015.

The Brown School provides superior support and experiential opportunities to foster maximum development for its graduate students and faculty. The School currently has two Kirschstein National Research Service Award (NRSA) Institutional Research Training grants. The NIMH funded Mental Health Research Training program (T32 MH19960, funded 1996-present) has supported 53 doctoral students and 12 post-doctoral researchers, and the NIDA funded Transdisciplinary Training in Addictions Research program (T32 DA015035, funded 2002-present) has supported 9 doctoral students and 6 post-doctoral researchers. Pre- and post-doctoral fellows have been very successful in their pursuit of research funding through competitive funding sources, with over 30 trainees securing external funding for their dissertation work over the past decade. The School has also established a strong track record in minority research training and development, successfully recruiting and retaining minority fellows and faculty to the Brown School.

A forerunner in many ways, the Brown School enjoys a solid reputation for its educational excellence, path-breaking research, and global embrace. Fifty full-time, tenured, tenure-track, and research faculty pioneer in the area of evidence-based practice and cultivate strong collaborations with service settings, maintaining relationships with over 200 community partners, and engaging in research in 28 locations around the globe. Annually, the Brown School publishes *Social Impact*, a substantial full-color magazine that focuses on the

significant contributions faculty, students, and graduates make locally, nationally, and internationally. The magazine aims to inspire discussion around critical issues of social policy, practice, and education.

#### **Facilities**

Dr. Luke's office is located in Goldfarb Hall on the University's Danforth Campus and provides ample workspace and capacity to support a productive, vibrant and collaborative research environment.

#### **Institutional Support within the Brown School**

The Brown School is an exceptional place, with a wide array of resources and supports to achieve proposal objectives. The School houses numerous multidisciplinary research centers and enterprising mechanisms:

- Center for Mental Health Services Research
- Center for Obesity Prevention and Policy Research
- Center for Public Health Systems Science
- Center for Social Development
- Center for Violence and Injury Prevention
- Envolve Center for Health Behavior Change
- Evaluation Center
- Health Communication Research Laboratory
- Institute for Advancing Justice Research and Innovation
- Kathryn M. Buder Center for American Indian Studies
- Prevention Research Center in St. Louis
- Social System Design Lab
- WU Center for Diabetes Translation Research
- Clark-Fox Policy Institute

Center for Mental Health Services Research (CMHSR): The CMHSR supports research on the mental health service delivery system, with a special emphasis on the quality of services delivered in public and social service settings. Recent foci include the dissemination and implementation of evidence-based mental health services, services to vulnerable populations, Medicaid funded services, and parent training to prevent serious emotional disorders among children.

Established in 1993 through a grant from the National Institute of Mental Health (NIMH), the CMHSR became the first Social Work Research Development Center (R24 MH50857). Subsequent funding (P30MH068579) positioned the CMHSR as the first Advanced Center for Interventions and Service's Research awarded to a school of Social Work. Currently the CMHSR is supported by a variety of federal and private grant awards.

Since 2008, the CMHSR has facilitated the NIMH funded Implementation Research Institute (IRI) (R25MH080916). The IRI is a unique learning collaborative which includes a week long intensive training in implementation science for mental health each summer. The summer institute, held on the Washington University campus, draws a team of 10-15 national experts in implementation science, along with 10-12 early stage investigators from across the country. To date, the IRI has trained over 50 implementation researchers, providing them experiential learning, didactic training, faculty mentoring, and support for pilot research and grant writing—all focused on helping participants shape an implementation research project for competitive external funding.

The CMHSR has been very effective in obtaining and carrying out funded research projects. Affiliated research staff and researchers have learned how to compete for federal funding, support budding research projects, and manage sophisticated research endeavors. The CMHSR benefits from an experienced research staff and specialized research assistants with expertise in structured and semi-structured interviewing; measuring psychosocial constructs and service system outcomes; conducting longitudinal and agency based research; working with complex data sets; capturing, cleaning, managing and analyzing qualitative and quantitative data; managing projects, and supporting dissemination of research findings.

Center for Obesity Prevention & Policy Research (COPPR): COPPR is a joint center of the Brown School and Washington University Medical School, and directed by Dr. Debra Haire-Joshu. The mission of COPPR is

to improve the health of vulnerable populations by engaging in transdisciplinary research that discovers and disseminates science to inform programs and policies designed to prevent obesity. The goals of COPPR are to conduct research designed to eliminate obesity in vulnerable populations; to collaborate with national partners to disseminate evidence based research through their organizational networks; to work with policymakers to ensure the development of evidence-based obesity policy; to support the development of transdisciplinary faculty; and to act as a catalyst to enhance collaborations within the University to prevent obesity.

COPPR is the organizational home to faculty and staff engaged in a series of research studies with community partners and other academic collaborators designed to prevent obesity. In addition, COPPR collaborates with public health advocates and policymakers to translate science to policy initiatives and legislation designed to prevent obesity.

COPPR occupies space on the Washington University campus in Hillman Hall. This space consists of private and shared offices, conference rooms with extensive state of the art technology capabilities, reception and kitchen areas, and information technology support. Each office and station has computers and access to printers, all which run on the Brown School network. This space is critical to COPPR functions including project preparation, planning, and data analysis.

Center for Public Health Systems Science (CPHSS): The CPHSS focuses on research and evaluation of public health programs and policies on national, state, and local levels. CPHSS has extensive experience in developing and managing large multi-site evaluations and in systems science research. The Center has become a leader in network analysis of tobacco control initiatives, developed tools to assist practitioners and advocates, and been an important stakeholder in regional tobacco control efforts.

CPHSS has conducted systems level evaluation and research and has received funding from the Centers for Disease Control and Prevention (CDC), the National Cancer Institute, the Legacy Foundation, and the Missouri Foundation for Health (MFH), among others. The Center's evaluation work has informed national public health reports and guidelines, including CDC's 2007 Best Practices for Comprehensive Tobacco Control Programs, NCI's 2007 monograph, Greater than the Sum: Systems Thinking in Tobacco Control, and CDC's Introduction to Process Evaluation in Tobacco Use Prevention and Control. The Center currently leads several projects, including: a collaboration with CDC to develop and disseminate a tool for assessing state and community program capacity for sustainability; an NCI-funded collaboration with UNC and Stanford researching how to maximize state and local policies restricting tobacco marketing at the point-of-sale; and multi-year evaluations of three MFH funding programs that support community health interventions to address tobacco use and obesity in the state of Missouri. Through current work and future plans, the Center strives to fulfill its mission to translate research and evaluation results to inform prevention policy and improve public health practice, leading to healthier communities.

**Center for Social Development (CSD):** The CSD conducts research that informs how individuals, families, and communities increase capacity, formulate and reach life goals, and contribute to the economy and society with a principal focus on marginalized families and communities.

The Center was founded in 1994 after Dr. Michael Sherraden published his ground-breaking book Assets and the Poor: A New American Welfare Policy (1991), in which he proposed asset-building policy as a new approach to development of families and communities. Dr. Sherraden was invited by the then dean of the Brown School, Shanti Khinduka – who recognized the potential of these ideas to reshape thinking about public policy – to serve as director of the new Center for Social Development. In 2012, Dr. Michael Grinstein-Weiss joined CSD as Associate Director, and in 2014 Dr. Shenyang Guo became CSD's Research Director.

CSD provides innovation and study of social development in the following main areas:

- Asset Building
- Financial Capability
- Financial Stability
- Civic Engagement
- Child and Youth Development

- Productive Aging
- Thriving Communities
- Sensible Justice
- Social Innovation

The Center designs and carries out large-scale, multi-method research, emphasizing experimental testing of social interventions and provides a stimulating environment for people working on diverse social development topics. The approach is multidisciplinary, drawing on experts from many fields. Projects connect academic and applied interests and incorporate public, nonprofit, and private sectors. Emphasis is on partnerships for joint study and joint action. CSD undertakes research, brings together expert scholars, holds workshops and conferences, publishes reports and scholarly papers, and informs policy at the local, state, national, and international levels.

Since its founding, CSD has established an extensive online working papers publication series, and online bibliographies. CSD has authored hundreds of publications including its working paper series, peer-reviewed journal articles research and policy reports, and Congressional testimonies. CSD has grown to 16 full-time staff, two post-doctoral research associates, 68 Faculty Directors and Faculty Associates, and an average of 20 graduate research associates and assistants each year.

Center for Violence and Injury Prevention (CVIP): The Center for Violence and Injury Prevention (CVIP), was established in 2009 with funding from the Centers for Disease Control and Prevention as a collaboration between the Brown School, the Washington University Medical School, Department of Psychiatry, Saint Louis University and the University of Missouri St Louis. The center is directed by Dr. Melissa Jonson-Reid of the Brown School with a focus on preventing child maltreatment, intimate partner violence, sexual violence, suicide and youth violence as well as intervening to prevent additional harm. The center mission is to "Promote Healthy Young Families and Healthy Young Adults through Advancing Evidence-Based Violence Prevention and Harm Reduction Education, Research, & Training"

Since its founding, CVIP has been able to leverage over 40 funded affiliated research and dissertation projects. More than 50 faculty from seven universities remain affiliated with the center from more than 10 disciplines and several universities, along with graduate and doctoral students from the fields of social work and public health. In 2010 a graduate student certificate program was launched and has subsequently developed into both a certificate and as of 2015, a MSW concentration in violence and injury prevention with foci on young families, adolescence through young adulthood, women and American Indians/Native Alaskans. The center sponsors and co-sponsors outreach activities in the form of guest lectures, trainings, newsletters, policy briefs and the Missouri Family Impact Seminar.

The Envolve Center for Health Behavior Change: is an innovative industry-academic partnership between the Brown School, Duke University, and Centene Corporation, a leading Fortune 500 managed care company. Launched in 2015, the Envolve Center focuses efforts on translating evidence-based healthcare methods into real-world settings to actively improve the lives and health of vulnerable populations. Current research priorities include using behavioral economics techniques to facilitate better health behavior, implementing lifestyle interventions to break the intergenerational cycle of obesity and diabetes, and employing tailored online, telephonic, and in-person communications to improve health outcomes.

**The Evaluation Center** is committed to helping you understand your work and why it matters. They specialize in client-driven evaluation services and training for non-profits organizations, funders, universities, and governmental agencies. Their mission is to advance evaluation science and practice to help organizations create lasting social impact.

**Health Communication Research Laboratory (HCRL):** Founded and led from 1996-2013 by Matthew Kreuter, PhD, MPH, Associate Dean for Public Health, the Brown School's Health Communication Research Laboratory (HCRL) is now co-led by Charlene Caburnay, PhD, MPH; and Amy McQueen, PhD. The HCRL seeks to increase the reach and effectiveness of health information to low-income and minority Americans to help eliminate health disparities.

Consistent with this mission, the HCRL develops and tests computer-based programs for health promotion and disease prevention, and is actively involved in research projects testing the application of new technologies in innovative health education programs. HCRL staff have developed communication programs in the areas of cancer prevention and screening, health promotion referral systems, smoking prevention and cessation, alcoholism recovery, childhood immunization, cholesterol screening, cholesterol management, depression screening, diet and nutrition, health risk appraisal, hormone replacement therapy, lead poisoning prevention, medication compliance, nutrition label reading, osteoporosis prevention, physical activity, physician prompting,

safe gun storage, child injury prevention, seat belt use, influenza vaccination, smoke detector use, stress management, and weight management. From 2003-2014, the HCRL was home to an NCI-funded Centers of Excellence in Cancer Communication Research (CECCR). The HCRL collaborates with other Brown School and Institute for Public Health investigators at Washington University.

Institute for Advancing Justice Research and Innovation: Under the leadership of Dr. Carrie Pettus- Davis the institute formed in 2015, as a results of unprecedented support from public officials, corporate leaders, service providers, formerly incarcerated individuals, and academic thought-leaders in St. Louis, Missouri dedicated to finding long lasting solutions to reducing high re-incarceration rates. Since its forming, the Institute has received private, public, and academic financial support to develop new conceptual frameworks and program manuals to guide 21st century capacity building efforts aimed at improving well-being and success of those who come into contact with the criminal justice system.

The Institute is a groundbreaking social work research center that seeks to invent, test, leverage, and coordinate the best criminal justice-related practice and policy contributions for dissemination and social capacity building.

The inaugural project of the Institute involved researchers, practitioners, and formerly incarcerated individuals reviewing 107,515 peer-reviewed studies of treatment programs tested with vulnerable and marginalized populations worldwide. The team then braided together the most potent and effective practices obtained from this review to form an integrated and holistic reentry model - Five Key Interventions for Reentry Well-Being.

The Institute is first-of-its-kind in a school of social work -- a research center focused entirely on justice-involved individuals and their families. At the Institute we prioritize highly active research-practice-policy partnerships. Through these partnerships, evidence informs practice/policy strategies and policy/practice strategies shape research agendas. We have designed a research-to-practice/practice-to-research methodology that can be employed in the context of a research trial in order to speed the translation of learnings to almost real-time.

**Kathryn M. Buder Center for American Indian Studies:** The Buder Center for American Indian Studies (the Buder Center), established in 1990, provides a base for research with American Indian/Alaska Natives. The Buder Center sponsors a comprehensive program of social work study for American Indians that emphasizes social welfare research, health and mental health, leadership training, and social policy. This research also provides many methodological parallels for investigators conducting research targeting other "at risk" minority populations.

The Buder Center is designed to play an integral part in the restoration and reclamation of American Indian communities and tribal governments through education, research, and development; in addition the Center works to facilitate research involving the American Indian community, and to address their needs. Most of the Buder Center's research collaborations are with tribal nations, agencies, and populations in states other than Missouri. This is evidence of the Brown School's successful record of accomplishment in conducting "long distance" research.

Numerous projects between the Buder Center and partners provide American Indian scholars essential skills and training to help their respective tribal communities and contribute to the success of tribal nations. On one such project, the Buder Center partnered with the Health Communications Research Lab (HCRL) on the Graphic Cigarette Label Study, funded by the Food and Drug Administration, to research the effectiveness of graphic warning labels on cigarettes among different populations, including American Indians.

In 2012, a strategic partnership was developed between the Buder Center and the Program for the Elimination of Cancer Disparities (PECaD). PECaD is a collaboration of the Siteman Cancer Center, Barnes Jewish Hospital, and Washington University in St. Louis Medical Center. One result of the Buder collaboration was the decision to offer preventative education and screening for women at the 2013 Washington University in St. Louis Pow Wow. The Buder Center plans to replicate the Susan G. Komen mammography van project during the 2016 Washington University in St. Louis Pow Wow. Another successful project, now in its third year, allows American Indian/Alaska Native scholars from the Buder Center to continue to work with Bon Appetit Chefs on the university campus. This collaboration seeks to increase awareness surrounding traditional Native foods

and to identify what it means to be a healthy human being, informed by the Native phrase, "Hunt. Fish. Gather." The overarching project goal is to redefine health with a focus on body, spirit, mind, and environment.

Prevention Research Center in St. Louis (PRC-StL): The PRC-StL is comprised of community, practice and academic partners. Established in 1994, the center is led by Dr. Ross Brownson and is funded by multiple federal agencies and foundations. The Center's mission is to prevent chronic diseases and improve population health by adapting, implementing, evaluating, and disseminating evidence-based interventions. It conducts research related to the built environment, physical activity, chronic disease prevention, policy, dissemination and implementation, healthy eating, and evidence-based decision making in public health. Through this work, the PRC-StL strives to provide tools and resources that facilitate the application of evidence-based interventions to real-life public health practice. The PRC-StL is housed on the second floor of Hillman Hall in the Brown School on the Danforth Campus. The Center workspace incorporates several evidence-based initiatives to support workplace health and well-being, such as adjustable-height sit/stand desks, group physical activity challenges, plentiful compost and recycling bins, and strategic diffusion of natural light.

**Social System Design Lab (SSDL):** was founded in 2009 to advance the science application of system dynamics modeling and computer simulation in human service organizations and communities. The SSDL is led by Dr. Peter Hovmand and has a scientific research agenda that focuses on advancing methods for design of social systems using participatory methods for community engagement and system dynamics modeling with formal computer simulation. The SSDL is unique in combining system dynamics, social work, public health, and human services leadership and administration to tackle socially complex issues in both a domestic and international context with applications in prevention research, health and human services, quality improvement, evaluation research, and public policy. The SSDL has three main objectives:

- Advance methods in system dynamics, group model building, and prevention science;
- Promote the application of system dynamics to the improved design of social systems through collaborations with communities, professionals, government, nongovernmental organizations, and researchers;
- Train a generation of professions in the development and application of system dynamics modeling in real-world settings.

To date, the SSDL's work has been funded by the National Science Foundation, National Institutes of Health, Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, Bill and Melinda Gates Foundation, Robert Wood Johnson Foundation, and Lupina Foundation among others. The SSDL currently has active collaborations in St. Louis with a variety of organizations and internationally including India, China, Singapore, Australia, New Zealand, Kenya, United Kingdom, Canada, Mexico, Honduras, and Panama in both rural and urban settings and indigenous communities.

The Washington University Center for Diabetes Translation Research (WU-CDTR) is a direct result of three decades of translational diabetes research and focuses on translating interventions that have demonstrated efficacy into real world health care settings, communities, and populations at risk, leveraging in this effort the immense scientific resources of multiple NIH and other funded centers relevant to the prevention of Type 2 diabetes at Washington University. The WU-CDTR is funded by the National Institute of Diabetes and Digestive and Kidney Diseases (P30 DK092950).

The mission of the CDTR is to eliminate disparities in Type 2 diabetes by translating evidence-based interventions to diverse communities through two interacting scientific themes: 1) The root causes of diabetes and disparities and 2) Obesity as a major contributing factor to Type 2 diabetes.

The primary aims of the WU-CDTR are to support transdisciplinary investigators conducting type II translation research through the following six research cores: 1) The Health Communication and Health Literacy Core, which will advance the study of health communication science to test strategies for addressing health disparities in diabetes prevention and care (led by Matthew Kreuter, PhD, Professor of Public Health and Director of the Health Communication Research Laboratory); 2) The Dissemination and Implementation in Diabetes Research Core, which will advance the study of implementing, disseminating, and sustaining evidence-based approaches through integration in real world settings to improve diabetes prevention and care (led by Enola Proctor, PhD, Frank J. Bruno Professor of Social Work Research and Rachel Tabak, PhD); 3) The Health Informatics in Diabetes Research Core, which aims to expand the use of state-of-the-art Health

Informatics methods for diabetes translation research and increase the capacity for use of health informatics in diabetes research among CDTR investigators; *4*)The Policy and Systems Science Analysis in Diabetes Research Core, which will advance the study of economic and policy level interventions to eliminate disparities and social systems in diabetes prevention and care (led by Timothy McBride, Professor of Public Health and Doug Luke, Professor and Director of the Center for Public Health Systems Science); *5*) The Research Partnerships with American Indian/Alaska Native Communities Core, which will increase the capacity of researchers to engage in translational research to prevent obesity and Type 2 diabetes in American Indian and Alaska Native (Al/AN) communities (led by Malia Villegas, Director, Policy Research Center, National Congress of American Indians); and *6*) the Solutions to Diabetes in Black Americans Core, which aims to improve the relevance and salience of diabetes prevention and control interventions for black Americans and increase understanding and use in intervention designs of information about the effects of commercial marketing on eating, physical activity, and weight control (led by Shiriki Kumanyika, Director of the African American Collaborative Obesity Research Network).

The secondary aims of the WU-CDTR are to support a Pilot and Feasibility Program designed to attract and retain young transdisciplinary investigators; support an Enrichment Program that promotes transdisciplinary research, education, and training opportunities for junior and early stage investigators related to type II translation diabetes research; and enhance the awareness of the WU-CDTR as a regional and national resource for translational diabetes research.

**Clark-Fox Policy Institute:** The Maxine Clark and Bob Fox Policy Institute has evolved from the Policy Forum which was conceived in 2008 as part of the Brown School Strategic Plan, Impact 2020. The goal of the Policy Forum was to build the capacity of the Brown School to apply research to important policy questions with the goal of producing more informed, evidence-based public policy outcomes. During its initial phase of development, the Policy Forum engaged a diverse set of communities and individuals—including researchers, practitioners, media partners, community organizations, and policy makers—in policy discussion and debate through lectures, panels and discussions, often in collaboration with other organizations.

When St. Louis Business and civic leaders Maxine Clark and Bob Fox pledged \$3.75 million to support the Policy Forum, the Forum was renamed in their honor to the Clark-Fox Policy Institute. Through an active program of education, discourse, and dissemination, the Institute will continue to promote community engagement, connect research to policy, and bring sustained attention to significant policy issues.

#### **Institutional Support within the University**

The scientific expertise and state-of-the-art facilities available at Washington University in St. Louis provide a uniquely suited environment to support this project and its aims.

## The Institute for Public Health (IPH)

Formed in 2008, the Institute for Public Health brings together many disciplines and diverse partners from across Washington University to solve the complex health challenges facing the St. Louis region and the world. The Institute is championed by Chancellor Mark S. Wrighton as one of WUSTL's key initiatives in the University's overarching goal of enhancing our leadership today to benefit America and the world tomorrow.

The Institute organizes conferences, lectures, seminars, and other events that allow experts within and beyond the university to learn, share, and connect with one another. Its scholar network connects faculty in all seven schools of the university. It develops forums and funding opportunities for both faculty and students that encourage innovative collaborations and research. Its five university-wide centers—which focus on aging, community health, global health, data & training, and dissemination & implementation—break down silos and harness the strengths of Washington University's research and practice in all disciplines. Through these efforts, the Institute amplifies and accelerates Washington University's ability to impact public health in St. Louis and around the world. The IPH currently focuses its efforts through five University-wide centers:

**The Center for Community Health & Partnerships** works to enable community-academic partnerships that effectively address the health needs of the St. Louis community. It serves as a resource center for students, faculty, and community partners to facilitate collaborative health initiatives. It also builds and sustains community partnerships, coordinates community health initiatives across Washington University, and provides training and education opportunities that focus on effective community engagement strategies.

The Harvey A. Friedman Center for Aging was established in 1998 under the direction of Chancellor Mark S. Wrighton, on the University's Medical Campus. To expand its connection to all university campuses, the Friedman Center joined the Institute for Public Health in 2012. The Friedman Center provides academic and administrative leadership to: encourage and support interdisciplinary research, increase gerontology and geriatric education all campuses, and develop community partnerships to improve the quality of life for older adults and their families. The Friedman Center hosts monthly seminars and an annual lecture open to all University faculty, staff, students and community partners; provides professional development awards promoting outstanding research and practice in geriatrics and gerontology; works with the University's McDonnell International Scholar Academy to expand education and research on global aging issues; and facilitates research interest groups on areas such as lifelong communities, living with multiple chronic conditions, and global aging.

**The Center for Dissemination & Implementation** seeks to close the gap between research and practice to improve public health. By working with campus, community, and healthcare partners, the center supports research and activities that help move the most effective interventions, programs, and policies into practice. It leads and coordinates Washington University's efforts in this crucial emerging field by supporting a growing network of researchers that investigate methods for the implementation of proven clinical treatments, programs, and policies into real-world settings.

**The Center for Global Health** works to improve global health through transdisciplinary programs and partnerships across Washington University and around the world. It brings the campus community and partners together to focus on global health issues through events and programs. The center encourages innovation and cross-disciplinary research in global with a focus on five key areas: infectious diseases; nutritional deficiency; maternal and child health; productive aging; and cancer and chronic disease.

The Public Health Data & Training Center puts public health data into action by promoting its effective use in research, practice, and policy. Through training programs and educational opportunities it builds the capacity of students, faculty, and community partners to use and interpret data, supporting an evidence-based approach to public health. It also aims to provide centralized access to diverse public health datasets, and create opportunities to share important public health data with the community. Through these efforts, the Public Health Data & Training Center works to build a strong foundation supporting Washington University's ability to impact public health in St. Louis, across the country, and around the world.

Washington University School of Medicine (WUSM) has a rich history of success in research, education, and patient care, earning a reputation as one of the premier medical schools in the world. Since its founding in 1891, WUSM has trained nearly 8,000 physicians and has contributed groundbreaking discoveries in many areas of medical research. WUSM ties for 6th place in the research category among medical schools according to *U.S. News & World Report*, and is accredited by the Association of American Medical Colleges Liaison Committee on Medical Education. As one of the five largest academic clinical practices in the nation, Washington University Physicians comprise over 1,250 university-employed physicians, representing more than 76 specialties and subspecialties in medicine and surgery. The highly active clinical practice group delivers comprehensive patient care at more than 49 clinical sites throughout the greater St. Louis area and surrounding counties.

**BJC HealthCare** is one of the largest nonprofit health care organizations in the United States, delivering services to residents primarily in the greater St. Louis, southern Illinois and mid-Missouri regions. With net revenue of \$3.6 billion, BJC serves urban, suburban and rural communities; and includes 13 hospitals and multiple community health locations. Services include inpatient and outpatient care, primary care, community health and wellness, workplace health, home health, community mental health, rehabilitation, long-term care and hospice. Hospitals in the Washington University Medical Center include Barnes-Jewish Hospital, St. Louis Children's Hospital, and The Rehabilitation Institute of St. Louis. *U.S. News & World Report* ranks Barnes-Jewish Hospital nationally in 15 adult specialties and No. 1 in Missouri in its annual exclusive list of "Best Hospitals". St. Louis Children's Hospital ranks 6<sup>th</sup> nationally in the elite *U.S. News & World Report* list of "Best Children's Hospitals" with distinction as a facility ranked in all ten specialties covered by the annual report.

**The Alvin J. Siteman Cancer Center (SCC)** at Barnes-Jewish Hospital and Washington University School of Medicine is an international leader in cancer treatment, research, prevention, education and community outreach. It is the only cancer center in Missouri to hold the prestigious Comprehensive Cancer Center designation from the National Cancer Institute and membership in the National Comprehensive Cancer

Network. This comprehensive status is based on strong basic and clinical research programs; programs in cancer prevention, control and population-based research; and a body of interactive research bridging these areas; as well as recognition for outreach and education efforts aimed at residents of the St. Louis region and health-care professionals. Siteman offers the expertise of more than 350 Washington University research scientists and physicians who provide care for more than 8,000 newly diagnosed cancer patients each year, and hold more than \$160 million in cancer research and related training grants.

#### SCC shared resource cores include:

- Biologic Therapy Core
- Biomedical Informatics Core
- Biostatistics Core
- Clinical Trials Core
- Murine Embryonic Stem Cell Core
- Health Behavior, Communication & Outreach Core
- Hereditary Cancer Core

- High-Throughput Screening Core
- Imaging & Response Assessment Core (IRAC)
- Genome Technology Access Center
- Proteomics Core
- Siteman Flow Cytometry Core
- Small Animal Cancer Imaging Core
- Tissue Procurement Core

The Health Behavior, Communication and Outreach Core (HBCOC) provides services to investigators engaged in Prevention and Control and Clinical/Translational research. Core faculty and staff have developed high quality services in behavioral science, epidemiology, health education and communication, program evaluation, psychological quality-of-life assessments, and geocoding and spatial statistics. The HBCOC is a shared resource with components both at Washington University's School of Medicine and Brown School.

The Institute of Clinical and Translational Sciences (ICTS) was established in 2007 through major funding from the National Institutes of Health's Clinical and Translational Science Award (CTSA) program, as well as institutional support from Washington University and BJC HealthCare. The ICTS leverages partnerships with other local and regional academic, healthcare, and community partners, and helps ensure that ICTS investigators have access to state-of-the-art research infrastructure, financial support, and education, facilitates translational research, assists in the creation and sustaining of interdisciplinary research collaborations, and helps move research findings from the initial discovery phase into new diagnostics, therapeutics, and prevention strategies to improve human health.

## The Washington University ICTS Cores and services include:

- Brain, Behavior and Performance Unit
- Center for Administrative Data Research
- Center for Applied Research Sciences
- Center for Biomedical Informatics
- Center for Clinical Research Ethics
- Center for Community-Engaged Research
- Clinical Research Training Center
- Clinical Research Unit
- Clinical Trials Unit
- Dissemination & Implementation Research Core
- Genome Technology Access Center
- Human & Mouse Linked Evaluation of Tumors
- Human Imaging Unit
- Lifestyle Intervention Research Core

- Proteomics & Mass Spectrometry Program
- Recruitment Enhancement Core
- Regulatory Support Center
- Research Design & Biostatistics Group
- Tissue Procurement Core
- Translational Cardiovascular Biobank & Repository
- Translational Research Methods & Analysis Center
- Washington University Pediatric & Adolescent Ambulatory Research Consortium (WU PAARC)
- Pediatric Clinical Research Unit

The Center for Administrative Data Research (CADR) assists ICTS investigators interested in using existing administrative data for clinical epidemiologic, health services, and comparative effectiveness research. Led by researchers with a background in medicine, epidemiology and health policy, the CADR assists with selecting appropriate administrative databases; obtaining data; storing data securely; using data; providing tools, programs, and resources; and collaborating with others.

**The Center for Community-Engaged Research (CCER)** is a transformative initiative that fosters collaborative research partnerships between and among the community at large, community organizations,

academic institutions, community-based health providers and researchers. CCER enhances the practice-based research network (PBRN) of community practitioners affiliated with WUSM; provides training on approaches to properly conduct community-based participatory research (CBPR) in culturally diverse populations; establishes core support functions to facilitate the participation of underrepresented populations in research; assesses community perceptions about research and needs for services; works with community practitioners, provider organizations, health agencies, policy makers and trainees to improve the relevance, conduct, and impact of research; and links the community to appropriate services.

The Dissemination and Implementation Research Core (DIRC) provides methodological expertise to advance translational (T2) research to inform and move efficacious health practices from clinical knowledge into routine, real-world use. The DIRC works with ICTS scientists to move forward scientific agenda and grant writing related to dissemination and implementation (D&I) of health care discoveries, and develops tools and methods for studying D&I.

The Translational Research and Analysis Core (TRAC) provides investigators with expertise in observational studies, clinical trial design, and biostatistical analysis and interpretation, and serves as an integral component of research from the planning through the execution to the dissemination of results phase.

The Research Design & Biostatistics Group (RDBG) aims to extend epidemiologic and biostatistical collaboration support and mentoring by assisting with protocol/proposal preparation, providing methodological support, supervising study review and monitoring, and coordinating multi-institutional studies. RDBG also ensures access to necessary informatics resources to support protocols; supports training in biostatistical methods; and develops and expands biostatistical methodology research. RDBG directly supports T1, T2, T3 and T4 research.

## The Washington University Network for Dissemination and Implementation Research (WUNDIR),

established in 2010, is an informal network of researchers with a common interest in dissemination and implementation science in a variety of different settings and sectors (e.g., mental health services, public health, acute care, emergency medicine, cancer, tobacco). WUNDIR holds monthly half day meetings to learn about new resources for D&I science, to provide peer critique of papers and grant proposals, and to plan joint projects. The group, currently with 74 members, works to forge a trans-disciplinary understanding of the methodological issues and conceptual challenges required for multi-year dissemination and implementation research grants.

The Gephardt Institute for Public Service, founded in 2005, promotes lifelong civic engagement and sustained community impact through educationally-based service initiatives at the University. Current initiatives include increasing its brokering of interdisciplinary partnerships and activities to maximize internal resources and faculty expertise; supporting core community-based courses; enhancing the cross-cultural training and academic knowledge necessary for successful international service trips and programs; removing barriers experienced by students in their desire to pursue social change; equipping students with the skills necessary for effective political action and public service careers; and developing programming to leverage alumni service leadership across the nation and the world.

The Office of the Vice Chancellor of Research (OVCR) exists to promote and support Washington University researchers as they seek funding sponsors, conduct world-class research, and share their research results through publication and commercialization for the use and benefit of the public. The University's OVCR is committed to providing leadership, support, and service to assure that investigators pursue and conduct the highest quality research and innovation, and that each individual conducting, reporting, and administering research understands and upholds the highest standards of ethical and professional conduct.

#### **Library Resources**

**The Washington University Libraries** are a powerful network of academic resources featuring 14 libraries across its campuses: the John M. Olin Library (the main library), Art & Architecture Library, Kopolow Business Library, Chemistry Library, Earth & Planetary Sciences Library, East Asian Library, Film & Media Archive, Law Library, Modern Graphic History Library, Gaylord Music Library, Pfeiffer Physics Library, Social Work (Brown School) Library, Bernard Becker Medical Library, West Campus Library and the University Archives.

Washington University Library holdings include 4.5 million books, periodicals, and government publications; 3.6 million microforms; more than 137,00 audiovisual titles; extensive collections of special and rare books, manuscripts and archives; and access to more than 65,000 electronic journals and more than 500,000 ebooks. The Libraries are a member of the Association of Research Libraries, the Center for Research Libraries, the HathiTrust, the Greater Western Library Alliance, and MOBIUS, among other organizations. Washington University Libraries have been a government documents depository since 1912, providing access to federal information in a variety of formats.

The Washington University community has instant 24/7 online access to its vast and ever-growing electronic library resources from virtually anywhere in the world. The Digital Gateway, maintained by Digital Library Services (DLS), offers services for developing digital projects, digital preservation, and making the scholarship of the University available open access.

The Bernard Becker Medical Library integrates a modern health sciences library, a media/learning resources center, a computer teaching and information management laboratory, and a health information network that links regional, national, and international information resources. The 8-level, 114,000 square foot facility houses more than 269,000 volumes and an extensive media collection, and is also one of the most technologically advanced health sciences libraries in the world.

The Brown School Library is home to one of the finest collections in the nation in the fields of child welfare, community development, family therapy, mental health, children and youth, gerontology, public health, public welfare, management of human services, and social policy. Approximately 52,000 books, journals, publications and audiovisuals comprise the library's total collection. The library subscribes to more than 450 periodicals in paper and electronic format and has access to numerous online databases and full-text journals.

## **Brown School Administrative Resources**

The Brown School houses numerous administrative supports that work in conjunction with each other and central University offices to support and facilitate research efforts.

**The Office of Research Administration** provides quality research administration and service coordination to facilitate research and scholarly activities at the Brown School. Services include proposal development support, comprehensive pre- and post -award management, administrative and compliance oversight, and analysis to inform strategic planning for sponsored research activity.

**The Business Office** provides accounting and bookkeeping for all externally funded research and manages processes for tracking and processing payroll, purchasing, and reimbursement activities and documentation.

**The Service Center** provides a variety of services tailored to support the educational, research, service and outreach activities of the School. Services include assistance with reproduction and copying services, mail and shipping services, meeting and event coordination, operations, and facilities and maintenance expedition.

**The Office of Communications** advances the reputation and visibility of the School by directing internal and external communication efforts. Services include oversight of initiatives to promote academic and research activities through print, broadcast, online and social media outlets, assistance in the execution of creative strategy, and production and copyediting support.

The Office of Information Technology (IT) provides a range of technical support services encompassing the following areas: desktop support, application development, audio visual services, and network and server administration.

#### **Technology Resources**

Washington University maintains a state-of-the-art technological support system for faculty and staff. All computer systems throughout Washington University are on a campus-wide network that supports both TCP/IP allowing rapid communication of data among investigators. The Washington University core network provides enterprise services for the faculty, staff, schools and departments of Washington University. The core network is comprised of the network hardware and the services and infrastructure to support the Core. The enterprise core network is comprised Dual Cisco Nexus 7009; connection to internet and internet 2; DNS/DHCP services provided by InfoBlox appliances; wireless network using a combo Cisco and Meru Wireless; SPAM filtering and

email redirection using redundant IronPort appliances; fiber infrastructure; CATV infrastructure that supports cable TV; and telecommunications rooms that house fiber, cable, network equipment and UPSs.

The Brown School provides email (Microsoft Exchange), Web Platform (Microsoft SharePoint and .NET), database (Microsoft SQL Server) and file share services. All services are housed in a University datacenter with redundant power and environmental control, staffed 24/7. This datacenter has a connection to the University's fiber infrastructure, providing access to the rest of campus as well as the Internet. Available software includes Windows 7, OSX, Lisrel, Stata, NVivo, SPSS, SAS, Microsoft Office, Qualtrics, and ARCVIEW/GIS 10.0.

The Brown School leverages the University's Cisco firewall to provide data and communication security for the perimeter of the network, and allows administrators to control resources accessible to external sources. VPN services are provided for secure access from outside the firewall. The School secures its web infrastructure with 2048-bit SSL certificates.

Washington University's Geographic Information Systems (GIS) capacity is supported by faculty and staff who lead the University's GIS initiative and Geographic Information Systems Office. The Brown School benefits from the University-wide license to use GIS technology, as it permits students, staff, and faculty across the entire campus accessibility to this critical, 21st century technology. Current objectives include providing GIS educational opportunities to the University community, building the technological infrastructure, developing and expanding GIS as a research tool, and coordinating with the local and regional GIS community. Through the GIS initiative, Washington University in St. Louis is committed to being a leader in utilization and education concerning spatial technologies.

#### The Clark-Forum

At the heart of the new Hillman Hall is the Forum, a multiuse public space designed to host conferences, community events, and university programs. The Forum enhances the Brown School's ability to engage with community partners and stimulate dialogue among social work, public health, and policy experts. Mirroring the mission of the school, the expansion's glass facade welcomes the community with transparency and openness. It creates a strong visual connection between the future impact of the Brown School and its established traditions of innovation and foresight.

• Research Space: More than 20,000 square-feet of space for research centers and programs. The building design actively communicates the research findings of the Brown School and promotes collaboration internally and externally.

**Instruction Space:** Seven new, highly flexible classrooms, create a total of 17 for the school to accommodate a recent increase of 40 percent in the student population. The project also includes two new, state of the art pooled classrooms for the University's use.

**Student Space:** Flexible furnishings and technology are zoned to create areas of intense collaboration or quiet reflection. Rooms are designed to serve multiple purposes, anticipate changing teaching styles and tools, and maintain a longer functional life.

**Faculty Space:** Sixty-eight faculty offices across Brown Hall, Goldfarb Hall, and Hillman Hall to accommodate the recent 81% expansion of the Brown School faculty.

**Social Space:** More than 3,000 square feet of space designed to promote faculty, staff, and student interaction and collaboration. Multi-use spaces like the Forum and Nussbaum Plaza serve as a gathering space that fosters impromptu collaboration among students, faculty, staff, and the community.

**Meeting Space:** The school has more than 10 meeting rooms dispersed across the Brown School complex, available for use by faculty, staff, students and community organizations. The second floor of Hillman Hall features large, open spaces to encourage informal meetings and collaboration among Brown School's 34 different disciplines.

# **EQUIPMENT**

No article of tangible nonexpendable personal property having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit., per the definition as stated in 45 CFR Parts 74 and 92, will be utilized in this study.

Equipment Page 35

Contact PD/PI: NAAR, SYLVIE

OMB Number: 4040-0010 Expiration Date: 12/31/2022

# RESEARCH & RELATED Senior/Key Person Profile (Expanded)

			PROFILE - Project Dire	ctor/Principal Investigator	
Prefix:	First Name*:	SYLVIE	Middle Name	Last Name*: NAAR	Suffix:
Position/Title	<b>)</b> *:	Professor			
Organization	Name*:	FLORIDA STA	ATE UNIVERSITY		
Department:					
Division:					
Street1*:					
Street2:					
City*:					
County:					
State*:					
Province:					
Country*:					
Zip / Postal (	Code*:				
Phone Numb	per*:		Fax N	lumber:	
E-Mail*:					
Credential, e	e.g., agency log	gin:			
Project Role	*: PD/PI		Othe	Project Role Category:	
Degree Type	e: PHD		Degr	ee Year: 1995	
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Attach Curre	nt & Pending S	Support: File Na	me:		

			PROFILE - Ser	nior/Key Person	
Prefix:	First Name	:: DOUGLAS	Middle Name A	Last Name*: LUKE	Suffix:
Position/Ti	tle*:	Professor of	Social Work		
Organizati	on Name*:	Washington	University		
Departmer	nt:				
Division:					
Street1*:					
Street2:					
City*:					
County: State*:			I		
Province:					
Country*:					
Zip / Posta	l Code*:				
Phone Nur	mber*:		Fax N	lumber:	
E-Mail*:					
Credential	, e.g., agency l	ogin:			
Project Ro	le*: Other (Sp	pecify)	Other	Project Role Category: Lead Consortiu	m Investigator
Degree Ty	pe: PHD,BA		Degre	e Year: 1989	
Attach Bio	graphical Sket	ch*: File N	ame: Biosketch_l	_uke_2020_SN.pdf	
Attach Cur	rent & Pending	g Support: File N	lame:		

			PROFILE - Sen	ior/Key Person	
Prefix:	First Name*	: Ellis Midd	lle Name A	Last Name*: Ballard	Suffix:
Position/T	tle*:	Associate Director			
Organizati	on Name*:	Washington Univer	sity		
Departme	nt:				
Division:					
Street1*:					
Street2:					
City*:					
County:					
State*:					
Province:					
Country*:					
Zip / Posta	al Code*:				
Phone Nu	mber*:		Fax N	umber:	
E-Mail*:					
Credential	, e.g., agency lo	ogin:			
Project Ro	le*: Co-Invest	tigator	Other	Project Role Category:	
Degree Ty	pe: MSW,MP	H,BA	Degre	e Year: 2015,2015,2007	
Attach Bio	graphical Sketc	h*: File Name:	Ballard_bios	ketch-NIH_format_Sept2020_SN.pdf	
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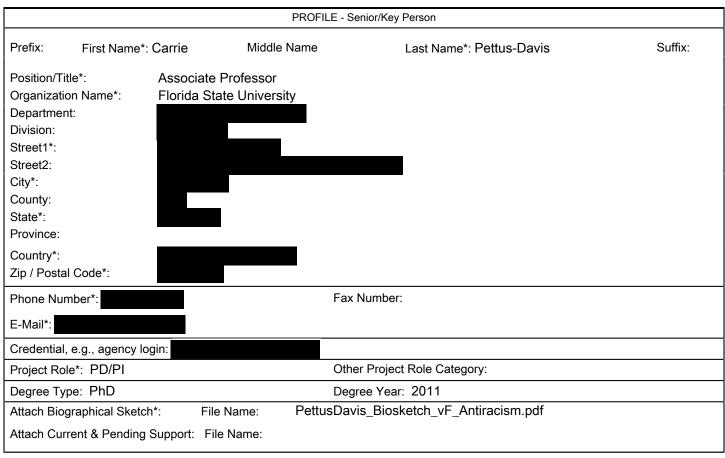
			PROFILE - Senior/	Key Person	
Prefix:	First Name*: T	odd Middl	e Name Bryan	Last Name*: Combs	Suffix:
Position/T	itle*:	Research Assistant	Professor		
Organizat	ion Name*:	Washington Univers	sity		
Departme	nt:				
Division:					
Street1*:					
Street2:					
City*:					
County:	Ī				
State*: Province:					
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Country*:	10.1				
Zip / Posta	al Code*:				
Phone Nu	mber*:		Fax Num	nber:	
E-Mail*:					
Credentia	l, e.g., agency logi	n:			
Project Ro	ole*: Co-Investiga	ator	Other Pr	oject Role Category:	
Degree Ty	/pe: PHD,MA,MA	A,BA	Degree \	Year: 2014,2008,2011,2002	
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			PROFILE -	Senior/Key Person	
Prefix:	First Name*: HEA	THER Middle N	lame A	Last Name*: FLYNN	Suffix:
Position/Tit Organization Department Division: Street1*: Street2: City*: County: State*: Province:	on Name*: FLC	ociate Professor PRIDA STATE UNIV	VERSITY		
Country*: Zip / Posta	I Code*:				
Phone Nun	nber*:		Fa	x Number:	
E-Mail*:					
Credential,	e.g., agency login:				
Project Rol	e*: Co-Investigator		Ot	her Project Role Category:	
Degree Typ	pe: PHD,MS,BS		De	egree Year: 1996,1992,1990	
	graphical Sketch*: rent & Pending Suppo	File Name: ort: File Name:	FlynnE	Biosketch_2020_Disparities_SN.pdf	

PROFILE - Senior/Key Person Suffix: Prefix: First Name\*: Norman Middle Name B. Last Name\*: Anderson Position/Title\*: Professor Florida State University Organization Name\*: Department: Division: Street1\*: Street2: City\*: County: State\*: Province: Country\*: Zip / Postal Code\*: Phone Number\*: Fax Number: E-Mail\*: Credential, e.g., agency login: Project Role\*: PD/PI Other Project Role Category: Degree Type: PhD Degree Year: 1983 Attach Biographical Sketch\*: Anderson\_NIH\_biosketch\_for\_FSU\_Tr01.pdf File Name: Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person Prefix: First Name\*: Penny Middle Name Ann Suffix: Last Name\*: Ralston Position/Title\*: Professor, Dean Emeritus & Director Organization Name\*: Florida State University Department: Division: Street1\*: Street2: City\*: County: State\*: Province: Country\*: Zip / Postal Code\*: Fax Number: Phone Number\*: E-Mail\*: Credential, e.g., agency login: Other Project Role Category: Project Role\*: Co-Investigator Degree Type: PHD,MED,BS Degree Year: 1978,1974,1971 2020\_Biosketch\_Penny\_Ralston\_SN.pdf Attach Biographical Sketch\*: File Name: Attach Current & Pending Support: File Name:

Prefix:			FROITEL - Selli	or/Key Person	
rielix.	First Name*	: CHRIS M	iddle Name W	Last Name*: SCHATSCHNEIDER	Suffix:
Position/Tit	le*:				
Organizatio	n Name*:	Florida State Uni	versity		
Departmen	t:	Psychology			
Division:					
Street1*:					
Street2:					
City*:					
County:					
State*:					
Province:					
Country*:					
Zip / Postal	Code*:				
Phone Nun	nber*:		Fax Nu	ımber:	
E-Mail*:					
Credential,	e.g., agency lo	ogin:			
Project Rol	e*: Co-Inves	tigator	Other I	Project Role Category:	
Degree Typ	e: PHD,BA		Degree	Year: 1994	
Attach Biog	raphical Sketo	ch*: File Name:	NIH_Schatso	chneider_biosketch_Sylvie_2020.pdf	
Attach Curr	ent & Pending	Support: File Name	:		



Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.** 

NAME: Sylvie Naar

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Distinguished Endowed Professor

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Michigan- Ann Arbor, MI	BA	1989	Psychology
University of Colorado – Boulder, CO	MA	1993	Clinical Psychology
University of Colorado – Boulder, CO	PhD	1995	Clinical Psychology
Wayne State Univ/CHM – Detroit, MI	Residency	1995	Pediatric Psychology
Wayne State Univ/CHM – Detroit, MI	Fellowship	1996	Pediatric Psychology

#### A. Personal Statement

**Role on Project:** For the proposed study, I will serve as the contact MPI and oversee project components as delineated in the MPI plan.

Qualifications: My work includes studies across the translation spectrum including T1 behavioral translation research (basic behavioral science to intervention development) as evidenced by a U01 and an R01 focused on phased T1 translation as well as T2, T3, and T4 translation (efficacy to implementation) with multiple R01s and a U19 addressing health equity in primarily Black and African Americans. I have led several workshops and published papers on innovative methods for T1 translation in the behavioral sciences in collaboration with leading experts in the field and NIH program directors that included translating systems science methods for public health. I direct the Center for Translational Behavioral Science at FSU with a mission of addressing health equity. I am the new director of the KL-2 training program as part of the Florida Clinical and Translational Science Award. I am experienced in managing complex, multicomponent extramurally funded projects with a focus on team science and community-engagement. I have development community advisory councils for research centers and programs and have developed a new model of community engagement by supporting our sexual and gender minority youth advisory council to form their own non-profit. I have had several research projects translating basic communication science and stigma research into provider interventions and have tested such interventions in two NIH Centers, one focusing on African Americans with obesity and one focusing on persons living with HIV. I have also utilized measurement development methods to develop observational rating scales of patient-provider communication in marginalized populations. I work closely with the Florida Department of Health on transforming sexual health and integrated mental and physical services for young adults of color.

- Czajkowski SM, Powell LH, Adler N, Naar-King S, Reynolds KD, Hunter CM, Laraia B, Olster DH, Perna FM, Peterson JC, Epel E, Boyington J, Charlson M. for the Obesity Related Behavioral Intervention Trial (ORBIT) Consortium. (2015). From Ideas to Efficacy: The ORBIT Model for Developing Behavioral Treatments for Chronic Diseases. *Health Psychology.* 34(10), 971-982. PMCID: PMC4522392
- 2. **Naar S**, Czajkowski S, Spring B. (2018). Innovative Study Designs and Methods for Optimizing and Implementing Behavioral Interventions to Improve Health. *Health Psychology*, 37(12):1081-1091.

- 3. **Naar S**, Hudgens MG, Brookmeyer R, Carcone A, Chapman J, Chowdhury S, Ciaranello A, Comulada WS, Ghosh S, Horvath KJ, Ingram L, LeGrand S, Reback CJ, Simpson K, Stanton B, Starks T, Swendeman D. (2019). Improving the Youth HIV Prevention and Care Cascades: Innovative Designs in the Adolescent Trials Network for HIV/AIDS Interventions. *AIDS Patient Care and STDs*, 33:9, 388-398. PMCID: PMC6745528
- 4. **Naar S**, Pennar A, Wang B, Brogan Hartlieb K, & Fortenberry D. (in press). Tailored Motivational Interviewing (TMI): Translating Basic Science in Skills Acquisition in a Behavioral Intervention to Improve Community Health Worker Motivational Interviewing Competence for Youth Living with HIV. *Health Psychology*.

# B. Positions and Honors Positions and Employment

1998 - 2003 2003 - 2007 2007 - 2012 2011 - 2015	Assistant Professor, Wayne State University, School of Medicine Assistant Professor, Wayne State University School of Medicine, Department of Pediatrics Associate Professor, Wayne State School of Medicine, Department Pediatrics and Psychiatry Associate Director, Wayne State School of Medicine, Pediatric Prevention Research Center
2012 - 2016 2012 - 2017	Director, Wayne State University, Interdisciplinary Program for Obesity Research and Education Professor, Wayne State University School of Medicine, Department Pediatrics and Psychiatry
2015 - 2016	Interim Director, Wayne State School of Medicine, Pediatric Prevention Research Center
2016 - 2017	Director, Division of Behavioral Sciences, Department of Family Medicine, Wayne State
	University School of Medicine
2018 - 2019	Adjunct Research Professor in the Quantitative Methodology Program in the Survey Research Center (SRC) of the Institute for Social Research (ISR) at the University of Michigan, Ann Arbor, Michigan
2017 -	Distinguished Endowed Professor, Florida State University, College of Medicine, Department of
	Behavioral Sciences and Social Medicine
2017 -	Director, Center for Translational Behavioral Science, Florida State University
2018 -	Director, K Scholar Program (CTSA KL2), Florida State University, Tallahassee, Florida

## Other Experience and Professional Memberships

1996 - 2017	Staff Psychologist, Children's Hospital of Michigan
1997 - 2017	Director, Project Challenge: Psychosocial Services for Children Affected by HIV
2002 - 2008	Co-Director, Horizons Project – A Comprehensive Continuum of HIV Services for Youth
2005 -	Motivational Interviewing Network of Trainers

## **Honors**

2005	Robert B. Johnson Diversity Award from the DMC Diversity Action Council
2011	Career Development Chair, Wayne State University
2011 - 2016	Helppie Endowed Professorship of Urban Health Research
2012	Wayne State University Board of Governors Faculty Recognition Award

#### C. Contribution to Science

- 1. I have focused my career on developing and testing empirically supported behavioral interventions to reduce health disparities in adolescents and young adults, targeting diseases disproportionately affecting Black and African Americans such as obesity, diabetes, and asthma and have been consistently extramurally funded for over a decade. I was the co-chair of the steering committee for the NIH ORBIT network (Obesity Research Behavioral Intervention Trials) I have authored over 160 articles in peer reviewed journals.
  - a. Ellis DA, **Naar-King S,** Chen X, Moltz K, Cunningham P.B, Idalski Carcone A. (2012). Multisystemic therapy compared to telephone support for youth with poorly controlled diabetes: Findings from a randomized controlled trial. *Annals of Behavioral Medicine*, 44, 207-215. PMCID: PMC3443313.
  - b. Ellis DA, Carcone AI, **Naar-King S**, Rajkumar D, Palmisano G and Moltz K. (2017). Adaptation of an evidence-based diabetes management intervention for delivery in community settings: Findings from a pilot randomized effectiveness trial. *Journal of pediatric psychology*, *44*(1), January/February 2019, pp.110 -125. PMID: 29186562.

- c. **Naar S**, Ellis D, Cunningham P, Pennar AL, Lam P, Brownstein NC, Bruzzese JM. (2018). Comprehensive Community-Based Intervention and Asthma Outcomes in African American Adolescents. *Pediatrics*, *142*(4):e20173737
- d. **Naar S,** Ellis DA, Carcone AI, Jacques-Tiura A, Cunningham PB, Templin T, Brogan Hartlieb K, Jen KL. (2019). Outcomes from a Sequential Multiple Assignment Randomized Trial (SMART) of Weight Loss Strategies for African American Adolescents with Obesity. *Annals of Behavioral Medicine*, 53:10, 928-938. PMCID: PMC6736439.
- 2. Program of research at the intersection of sexual, gender and ethnic minority communities. I have been involved with the NIH Adolescent Trials Network for HIV/AIDS interventions since 2001 as a member of the Behavioral Leadership and more recently as the chair of the Executive Committee, contributing to the intellectual and scientific direction of the behavioral research across the network. I have been protocol chair of several intervention studies across the translational spectrum, and am currently PI of a U19 focusing on scale up of such interventions.
  - a. Naar-King, S., Parsons, J.T., Murphy, D.A., Chen, X., Harris, R., Belzer, M. & the ATN Protocol Team. (2009). Improving health outcomes for youth living with HIV: A multisite randomized trial of a motivational intervention targeting multiple risk behaviors. *Jama Pediatrics*, 163(12):1092-1098. PMCID: PMC2843389.
  - b. Outlaw AY, **Naar-King S**, Parsons JT, Green-Jones M, Janisse H & Secord E. (2010). Using motivational interviewing in HIV field outreach with young African American men who have sex with men: A randomized clinical trial. *American Journal of Public Health*, 100:S146-S151. Epub 2010 Feb 10. PMID: 20147689. PMCID: PMC2837438.
  - c. Tanney M, **Naar-King S,** MacDonell K. (2012). Depression and stigma in high risk youth living with HIV (YLH): A Multisite Study. *Journal of Pediatric Health Care*, 26(4), 300-305. PMCID: PMC3383773.
  - d. Naar S, Robles G, MacDonell K, Dinaj-Koci V, Simpson KN, Lam P, Parsons JT, Sizemore KM, & Starks TJ. (2020). Comparative Effectiveness of Community vs Clinic Healthy Choices Motivational Intervention to Improve Health Behaviors Among Youth Living with HIV: A Randomized Trial. JAMA Open Network.
- 3. I have spent the last decade developing and testing implementation strategies to promote the diffusion of behavioral innovations in health care settings. In addition to addressing patient-provider communication, I have collaborated with leaders in implementation science to develop and test implementation strategies to address barriers and promote facilitators of uptake and sustainment of such innovations. Through community partnerships at the individual patient, provider and public health systems level, I am committed to community engagement at every step of the translational process. I co-lead the implementation science core for the Adolescent Trials Network, am current chair of the Community-Engaged Dissemination/Implementation Research working group and lead the community stakeholder panel the for the network. I am an implementation science consultant for the NIH Centers for AIDS Research.
  - a. Idalski Carcone A, Naar-King S, Brogan KE, Albrecht T, Barton E, Foster T, Martin T, Marshall S. (2013). Provider Communication Behaviors that Predict Motivation to Change in Black Adolescents with Obesity. *Journal of Development and Behavioral Pediatrics*, 34(8), 599-608. PMCID: PMC4184411.
  - b. Idalski Carcone A, Coyle K, Gurung S, Cain D, Dilones RE, Jadwin-Cakmak L, Parsons JT, **Naar, S**. (2019). Implementation Science Research Examining the Integration of Evidence-Based Practices Into HIV Prevention and Clinical Care: Protocol for a Mixed-Methods Study Using the Exploration, Preparation, Implementation, and Sustainment (EPIS) Model. *JMIR Res Protoc*, 8:5, e11202. PMCID: PMC6552408
  - c. **Naar S,** Parsons J, Stanton BF. (2019). Adolescent trials network for HIV-AIDS Scale It Up program: protocol for a rational and overview. *JMIR Research Protocols*, 8(2);e11204. PMCID: PMC6376339. doi: 10.2196/11204.
  - d. **Naar S,** MacDonell K, Chapman J, Todd L, Gurung S, Cain D, Dilones RE, Parsons JT. (2019). Testing a Motivational Interviewing Implementation Intervention in Adolescent HIV Clinics: Protocol for a Type 3 Hybrid Implementation-Effectiveness Trial. *JMIR Research Protocols*, 8(6): e11200. http://doi: 10.2196/11200. PMCID: PMC6682301.

- 4. I am a member of the Motivational Interviewing Network of Trainers (MINT), an interdisciplinary group focused on diffusing an evidence-based approach to patient provider communication, one that has been shown to be particularly effective with minority populations. I provide numerous MI trainings to agencies and treatment organizations locally, nationally and internationally, and I have conducted early phase trials, clinical trials, and most recently implementation science studies. I worked closely with the developers of MI (Miller and Rollnick) to author the first textbook on the use of MI with adolescents and young adults.
  - a. **Naar-King, S.** & Suarez, M. (2011). *Motivational Interviewing with Adolescents and Young Adults*. Guilford Press, New York, NY.
  - b. **Naar-King S.**, Earnshaw P., Breckon J. (2013). Toward a universal maintenance intervention: Integrating cognitive-behavioral treatment with motivational interviewing for maintenance of behavior change. *Journal of Cognitive Psychotherapy*, *27*(2), 126-137.
  - c. Naar S, Flynn H. *Motivational Interviewing and the treatment of depression*. In: Arkowitz H, Miller WR, Rollnick S, editors. Motivational Interviewing in the treatment of psychological problems. New York: The Guilford Press; 2015. pp. 170–192.
  - d. **Naar, S.** & Safren, S. (2017). *Integrating Motivational Interviewing and Cognitive-Behavioral Interventions*. Guilford Press, New York, NY.

#### Complete List of Published Work in MyBibliography:

http://www.ncbi.nlm.nih.gov/sites/myncbi/sylvie.naar-king.1/bibliography/40724428/public/?sort=date&direction= descending

## D. Research Support

**Ongoing Support** 

R01 HL138633 (NIH) Ellis (PI) 8/1/17 - 6/30/22

Translating an Efficacious Illness Management Intervention for African American Youth with Poorly Controlled Asthma to Real World Settings

The goal of the study is to deliver a family based behavioral intervention for asthma management in real-world inner-city settings.

Role: Consultant

R01 HL133506 (NIH/NHLBI)

MacDonell (PI)

9/1/16 - 3/30/21

Multi-Component Technology Intervention for African American Emerging Adults with Asthma The purpose of this project is to test a brief multi-component, technology-based intervention, rigorously developed with pilot funding from NHLBI, to improve asthma controller medication adherence in urban African American emerging adults.

Role: Consultant

3U19HD089875-03S2 (NIH)

Naar (PI)

9/30/16 - 5/31/21

Scale It Up: Effectiveness-implementation research to enhance HIV-related self-management among adolescents and young adults

The goal of this program is to conduct research, both independently and collaboratively, with HIV-infected and HIV-at-risk pre-adolescents, adolescents, and young adults up to the age of 25.

Role: PI

5U24HD089880 (NIH)

LaVange (PI)

6/1/18 - 5/31/21

University of North Carolina at Chapel Hill

Adolescent Medicine Trials Network for HIV/AIDS interventions (ATN) Coordinating Center Funding for participation in the Executive Committee of the ATN, lead of the Community-Engaged Dissemination and Implementation Research Working Group, and protocol lead of an electronic health records initiative.

Role: Subaward PI

R01 MH108442-01 (NIH/NIMH)

Outlaw (PI)

8/1/15 - 4/30/21

Motivational Enhancement System for Adherence (MESA) in Youth Starting ART

The goal of this study is to test a brief, 2-session, computer-based motivational intervention to prevent adherence difficulties among youth newly recommended to begin ART.

Role: Co-I

## **Completed Research Support**

UL1TR001427 (NIH)

Sheffler (PI)

4/1/19 - 4/1/20

Early phase feasibility trial: Examining the effects of diet on genetic and psychosocial risks for Alzheimer's

disease

Funding from University of Florida and its Clinical Translational Science Award (NIH Award Number UL1TR001427). Role: Co-Investigator

1R01AA022891-01 (NIH/NIAAA)

Naar (PI)

9/1/13 - 8/31/18

Comparing the effectiveness of two alcohol+adherence interventions for HIV+ youth

The goal is to conduct a comparative effectiveness trial in real-world clinic settings to test an efficacious intervention designed to reduce alcohol use and improve medication adherence and HIV-related health outcomes among HIV-positive youth.

1U65PS005033-01 (CDC PS15-1510)

Outlaw (PI)

9/30/15 - 9/29/18

Health Department Demonstration Projects for Comprehensive Prevention, Care, Behavioral Health, and Social Services for Men Who Have Sex with Men (MSM) of Color at Risk for and Living with HIV Infection This goal of this project is to provide training and technical assistance to health departments to ensure comprehensive, competent (culturally, developmentally, and linguistically) service provision for MSM of color.

Role: Co-I

R34 MH103049-01A1 (NIH/NIMH)

MacDonell/Naar (PIs)

8/1/15 - 5/31/18

Development of an MI Implementation Intervention in Adolescent HIV Care Settings

The goal of this study is to develop an implementation intervention to increase evidence-based patient-provider communication strategies using a Motivational Interviewing framework.

Role: Co-PI

1R01DA034497-01 (NIH/NIDA)

Naar-King/Woods (PIs)

8/01/12 - 5/31/18

Targeting Prospective Memory to Improve HIV Adherence in Adolescents at Risk for Substance Abuse This grant includes three phases to develop and pilot test a new intervention to improve adherence among youth living with HIV by targeting prospective memory.

Role: Co-PI

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Luke, Douglas A.

era commons user name:

POSITION TITLE: Professor of Public Health; Director, Center of Public Health Systems Science

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Washington University, St. Louis, MO	B.A.	1983	Psychology
University of Illinois, Urbana, IL	M.A.	1988	Clinical Psychology
University of Illinois, Urbana, IL	Ph.D.	1990	Community/Clinical Psychology

#### A. Personal Statement

**Role on Project:** I will lead the systems science team and liaison to the other teams for all aims. I will participate in dissemination efforts. I have worked closely with MPI Pettus-Davis when she was at my university prior to FSU and look forward to continued collaborations. MPI Naar has leveraged my systems science work in public health for early phase translational behavioral science presented at NIH intervention development workshops.

#### **Qualifications:**

I am currently Professor and Director of the Center for Public Health Systems Science (CPHSS) at the Brown School at Washington University in St. Louis. I am a leading researcher in the areas of health policy, tobacco control, systems science, and implementation science. The work that I direct at CPHSS focuses on the evaluation, dissemination, and implementation of evidence-based public health policies. Much of this work has focused on tobacco control, particularly how local, state, and national public health systems can design, implement, and evaluate evidence-based tobacco control policies. This work has been disseminated in top public health journals as well as in important policy documents such as CDC's Best Practices for Comprehensive Tobacco Control. I was co-PI (along with Kurt Ribisl and Lisa Henriksen) of a 5-year, NCI funded study (Maximizing State & Local Policies to Restrict Tobacco Marketing at Point of Sale) that developed the first ever national surveillance system of point-of-sale policies in tobacco retailers. I have promoted the use of systems science methods in public health for over 15 years, particularly network analysis and agent-based modeling. I published the first comprehensive reviews of network methods and systems science methods in public health. More recently, I was a member of the panel that produced the recent Institute of Medicine Report, Assessing the Use of Agent-Based Models for Tobacco Regulation, which provided the FDA and other public health scientists with guidance on how best to use agent-based computational models to inform tobacco control regulation and policy. I have also served for the past ten years as the director of the evaluation core for the Institute of Clinical and Translational Sciences (ICTS) at Washington University.

- a. **Luke, D. A.**, & Stamatakis, K. A. (2012). Systems science methods in public health: Dynamics, agents, and networks. *Annual Review of Public Health*, *33*, 357-376. PMCID: PMC3644212.
- b. Schell, S. F., **Luke, D. A.,** Schooley, M. W., Elliott, M. B., Herbers, S. H., Mueller, N. B., & Bunger, A. C. (2013). Public health program capacity for sustainability: A new framework. *Implementation Science*. *8(1)*.
- c. Luke, D. A. (2015). A User's Guide to Network Analysis in R. Springer.
- d. **Luke, D. A.,** Hammond, R. A., Combs, T., Sorg, A., Kasman, M., Mack-Crane, W., Ribisl, K. M., & Henriksen. (2017). Tobacco Town: Computational modeling of policy options to reduce tobacco retailer density. *American Journal of Public Health*, *107*(5), 740-746.

#### **B.** Positions and Honors

## **Positions and Employment**

1990-1994	Visiting Assistant Professor of Psychology, Michigan State University, East Lansing, MI
1994-2000	Assistant Professor in Community Health-Biostatistics, Saint Louis University, School of Public
	Health, Department of Community Health, St. Louis, MO
2000-2001	Visiting Associate Professor, Department of Psychology, Harvard University
2000-2007	Associate Professor of Community Health and Director, Center for Tobacco Policy Research.
	Saint Louis University, School of Public Health, St. Louis, MO
2007-2008	Professor of Community Health in Biostatistics and Director, Center for Tobacco Policy
	Research, Saint Louis University, School of Public Health
2008-present	Professor of Public Health and Director, Center for Public Health Systems Science, Brown
	School, Washington University, St. Louis, MO

## Other Experience, Professional Memberships, Honors

1999	Setting phenotypes in a mutual help organization: Expanding behavior setting theory selected as one of the 10 most influential methodology articles published in the first 25 years of the
	American Journal of Community Psychology
2006-2011	Member, NIH CSR Study Section: Community Influences on Health Behavior, National Institutes
	of Health
2012-2014	Member, Interagency Committee on Smoking and Health, Dept. of Health and Human Services
2014-2015	Member, Committee on the Assessment of Models Used to Predict the Effect of Policies
	Related to Tobacco Regulation, Institute of Medicine
2016	Elected to Delta Omega, Public Health Honorary Society
2019	Faculty Achievement Award, Brown School

#### C. Contributions to Science

## 1. Tobacco control policy

Tobacco use remains the leading preventable cause of death in the U.S. and around the world. Most of my public health policy work has focused on evaluation of evidence-based tobacco control policies, as well as research on how the tobacco industry impedes the dissemination and implementation of effective policies. Our early work helped to counter the tobacco industry's assertions that it did not engage in targeted marketing of tobacco products to minorities and other at risk groups. Our more recent work has focused on the dissemination and implementation of effective tobacco control policies, especially at retailer settings. We have been active disseminators of this work; for example a number of our studies have been entered as public comments in support of FDA's tobacco regulatory efforts. More notably, the Office of Smoking and Health (OSH) at the Centers for Disease Control and Prevention (CDC) have incorporated results of our research and evaluation into their latest evidence-based guideline *Best Practices for Comprehensive Tobacco Control Programs*, as well as their latest funding RFA for state tobacco control programs.

- a. **Luke, D.A.,** Esmundo, E., & Bloom, Y. (2000). Smoke signs: Patterns of tobacco billboard advertising in a metropolitan region. *Tobacco Control, 9,* 16-23.
- b. **Luke, D.A**., & Krauss, M. (2004). Where there's smoke there's money: Tobacco industry campaign contributions and U.S. Congressional voting. *American Journal of Preventive Medicine, 27,* 363-372.
- c. **Luke, D. A.,** Ribisl, K. M., Smith, C., & Sorg, A. A. (2011). Family Smoking Prevention and Tobacco Control Act: Banning outdoor tobacco advertising near schools and playgrounds. *American Journal of Preventive Medicine, 40,* 295-302. PMID: 21335260
- d. **Luke, D. A.,** Sorg, A. A., Combs, T., Robichaux, C. B., Moreland-Russell, S., Ribisl, K. M., & Henriksen, L. (2016). The tobacco retail policy landscape: A longitudinal survey of US states. *Tobacco Control, 25,* i44-i51. doi:10.1136/tobaccocontrol-2016-053075
- 2. Systems science methods in public health research and evaluation
  Systems approaches have received increasing attention in public health because traditional linear and
  reductionist study design and analytic approaches yield limited insights in the context of complex dynamic

systems. Over the past five years much of my work has been part of a call to incorporate more systems science methods in public health, especially in public health policy. In 2012 I published the first comprehensive review of systems science methods in the *Annual Review of Public Health*; in this paper I argued for greater use of new methods including system dynamics, network analysis, and agent-based modeling. In 2012, I was part of a team at Washington University that hosted NIH's Institute on Systems Science and Health, a national training conference in systems science methods. I served as the lead instructor for network analysis methods at that institute. In 2013 we received funding from NCI to build an agent-based model (called *Tobacco Town*) that is being used to study and test the effects of tobacco control policies in ways that are not possible in real-world settings, the first paper from this project has just been accepted by the *American Journal of Public Health*. Based on this systems science and tobacco control expertise, I was invited in 2014 to be a member of an Institute of Medicine (IOM) panel to review agent-based modeling for tobacco control policies, and provide guidance to the FDA in their tobacco regulatory efforts. This report included the development of the first ever evaluation framework for policy-relevant agent-based models.

- a. **Luke, D. A.**, & Stamatakis, K. A. (2012). Systems science methods in public health: Dynamics, agents, and networks. *Annual Review of Public Health*, *33*, 357-376. PMCID: PMC3644212.
- b. Institute of Medicine. (2015). Assessing the use of agent-based models for tobacco regulation. Washington, DC: The National Academies Press.
- c. **Luke, D. A.** (2017). Social networks in human disease. To appear in J. Loscalzo, A. L. Barabasi, and E. K. Silverman (Eds.), *Network medicine: Complex systems in human disease and therapeutics.*
- d. Luke, D. A., Hammond, R. A., Combs, T., Sorg, A., Kasman, M., Mack-Crane, W., Ribisl, K. M., & Henriksen. (2017). Tobacco Town: Computational modeling of policy options to reduce tobacco retailer density. *American Journal of Public Health*, 107(5), 740-746.

# 3. Dissemination & implementation science

A new field has emerged over the past decade or so, called (in the U.S. at least) dissemination and implementation science. The benefits of our investment in public health research can only be fully realized if the new evidence-based practices and policies that derive from public health science are widely disseminated and effectively implemented in healthcare settings, communities, and states. Much of my work has focused on how to improve dissemination and implementation of evidence-based policies, especially in tobacco control. Our evaluation of tobacco control state programs for CDC showed how tobacco control managers were aware of evidence-based guidelines, but community leaders and public health coalitions have much less awareness. We have also demonstrated a gap between tobacco control basic sciences and policy scientists, which slows down the process of translating science into public policy. My Center has produced over 50 reports, guidelines and other products that translate public health and clinical science and tailors this information for a wide variety of non-scientific audiences, including public health managers, funders, and policymakers. Recently, with funding from CDC, we have developed the first reliable and validated framework and assessment tool for measuring the sustainability of public health programs, the *Program Sustainability Assessment Tool* (PSAT). The PSAT has been used by over 5,000 public health and human service programs in the past six years, both domestically and internationally.

- a. Mueller, N.B., **Luke, D.A**., Herbers, S.H., & Montgomery, T.P. (2006). The *Best Practices:* Use of the guidelines by ten state tobacco control programs. *American Journal of Preventive Medicine*, *31*, 300-306. PMID: 16979454
- b. Harris, J.K., **Luke, D.A**., Zuckerman, R., & Shelton, S.C. (2009). Forty years of secondhand smoke research: The gap between discovery and delivery. *American Journal of Preventive Medicine, 36*, 538-548. PMID: 19372026
- c. **Luke, D. A.,** Calhoun, A., Robichaux, C. B., Elliott, M. B., & Moreland-Russell, S. (2014). The Program Sustainability Assessment Tool: A new instrument for public health programs. *Preventing Chronic Disease*, *11*, 130184. PMCID: PMC3900326.
- d. **Luke, D. A.,** Baumann, A. A., Carothers, B. J., Landsverk, J., & Proctor, E. K. (2016). Forging a link between mentoring and collaboration: a new training model for implementation science. *Implementation Science*, *11*(1), 137.

## 4. Network analysis in public health research and evaluation

There has been a growing understanding of the importance of social networks in public health science. Social networks influence health behavior (e.g., tobacco use), public health systems organize themselves

in networks (e.g., coalitions), and new scientific discoveries, policies, and practices are diffused through public health organizational networked systems. Much of my scientific career has focused on illustrating the utility of network analysis for studying public health organizations and systems. We published the first *Annual Review of Public Health* paper on network analysis in public health (receiving over 350 citations in the past nine years). Our empirical work has used network analysis to describe how state tobacco control programs are similarly organized; and has developed predictive models for collaboration among national tobacco control programs. We have also used network analysis to identify factors that support or impede dissemination of scientific discoveries and evidence-based guidelines across public health systems.

- a. **Luke, D.A**., & Harris, J.K. (2007). Network analysis in public health: History, methods and applications. *Annual Review of Public Health*, 28, 69-93. PMID: 17222078
- b. **Luke, D. A.**, Harris, J. K., Shelton, S., Allen, P., Carothers, B. J., & Mueller, N. B. (2010). Systems analysis of collaboration in 5 national tobacco control networks. *American Journal of Public Health,* 100, 1290-1297. PMCID: PMC2882404
- c. **Luke, D. A**. (2015). *A user's guide to network analysis in R.* Springer International Publications.
- d. Dhand, A., **Luke, D. A.,** Carothers, B. J., & Evanoff, B. A. (2016). Academic cross-pollination: The role of disciplinary affiliation in research collaboration. *PLoS ONE, 11(1):e0145916.*

## 5. Quantitative methods and research design

Public health science benefits if it has a wide variety of quantitative and analytic tools that are frequently used and taught to new public health scholars and students. Over the past few decades I have used a variety of quantitative methods in my empirical research, I have written tutorials and textbooks highlighting these same methods, and have developed and delivered numerous workshops, training sessions, and graduate-level courses focused on these methods. In several methodological papers I suggest that public health and the health sciences underutilize methods that can appropriately assess contextual effects, capture changes over time, or describe relational patterns in networks and complex systems. Specifically, I have used and highlighted the utility of cluster analysis, survival analysis, mixed-effects and multilevel modeling, longitudinal analysis, GIS, network analysis, and agent-based modeling. My book *Multilevel modeling* has been cited over 1,000 times, and it is among the top 20 best selling books of the Sage 'Green Book' series. My 1999 paper *Expanding behavior setting theory: Setting phenotypes in a mutual help organization* which used cluster analysis to identify stable patterns of change in a self-help organization, was selected as one of the 10 most influential methodology articles published in the first 25 years of the *American Journal of Community Psychology*.

- a. Rapkin, B., & **Luke, D. A.** (1993). Cluster analysis in community research: Epistemology and practice. *American Journal of Community Psychology, 21,* 247-277.
- b. **Luke, D. A.**, & Homan, S. M. (1998). Time and change: Using survival analysis in clinical assessment and treatment evaluation. *Psychological Assessment*, *10*, 360-378.
- c. **Luke, D.A**. (2004). *Multilevel modeling*. Sage University Papers Series on Quantitative Applications in the Social Sciences. Thousand Oaks, CA: Sage Publications.
- d. **Luke, D. A.** (2005). Getting the big picture in community science: Methods that capture context. *American Journal of Community Psychology*, *35*, 185-200.

#### Complete List of Published Work in MyBibliography:

http://www.ncbi.nlm.nih.gov/sites/myncbi/douglas.luke.1/bibliography/47634546/public/?sort=date&direction=ascending

# D. Research Support

## **Ongoing**

P01 CA225597-01 (Luke, Ribisl, Henriksen, MPIs)

09/01/2018 - 08/31/2023

University of North Carolina (Prime is UNC)

# ASPIRE: Advancing Science & Practice in the Retail Environment

The ASPiRE Program Project aims to build a rigorous, scientific evidence base for effective tobacco control in the retail environment to reduce tobacco use, tobacco-related disparities, and the public health burdens of tobacco including tobacco- related cancers.

Role: Principal Investigator (multi)

200-2015-87568 (Luke, Moreland-Russell, PI)

09/28/2012-09/27/2020

#### CDC

## **Program Sustainability Assessment Tool and User Guide Support Services**

The purpose of this acquisition is to provide ongoing support to CDC through the development of products and materials that help assess tobacco control programs with implementing evidence-based strategies, interventions, and activities.

Role: Co-Investigator

2 P30 DK092950-06

(Haire-Joshu, PI)

08/01/2016-07/31/2020

# **Washington University Center for Diabetes Translation Research**

The WU-CDTR is a resource to investigators committed to translating interventions that have demonstrated efficacy into healthcare settings, communities, and populations at risk.

Role: PASSA Core Co-Director

5 R25 MH080916-06

(Proctor, PI)

07/012015-03/31/2020

## Implementation Research Institute for Mental Health Services (IRI-MHS)

This R25 seeks support to build, maintain, and sustain an innovative mentoring network for implementation science in mental health. This network will extend in creative new ways the Implementation Research Institute, which has successfully trained 43 new mental health implementation researchers.

Role: Co-Investigator

5 R01 CA214530-03

(Brownson, PI)

04/01/2017-03/31/2022

## **Mis-Implementation in Cancer Prevention and Control**

This proposal seeks to describe the extent of cancer control mis-implementation and to identify leverage points for addressing mis-implementation in the United States.

Role: Co-Investigator

R01CA203844-01A1

(Moreland-Russell, PI)

08/05/2017 - 07/31/2021

## **Establishing the Program Sustainability Action Planning Training Model**

We propose a quasi-experimental effectiveness trial to evaluate the effectiveness of the Program Sustainability Action Planning Training Curricula in improving the sustainability capacity and institutionalization of state Tobacco Control (TC) programs.

Role: Co-Investigator

P50CA244431-01

(Brownson/Colditz, PI)

09/18/2019-08/31/2024

## **Center for Cancer Control (WU-ISCCC)**

The overall goal of the WU-ISCCC is to build a rigorous, scientific evidence base for rapid-cycle implementation research to increase the reach, external validity, and sustainability of effective cancer control interventions. Our focus is on disadvantaged and minority populations in rural and other under served communities.

Role: Co-Investigator

N/A

(Luke, PI)

07/01/2019-12/31/2022

# Interact for Health

## **Tobacco 21 Evaluation**

The overall goal of this award is the evaluation of Tobacco 21's prevention of youth and young adult smoking initiation by removing social sources, and changing attitudes and social norms.

Role: PI

## **Completed**

N/A

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.** 

NAME: BALLARD, Ellis A

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Incoming Director, Social System Design Lab; Assistant Professor of Practice, Brown School at Washington University in St. Louis, effective July 1, 2020

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Oberlin College, Oberlin, OH	BA	05/2007	History & English Literature
Washington University in St. Louis, MO	M.S.W	05/2015	Social Work
Washington University in St. Louis, MO	M.P.H	05/2015	Public Health

#### A. Personal Statement

**Role on Project:** For this transformative R01, I will participate in the systems science team and lead the community-engaged model building efforts for Aim 1. I will also participate in dissemination efforts.

**Qualifications:** I am the director of the Social System Design Lab, and an Assistant Professor of Practice at the Brown School at Washington University in St. Louis. I work closely Dr. Luke, head of systems science team and lead of the simulation modeling efforts at the same university. I am a community based researcher working to advance methods for participatory modeling with communities to advance health access and social justice.

I lead a team that develops system dynamics models with a specialization in developing community models using participatory group model building methods. I have extensive experience leading and training research teams in the design and use of participatory group model building exercises, as well as training front line staff and organizational partners in the use of system dynamics models for systems thinking. My work has contributed to research funded by the Robert Wood Johnson Foundation, Bill & Melinda Gates Foundation, Wellcome Trust, and the European Social Research Council. This work has included developing and training international teams to work with diverse stakeholders in multiple languages (e.g., English, Spanish, Portuguese, Hindi, Telegu, Kannada, Pashto, Dari), diverse settings including both rural and urban settings in low income settings internationally (e.g., rural India, rural Afghanistan) and within the United States.

#### **B. POSITIONS AND HONORS**

## **Positions and Employment**

2007-2010	In-Asia Fellow, Madurai, India, Oberlin Shansi Association
2010-2012	Program Development Manager, U.S. International Council on Disabilities
2012-2015	Field Coordinator, Rehabilitation of Afghans with Disabilities Impact Evaluation,
	Swedish Committee for Afghanistan & Washington University in St. Louis

2015- 2016 Program Manager for Global Health and Social Policy, Social System Design Lab 2016-2020 Associate Director, Social System Design Lab, Washington University in St. Louis 2020-Present Director, Social System Design Lab; Assistant Professor of Practice, Brown School

at Washington University in St. Louis

# Other Experience and Professional Memberships

2015-present Member, System Dynamics Society

#### C. CONTRIBUTIONS TO SCIENCE

## 1. Applying system dynamics approaches to community engaged health research

I have contributed methodological leadership on pioneering approaches to the use of group model building and community based system dynamics for implementation of evidence based social service and health interventions. These efforts are responding to the growing calls for the use of system science methods in implementation science, focusing on articulating the mechanics and value add of integrating community-based modeling approaches as well as more traditional modeling.

- Swierad, E., Huang, T. T.-K., Ballard, E., Flórez, K., & Li, S. (2020). Developing a Socioculturally Nuanced Systems Model of Childhood Obesity in Manhattan's Chinese American Community via Group Model Building. *Journal of Obesity*, 2020, 4819143.
- 2. Mui Y, **Ballard E**, Lopatin E, Thornton RLJ, Pollack Porter K, Gittelsohn J. (2019). A community-based system dynamics approach suggests solutions for improving healthy food access in a low-income urban environment. *PLOS ONE* 14(5): e0216985.
- 3. Ramsey, A.T.; Prentice, D; **Ballard, E.**; Chen, L; & Bierut, L.J. (2019). Mapping the way to improved hospital smoking cessation treatment: A systems approach with mixed methods. *BMJ Open, 9(7)*
- 4. Trani, J.-F., **Ballard, E.,** Bakhshi, P., Hovmand, P.S. Community based system dynamics as a method for understanding and acting on messy problems: a case study for global mental health intervention in Afghanistan. 2016. *Conflict and Health*.

## 2. Advancing methods for participation in system dynamics modeling

Advanced group model building approaches for building system dynamics models with local community participation, focusing on the methodological and ethical challenges of involving traditionally marginalized or ignored voices in the modeling process.

- 1. Liem, W. & **Ballard**, **E**. Advancing the methods for informing group model building sub-script design decisions and script adaptations. Accepted for presentation at the 2020 International Conference of the System Dynamics Society in Bergen, Norway.
- Kuhlberg, J.A.; Headen, I.; Ballard, E.; Martin, D. Leveraging CBSD to Advance Community Engaged Approaches to Identifying Structural Drivers of Racial Bias in Health Diagnostic Algorithms. Accepted for presentation to the 2020 International Conference of the System Dynamics Society in Bergen, Norway.
- 3. Werner, K.; **Ballard, E.** Kuhlberg, J.A. Provisional principles for the practice of Community Based System Dynamics. Accepted for presentation at the 2020 International Conference of the System Dynamics Society in Bergen, Norway.
- 4. **Ballard, E.**; Hovmand, P.S.; Zhu, Y.; Lin, S.; Hu, R.; & Zhao, D. (2019). Group model building in cross-cultural contexts: Sub-script unit testing for GMB workshop design and adaptation. Poster presented at the 2019 International Conference of the System Dynamics Society in Albuquerque, NM.

Advanced theory on conceptualizing impact of group model building and system dynamics modeling projects through the concept of "technological rules". This concept provides a theoretical grounding for the design and

measurement of impact of modeling interventions both through impact on policy or program efforts and through changes in mental models of stakeholders.

- 1. **Ballard, E.**; Priyadarshini, P.; & Werner, K. (Under review). What is the status of a boundary object when filtered through multiple layers of translation?
- 2. Hovmand, P.S. & **Ballard**, **E**. 2018. Moving from Mental Models to Technological Rules for Evaluating Impact. Presented at the International System Dynamics Conference 2018 in Reykjavik, Iceland

Contributed to the development of methods for the use of community-based system dynamics approaches to build alignment within transdisciplinary research collaborations. This approach to modeling focuses on building capabilities for modeling and understanding complex dynamic systems through the feedback perspective, and uses models to articulate the interdependencies between multiple disciplinary traditions, institutional goals, and contexts.

- Langellier, B.A.; Kuhlberg, J.A.; Ballard, E.. Slesinski, C.; Stankov, I.; Gouveia, N.; Meiesel, J.D.; Kroker-Lobos, M.F.; Sarmiento, O.L.; Teixeira, W.; & Diez Rous, A.V. (2019). Using community based system dynamics modeling to understand the complex factors that influence health in cities: The SALURBAL study. Health and Place, 60.
- 2. **Ballard, E.** Farrell, A. Long, M. (2020) Community-based system dynamics for mobilizing communities to advance school health. *Journal of School Health*.

Complete List of Published Work in MyBibliography: <a href="https://www.ncbi.nlm.nih.gov/myncbi/1xevxc9okv-wQP/bibliography/public/">https://www.ncbi.nlm.nih.gov/myncbi/1xevxc9okv-wQP/bibliography/public/</a>

## D. RESEARCH SUPPORT

# **Ongoing**

Hovmand (PI) 2019-2020

Fogarty International Center - NIH

"Real Options Strategies for Achieving Scale" focuses on developing innovative simulation modeling and community based modeling methods to inform implementation strategies for promoting LPG stove usage in rural India.

Role: Investigator

Purnell (PI) 2017-2020

Robert Wood Johnson Foundation

"Advancing systemic changes to promote healthy school environments" explores novel system science methods to inform implementation of the *Whole Child, Whole School, Whole Community* framework. The project utilized group model building with diverse stakeholder groups among two regional school districts. Role: Investigator

Diez Roux (PI, Drexel) 2017-2021

Wellcome Trust, UK

"Our Planet Our Health: What makes cities healthy, equitable and environmentally sustainable? Lessons from Latin America" focuses on understanding what makes cities healthy, equitable and environmentally sustainable in Latin America using systems science methods including community based system dynamics in three Latin American cities. The Social System Design Lab provided design leadership and training for a group of transdisciplinary researchers to facilitate community group model building workshops with policymakers and NGO representatives in three Latin American countries.

Role: Trainer and Modeler

## **Completed**

Munar (PI, George Washington University)

2017-2019

Bill & Melinda Gates Foundation

"Spreading lessons and sustaining improvements in primary health care (PHC) system performance in Mesoamerica" explores the use of system dynamics models and group model building for systems-informed policy dialogue in Mesoamerica. The Social System Design Lab worked with a team from the InterAmerican Development Bank to design two system dynamics-based policy dialogue workshops with policymakers from Mesoamerica.

Role: Investigator

Trani (PI) 2018-2022

Economic and Social Research Council, UK

"Strengthening school accountability mechanisms through participation: Addressing Education Quality and Equity in Afghanistan and Pakistan" focuses on applying and evaluating community based system dynamics with school improvement communities in Pakistan and Afghanistan in a randomized controlled trial.

Role: Trainer and Modeler

Hovmand (Co-I) 2018

Ministry of Social and Family (MSF) Development, Singapore

"Child Welfare Workforce Turnover" is an exploratory study to apply system dynamics to identify potential leverage points for reducing child welfare workforce turnover.

Role: Investigator

Ramsey (PI) 2017-2018

Barnes Jewish Hospital Foundation

"Racial disparities in inpatient smoking cessation prescription" focused on the use of group model building approaches to understand system structure drivers of emergent racial disparities in smoking cessation prescription. The research engaged prescribers, nurses and social workers, medical residents, and patients to develop system models of prescription decision making.

Role: Investigator

Munar (PI, George Washington University)

2016-2018

Bill & Melinda Gates Foundation

"Novel approaches to measuring demand-side community perceptions and barriers to family planning via social network analysis in Kenya" prototypes new system science methods for understanding modern conctraception uptake in Sub-Saharan Africa.

Role: Investigator

Hovmand (PI) 2016-2018

Lupina Foundation

"Understanding and Accelerating Healthcare Reforms in China for Urban Migrant Workers Using Community Based System Dynamics" focused on understanding the implementation of policies and programs to address social determinants of health in migrant workers and their families in Shanghai, China using system dynamics and group model building.

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.** 

NAME: Combs, Todd B.

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Research Assistant Professor

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Missouri, St. Louis, MO	BA	08/2002	Anthropology
University of Missouri, St. Louis, MO	MA	05/2011	Political Science & Public Policy
University of Missouri, St. Louis, MO	Ph.D.	05/2014	Political Science & Public Policy

#### A. Personal Statement

**Role on Project:** For this transformative R01, I will participate as co-investigator on the systems science team and lead the simulation models for Aim 2.

Qualifications: I am a Research Assistant Professor at the Brown School of Social Work at Washington University in St. Louis and serve as Assistant Director of Research for the Center for Public Health Systems Science in that school. Currently, I lead and manage projects and analyses for multiple projects including the design of data collection tools, collection of primary and secondary quantitative and qualitative data, data analyses, and preparation of dissemination products such as case studies, reports, policy briefs, and papers. Since 2011, I have taught statistical and research methods courses for students from a variety of disciplines including Criminology, Public Policy, Public Health, and Social Work at the undergraduate and graduate levels. For the proposed project, I bring experience and expertise in: systems science methods research and Dissemination & Implementation Science, as well as general social and public health research methods. These areas include various advanced statistical techniques, agent-based modeling, network science, the development of data collection tools, data visualization, and report, article, and presentation development for diverse audiences and stakeholders.

### **B.** Positions and Honors

<u>Positions</u>	
2011-2014	Adjunct Instructor, University of Missouri-St. Louis
2014-2016	Statistical Data Analyst II, Center for Public Health Systems Science,
	Brown School of Social Work, Washington University; St. Louis, MO
2015-2019	Instructor, Graduate Faculty, University of Missouri-St. Louis
2015-2019	Adjunct Faculty, Washington University; St. Louis, MO
2016-2019	Statistical Data Analyst III, Center for Public Health Systems Science,
	Brown School of Social Work, Washington University; St. Louis, MO
2017-	Assistant Director of Research, Center for Public Health Systems Science,
	Brown School of Social Work, Washington University; St. Louis, MO
2019-	Research Assistant Professor, Brown School of Social Work, Washington
	University; St. Louis, MO

#### Honors

Distinctions for Ph.D. qualifying exams, Comparative Politics and Quantitative Research Methods

Dissertation Fellowship, Graduate School, University of Missouri St. Louis
 Council of Graduate Schools/ProQuest Distinguished Dissertation Award

Nominee in Social Science, University of Missouri-St. Louis

#### C. Contributions to Science

## 1. Tobacco control policy analysis

Tobacco persists as one of the world's leading preventable causes of death and disease. The work I do in tobacco control focuses on translational research for policy analysis and evaluation. My previous experience in broader policy analysis is useful and relevant for evaluating the growing importance of retail-focused interventions as a key tobacco control strategy. As lead analyst for a multi-year NIH/NCI-funded study of state and local retail tobacco policy activity in the U.S., I have interviewed many tobacco control program managers at various levels of government. I have also built relationships with program leaders through collaborative efforts such as creating a crosswalk that connects items on a standardized retail tobacco assessment tool (S.T.A.R.S.) with actionable policies tailored to individual communities and states. I lead collection and analysis of both qualitative and quantitative data as well as taking a major role in writing, editing, and data visualizations for papers, reports, presentations, and other dissemination efforts. Many of these products, such as the *Point-of-sale Report to the Nation* (2015) are frequently used as a key resource by state and local tobacco control programs to aid in policy development and implementation.

- a. Luke, DA, Sorg A, **Combs TB**, Robichaux, CB, Moreland-Russell, S, Ribisl, KM, Henriksen, L (2016) Tobacco retail policy landscape: a longitudinal survey of US states, *Tobacco Control*, 25, i44-i51. PubMed Central PMCID: PMC5099223.
- b. Henriksen, L, Ribisl, KM, Rogers, T, Moreland-Russell, S, Barker, DM, Esquivel NS, Loomis, B, Crew, E, Combs, TB (2016) Standardized Tobacco Assessment for Retail Settings (STARS): dissemination and implementation research, *Tobacco Control*, 25, i67-i74. PubMed Central: PMCID: PMC5099212.
- c. Moreland-Russell S, Combs TB, Schroth, K, Luke DA (2016) Success in the city: the road to implementation of Tobacco 21 and Sensible Tobacco Enforcement in New York City, *Tobacco Control*, 25, i6-i9. PubMed Central: PMCID: PMC5099222.
- d. Combs **TB**, Brosi D, Chaitan VL, He Ed, Luke DA, Henriksen L (2019) Local retail tobacco environment regulation: early adoption in the United States, *Tobacco Regulatory Science*, 5(1), 76-86.

#### 2. Statistical Research Methods and Design

Translational policy research also benefits from new and different strategies for investigating problems. My work in this area includes a pilot study, the first of its kind, in which we tested the efficacy of smartphone and computer-based apps for measuring tobacco product displays. Such displays are familiar to most people around the world and youth, ex-smokers, people of lower socioeconomic status, and other populations most vulnerable to tobacco's omnipresent marketing and product placement are disproportionately exposed to large displays. The various tools in our study were not only reviewed for validity and reliability of measurement, but also assessed for feasibility of use in real-world tobacco retailers by non-professional data collectors. I have also tailored quantitative analytic strategies to investigate results from a CDC-funded study of the program sustainability toolkit for tobacco control and comprehensive chronic disease programs. This work has contributed to the refinement of the administration of the study's main instrument, the *Program Sustainability Assessment Tool*, and to the preparation of dissemination materials for various stakeholders.

- a. **Combs TB**, Moreland-Russell S, Roche J. (2015). Evaluation of Measurement Tools For Tobacco Product Displays: Is There an App for That? *AIMS Public Health*, 2(4), 810-820. PubMed Central PMCID: <u>PMC5690445</u>.
- b. Moreland-Russell S, Hastings M, **Combs TB**, Sequeira S, Polk L. (2018). The Sustainability Capacity of a Coordinated Approach to Chronic Disease Prevention. *Journal of Public Health Management & Practice*, 24(4). PubMed PMID: 29227422.
- 3. Systems Science Methods in Dissemination & Implementation Science

Systems science methods are not new to Public Health research; however they are increasingly employed to help explain and connect problems and solutions in Dissemination & Implementation research. My applications of systems science mainly utilize two methods: agent-based modeling (ABM) in tobacco policy science (Tobacco Town), and network science used to analyze and evaluate translational science research collaboration and dissemination (Washington University Institute for Clinical and Translational Sciences or ICTS). Tobacco Town is a NIH/NCI-funded project that investigated the potential impacts of various tobacco retailer reduction policies (e.g., buffers for school zones and retailer license caps) on overall cost (travel + time + price) for cigarettes. Using computer simulations based on observational data, this study illuminated the differential effects of the policies in varied contexts (e.g., urban poor or suburban rich areas). I also apply network science methodology to in my work on scholarly collaboration for the ICTS project. I investigate (1) predictors of interdisciplinary collaboration on publications and grantsmanship, (2) how engagement with ICTS infrastructure (e.g., use of core services and training, leadership, internal funding, mentoring) influences scholarly productivity, and (3) how these multi-investigator projects translate to and benefit the larger community beyond the university environment.

- a. Luke DA, Hammond RA, Combs TB, Sorg, A, Kasman, M, Mack-Crane, W, Ribisl, KM, Henriksen, L (2017) Tobacco Town: Computational Modeling of Policy Options to Reduce Tobacco Retailer Density. *American Journal of Public Health*, 107(5), 740-746. PubMed Central PMCID: PMC5388950.
- b. Luke DA, Morshed AB, McKay VR, Combs TB. (2017). "Systems Science Methods in Dissemination & Implementation Research" in *Dissemination & Implementation Research in Health*, 2<sup>nd</sup> ed., Brownson RC, Colditz GA, Proctor EK, eds. Oxford University Press: New York. ISBN: 9780190683214.
- c. **Combs TB**, Brossart L, Ribisl KM, Luke DA. (2018). "Case Study: Dissemination & Implementation Research in Retail Tobacco Control Policy" in *Optimizing the Cancer Control Continuum: Advancing Implementation Research*, Chambers DA, Norton WE, Vinson C, eds. Oxford University Press: New York. ISBN: 9780190647421.
- d. **Combs TB**, McKay VR, Ornstein J, Mahoney M, Cork K, Brosi D, Kasman M, Heuberger B, Hammond RA, Luke DA. (2019). Modelling the impact of menthol sales restrictions and retailer density reduction policies: insights from tobacco town Minnesota. *Tobacco Control*, accepted.

#### D. Additional Information: Research Support and/or Scholastic Performance

## **Ongoing Research Support**

NA Combs 09/01/2019 – 08/31/2020

Interact for Health

Evaluation of Tobacco Policy in Southwest Ohio

This project will evaluate the implementation and short- and mid-term impact of raising the minimum legal sales age for tobacco products to 21 in Cincinnati, Ohio. The evaluation team will finalize a logic model and evaluation plan for the policy, develop and administer data collection instruments in a mixed-methods design, and disseminate results to diverse stakeholders. Goals of the policy to be measured in the evaluation include decreasing youth and young adult tobacco use and changing attitudes toward tobacco in the city. Renewal of contract expected annually through 2022.

1P01CA225597-01 (multi PI, Ribisl contact)

07/01/2018 - 06/30/2023

NIH/NCI \$528,058 WÚ

ASPiRE: Advancing Science and Practice in the Retail Environment

Three innovative research projects will examine the degree to which tobacco retailer density contributes to tobacco use and tobacco-related disease over time using archival data, evaluate the impact of local retail interventions on tobacco use outcomes using data from a longitudinal panel of tobacco users adult smokers, and develop computational modeling to simulate community-level interventions to understand how changes in the built and consumer environments may lead to improved public health. Two shared resource cores that specialize in data management and biostatistics, and dissemination and implementation, will enhance the impact and reach of the scientific aims and increase synergy among the research and results from the three projects.

Contact PD/PI: NAAR, SYLVIE

Role: Co-Investigator

UL1TR002345 Evanoff 06/19/2017 - 02/28/2021

NIH/NCATS

Washington University Institute of Clinical and Translational Sciences Evaluation Program (Luke, Evaluation Director) and Multi-Disciplinary Team Science (Luke, Program Director) Implementation Science and Entrepreneurship

The Clinical and Translational Science Award (CTSA) is the main funding source for the Washington University Institute of Clinical and Translational Sciences (ICTS). The overall goal of this application is to accelerate advances in human health by engaging multiple stakeholders in the translation of scientific discoveries to drive improvements in health among diverse populations. Our proposal will improve clinical research through high quality and efficient methods/processes, develop a trained workforce skilled in team science, and disseminate research findings into real-world implementation to improve health and health care for patients, communities, and the nation.

Role: Senior Data Analyst

R01CA203844-01A1 Moreland-Russell 08/05/2017 - 07/31/2021

NIH

Establishing the Program Sustainability Action Planning Training Model

We propose a quasi-experimental effectiveness trial to evaluate the effectiveness of the Program Sustainability Action Planning Training Curricula in improving the sustainability capacity and institutionalization of state Tobacco Control (TC) programs.

Role: Co-Investigator

## **Recently Completed Research Support**

1R21MH115772-01 McKay 09/15/2017 – 07/31/2019

NIH/NIMH

De-Implementation of Low-Value HIV Prevention Interventions.

This project addresses evidence-based approaches to HIV prevention. Sparse knowledge exists regarding effective approaches for encouraging de-implementation of less effective HIV prevention interventions. Upon completion, our study will provide a better understanding of de-implementation and identify strategies for successful de-implementation of less effective interventions.

Role: Senior Data Analyst

N/A Purnell 07/15/2017 – 01/14/2019

Robert Wood Johnson Foundation

Research and Translation- For the Sake of All

To expand support from decision-makers, practitioners, and other key stakeholders who will ultimately be responsible for establishing and supporting policy, implementing best practices, and embracing school-change efforts that address the real conditions that support or impede children's health and learning. Role: Senior Data Analyst

RC 2016-0005 Luke 06/01/2016 – 05/31/2018

ClearWay Minnesota

Agent-Based Modeling to Measure the Impact of Menthol and Retailer Density Policies in Minnesota Employing agent-based modeling techniques that incorporate real-world retailer and demographic data from Minnesota communities to simulate the effects of policy implementation, specifically the impact of menthol sales restriction and tobacco retailer density strategies on Minnesota's priority populations and general population. We will identify particular policies' potential behavioral impact (e.g. cessation and initiation) on Minnesota's populations and identify the distinct, relative, and combined impact of specific policies on Minnesota's tobacco retailer landscape.

Role: Subcontract Senior Data Analysist and Program Manager

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.** 

NAME: Flynn, Heather A,

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Professor, Vice Chair

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Florida State University, Tallahassee, FL	B.S.	1990	Psychology
Florida State University, Tallahassee, FL	M.S.	1992	Clinical Psychology
Florida State University, Tallahassee, FL	Ph.D.	1996	Clinical Psychology
The Florida Mental Health Institute, University of South Florida, Tampa, FL	Clinical Internship	1996	Clinical Psychology
University of Michigan, Ann Arbor, MI	Postdoctoral	1998	Psychology

#### A. Personal Statement

Role on Project: For this transformative R01, I will serve as co-investigator and assist the MPIs in the coordination of the intervention development team. I have worked with the contact PI for many years as members of the Motivational Interviewing Network of Trainers, and recruited her to FSU several years ago. Qualifications: The overall goal of this proposal is diffuse innovations in social and behavioral science into novel interventions to combat racism, discrimination and bias in integrated primary health care setting serving ethnic minority and underinsured populations. I have been working in the area of mental health interventions since 1999, with a specific focus on psychological, social, and biological influences on mental health outcomes. I have a particular interest in underserved populations, including women and children with mental health risk, racial minorities, and people living in poverty. I am associate chair of research for the the Department of Behavioral Sciences and Social Medicine at FSU. My specific research focus has been on improved screening and treatment for depression and co-occurring risk, including substance abuse, in primary health care settings. I have experience in bringing together large networks to advance behavioral health integration in primary care. In 2009, I founded (and Co-Chair) the Women and Mood Disorders Task Force within the National Network of Depression Centers. Our network includes 56 women's health researcher-members from 22 US academic institutions that have been building the capacity to innovate the field through interdisciplinary collaboration in the field of Women's Mental Health for several years. Our capacity-building work has resulted in over 8,000 women completing standard assessments across a wide variety of women's health settings.

In Florida, I have coalesced an interdisciplinary team of investigators from all departments of the medial school as well as from across the University with the goal of building translational behavioral health research capacity and infrastructure. I am a trainer in a variety of evidence-based psychotherapeutic interventions including Motivational Interviewing, Cognitive Behavioral Therapy, and Interpersonal Psychotherapy. I also have formalized partnerships with local and statewide entities vital for sustainability of these kinds of interventions. have entered into formal partnerships with all three state agencies around maternal mental health change: the Department of Children and Families, the Medicaid Agency (Agency for Healthcare Administration-ACHA) and the Florida Department of Health (FDOH). I have worked closely with the FDOH since 2014 on policy and clinical health serve work in maternal mental health. I am co-chair of a statewide Maternal Mental Health Coalition, the Florida Maternal Mental Health Collaborative, which aims to improve perinatal mental health awareness, training, and treatment capacity on a statewide level. In addition, I am a steering committee

member of the Florida Health Equity Research Institute, which includes members from every college and university in Florida.

# B. Positions and Honors Positions and Employment

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1995-1996	Psychology Intern, Florida Mental Health Institute, Tampa, FL (APA-Accredited)
1996-1998	Postdoctoral Fellow, University of Michigan Alcohol Research Center, Ann Arbor, MI
1998-2003	Assistant Research Scientist, Department of Psychiatry, University of
	Michigan Addiction Research Center, Ann Arbor, MI
1998-2003	Clinical Associate II, University of Michigan, Department of Psychiatry, Ann Arbor, MI
2003-2010	Assistant Professor, Department of Psychiatry, University of Michigan, Ann Arbor, MI
2003-2010	Adjunct Assistant Professor, Department of Psychology, University of Michigan, Ann Arbor
2003-2010	Director, Psychotherapy Services Adult Ambulatory Psychiatry, Ann Arbor, MI
2006-2011	Director, Women's Mental Health Program, University of Michigan, Department of
	Psychiatry, Ann Arbor, MI
2010-2011	Associate Professor with Tenure, University of Michigan, Department of Psychiatry, Ann
	Arbor, MI
2011-Present	Adjunct Associate Professor, University of Michigan, Department of Psychiatry, Ann Arbor
2011-Present	Associate Professor and Vice Chair, Florida State University College of Medicine,
	Department of Medical Humanities and Social Sciences, Tallahassee, FL
2015-Present	Director, FSU Center for Behavioral Health Integration
2016-Present	Co-Chair, Florida Statewide Maternal Mental Health Coalition
2017-present	Professor and Vice Chair, FSU Department of Behavioral Sciences and Social Medicine

## **Other Experience and Professional Memberships**

2007- 2011	Founder and Co-Director, Women's Mental Health and Infants Program, University of
	Michigan, Department of Psychiatry
2009-2010	DSM-V Workgroup: Gender Differences in Anxiety Disorders, American Psychiatric
	Association
2009-Present	Founder and Chair, Women's Mood Disorders Task Group, National Network of Depression
	Centers
2015- Present	Executive Council, International Society for Interpersonal Psychotherapy

## **Honors**

1998	American Psychological Society Showcase Poster Award
1998	Research Society on Alcoholism Junior Investigator Award
2001	Rachael Upjohn Clinical Scholars Award
2010	Honorable Mention, University of Michigan Health System "Program of the Year" (Director,
	Women's Mental Health and Infants Program)
2010	Advanced Leadership Program, Center for the Education of Women
2012	Outstanding Senior Faculty Researcher, Florida State University College of Medicine
2012	Scholar, Harvard Macy Program for Leading Innovations in Health Care & Education
2012	The Florida State University Department of Psychology, Doctoral Graduate Award of
	Distinction
2013	Member of Excellence Award. National Network of Depression Centers
2014	Outstanding Senior Faculty Educator, Florida State University College of Medicine
2016	Visiting Professor Award, National Network of Depression Centers
2016	Elected to Alpha Omega Alpha Honor Medical Society

#### C. Contributions to Science

My overall research focus is on the improved detection and treatment of perinatal mental health disorders and co-occurring risk issues in primary health care as well as the effect on infant outcomes. In addition, I have aimed to improve the public health impact of maternal-child health overall by forming and leading

interdisciplinary collaborative clinical health networks and programs and by engaging community stakeholders to accelerate translation of findings. For every publication noted, I was the leader of the laboratory (either Primary of Co-Investigator on the grant or devised the paper idea based on data from my projects) and participated in or conducted the data analyses and dissemination.

1) Improvements in the detection and treatment of perinatal depression among underserved in primary health care settings. Depression and anxiety are among the most debilitating conditions in the world and peak prevalence occurs in women during the childbearing years. These mental health disorders in pregnancy are associated with poor pregnancy, labor and delivery outcomes, as well as lifelong medical, developmental and behavioral problems in children of depressed mothers. In the US, approximately 500,000 babies are born per year to mothers with Major Depressive Disorder, up to 75% of whom are untreated. Thus, there is an urgent need to document and address the very low rate of mental health detection and linkage with mental health treatment in the context of prenatal care. My studies were among the first to document the extent of poor detection and treatment rates of perinatal depression in obstetrics and other health care settings, and as well as the ineffective treatment of depression in those settings:

Marcus SM, Flynn HA, Barry KL, Blow FC. Depressive symptoms among pregnant women screened in obstetrics settings. Journal of Women's Health. 2003, May;12(4):373-80. PMID: 12804344

Flynn HA, Davis M, Marcus SM, Cunningham R, Blow FC. Rates of maternal depression in pediatric emergency department and relationship to child service utilization. General Hospital Psychiatry. 2004, Jul-Aug; 26(4):316-22. PMID: 15234829

Menke, R., & Flynn, H. (2009). Relationships between stigma, depression, and treatment in white and African American primary care patients. *The Journal of nervous and mental disease*, 197(6), 407-411.

Flynn HA,O'Mahen HA, Massey L, Marcus SM. The impact of a brief obstetric clinic-based intervention on treatment use for perinatal depression, Journal of Women's Health. 2006, Dec; 15(10):1195-204. PMID: 17199460

O'Mahen, H. A., Henshaw, E., Jones, J. M., & Flynn, H. A. (2011). Stigma and Depression During Pregnancy: Does Race Matter? *Journal of Nervous and Mental Disease*, 199(4), 257-262

2) <u>Co-Morbid psychiatric and behavioral risk among in primary health care settings and impact on infant outcomes.</u> Although depression is the most common psychiatric disorder in childbearing women, it seldom occurs in isolation. My studies have shown that depression in childbearing women commonly co-occurs with other psychosocial, behavioral, and medical risk factors including substance abuse, interpersonal violence, and medical problems. These maternal risk factors have an effect on early infant neurobiological outcomes, such as signs of sleep and neurodevelopmental disorders:

Flynn HA, Chermack ST. Prenatal alcohol use: the role of lifetime problems with alcohol, drugs, depression, and violence. Journal of Studies on Alcohol and Drugs. 2008, July 69(4), 500-09. PMID: 18612565

Armitage R, Flynn HA, Hoffman R, Vazquez D., Lopez J., Marcus SM. Developmental changes in sleep in infants: The impact of maternal depression. Sleep, 2009 vol 32(5): 693-696.

Flynn HA, McBride N, Cely A., Wang Y, DeCesare J (2015). Relationship of Prenatal Depression and Comorbidities to Infant Outcomes. CNS Spectrums Feb 20(1):20-8

3) Development of effective psychotherapeutic interventions for perinatal depression and anxiety. My earlier research documented the fact that up to 75% of women with clinically significant mental health and co-occurring risk factors were not receiving any evidence-based mental health treatment. In addition, my group and others showed the impact of under-treated depression on the on the infant. Therefore, a clear need emerged to develop and / or modify existing evidence-based treatments for these disorders in order to improve their uptake and effectiveness in primary health care settings. The need to develop accessible and effective non-pharmacological treatments for perinatal depression was particularly urgent given the widespread reluctance to use anti-depressants in pregnancy and breastfeeding. As a result, I led a team, using a mixed-methods approach, to develop and test such treatments:

Lancaster, C., Fedock, G., Forman, J., Davis, M., Henshaw, E., Flynn HA (2011). OB CARES: Providers' Perceptions of Addressing Perinatal Depression: A Qualitative Study. General Hospital Psychiatry. Gen Hosp Psychiatry. May-Jun;33(3):267-78

Henshaw, E., Flynn, H.A., Himle, J., O'Mahen, H.A., Forman, J., \*Fedock, G. (2011). Patient preferences for clinician interactional style in treatment of perinatal depression. Qualitative Health Research, March 23

O'Mahen, H, Fedock G, Henshaw E, Himle J, Forman J, Flynn HA. (2012). Modifying CBT for Perinatal Depression: What do Women Want? A qualitative study. Cognitive and Behavioral Practice 19. 2May: 359-371

O'Mahen H, Henshaw E., Himle J, Fedock G., Flynn HA. (2013). A pilot randomized controlled trial of Cognitive Behavioral Therapy for Perinatal Depression Adapted for Women with Low Incomes. Depression and Anxiety, Jan 14

4) Improvements in interdisciplinary and collaborative clinical health research related to depression. The field of perinatal mental health research, as with other fields of science, had and continues to show slower than needed translation to practice. Two primary reasons for this unacceptable pace of discovery and translation are related to lack of collaboration among researchers across the US engaged in similar work, and lack of integration of clinical health research in health care settings. To address this problem, I formed several interdisciplinary, collaborative entities that provided the capacity for this kind of collaboration and integration. For example, I founded and chair the National Women and Mood Disorders Network, which is a collaboration of 30 researchers across 21 academic institutions in the US (<a href="www.nndc.org">www.nndc.org</a>). I also created an interdisciplinary research, training and clinical care program at the University of Michigan known as the Women and Infants Mental Health Program. That program created a depression screening and registry program in obstetrics for facilitating coordinated research. In Florida, I have established a network of obstetrics practices engaged in research as well as a 23 member Maternal Mental Health Community Advisory Board:

Novick, D., Allbaugh, L., Zhoa, Z., Henshaw, E., Vazquez, D., Armitage, R., Flynn, H. (2014). Representativeness of Obstetrics Patients who Participate in Perinatal Depression Research: Findings from the Women's Mental Health and Infants Program (WMHIP) Integrated Dataset. Archives of Women's Mental Health Apr 17(2): 97-105.

Allbaugh L., Ford E. Marcus SM, Flynn HA. (2015) Detecting depression in Obstetrics and Gynecology: A system for screening and research recruitment. International Journal of Obstetrics and Gynecology Mar;128(3):260-3.

Weiss, S., Simeonova, D., Kimmel, M., Battle, C., Maki, P. & Flynn, H. (2016). Anxiety and physical health problems increase the odds of women having more severe symptoms of depression. Archives of Women's Mental Health Jun 19(3): 491-9.

Flynn HA, Weiss S, Deligiannidis K, Guille C, Rosenblum K, Maki P, Epperson N, Spino C (2017).). A Collaborative, Network-based Approach to Advance Women's Depression Research in the U.S.: Preliminary Findings. Journal of Women's Health

#### D. Research Support

#### **Ongoing Research Support**

HRSA (Flynn) 9/30/2019-9/29/2023 6.0CM

Department of Health

Development of a Sustainable Screening and Treatment Model to Improve Maternal Mental Health Outcomes in Florida

The goal is to work closely with the Florida Department of Health (FLDOH) project team as well as the MCPAP for Moms center and the Florida Maternal Mental Health Collaborative to direct key aspects of the five year project. This includes design, develop and provide training and appropriate resources to front-line mental health providers and establishing/strengthening linkages with mental health, primary care and social services in communities.

Florida Department of Health (Flynn PI) 4/2019-4/2021 Pediatric Behavioral Health Integration

The goal of this project is to provide training, technical assistance and other aspects of integration of behavioral health detection, referral, treatment and management of behavioral health risk in children and families in Pediatric settings.

NIMH (Hajcak, PI; Flynn Co-I)

EEG correlates of reward in pregnancy.

This project captures various assessments, including ERP via portable EEG to determine postpartum depression risk based on prenatal neurobiological and psychiatric factors prenatally in obstetrics settings.

Substance Abuse and Mental Health Services Administration (SAMHSA). Flynn(PI) 2/17-1/20 Gadsden Country Behavioral Health Integration.

This is an evaluation of a federal service aimed to integrate primary medical care within a community mental health center. The goals of the sub-contract are to create and maintain a research database, and to perform statistical analyses and evaluation of the behavioral health integration service.

R01 Wetherby(PI) 9/17-5/22

National Institute of Health (NIH)

Role: Co-I

Autism Adaptive Community-based Treatment to Improve Outcomes using Navigators (ACTION) Network
The overarching of this study is to conduct a SMART trial to investigate the effectiveness of family navigators trained in Problems Solving and Education with or without motivational interviewing to improve parental and child outcomes associated with Autism Spectrum Disorder.

R01 Wetherby(PI) 8/14-6/19

National Institute of Health (NIH)

Role: Co-I

Mobilizing Community Systems to Engage Families in Early ASD Detection and services
The aim of the study is to document the effectiveness of an online automated universal screen for
communication delay and autism initially at 18 months of age and decision rule for referral to an autism
spectrum disorder evaluation, and to study an evidence-based intervention to increase family engagement and
expedite receipt of screening, diagnosis, eligibility for early intervention (EI), and EI services.

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.** 

NAME: Norman B. Anderson

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Assistant Vice President for Research and Academic Affairs and Professor of Social Work, Florida State University

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
North Carolina Central University, Durham, NC	B.A.	05/1977	Psychology
University of North Carolina at Greensboro	M.A.	05/1980	Clinical Psychology
University of North Carolina at Greensboro	Ph.D.	05/1983	Clinical Psychology
Brown University School of Medicine		07/1982	Clinical Psyc Internship
Duke University School of Medicine		09/1985	Post-doctoral fellow

#### A. Personal Statement

**Role in Project**. As one of the MPIs on this project, my role will be to collaborate with the other MPIs on the overall direction and management of the project. In addition, I will be responsible organizing and overseeing the work of Scientific Advisory Council. I will also collaborate on several aspects of the project, including providing guidance and leadership to the study team related to the evaluation of community partner organizational systems, and defining and simulating anti-racism provider and organizational interventions. Further, I will also provide scientific input into all phases of the project

<u>Qualifications</u>. I began my career conducting interdisciplinary, team science research on issues related to health disparities and health equity, especially with regard to psychosocial and biobehavioral aspects of hypertension in African Americans. One line of this research focused specifically on the health, psychosocial, and biological effects of racism in African Americans (see Contributions section below).

While I was founding Director of the NIH Office of Behavioral and Social Sciences Research (OBSSR) during the mid-late 1990s, a major emphasis of the office was in fostering initiatives aimed at promoting transdisciplinary research in general, and especially in the context of understanding and eliminating health disparities (see Contributions section below). Later, while a member of the National Institute of Aging (NIA) Advisory Council, I was part of the Task Force on Minority Aging that developed the NIA research framework on health disparities and health equity, which emphasized transdisciplinary team science across the life course (see below).

While CEO of the American Psychological Association (APA), I led the creation of the Center for Psychology and Health, which focuses on (among other things) interprofessional, integrated primary care, with respect to the training of psychologists, research, and national health care policies.

#### **B.** Positions and Honors

#### **Positions:**

1986 - 1990 Assistant to Associate Professor of Medical Psychology and of Psychology, Duke University; Associate Director of NIH and Founding Director of the NIH Office of Behavioral and Social

Sciences Research (OBSSR)

2000 - 2003 Professor of Health and Social Behavior, Harvard School of Public Health

2003 - 2016 CEO, American Psychological Association (APA)

2016 - Present Principal, Anderson Leadership Coaching and Consulting, LLC

2017 - Present Assistant Vice President for Research and Academic Affairs, Professor of Social Work,

and Director of the Faculty Leadership Development Program at Florida State University.

## Honors (selected):

1986	New Investigator Award, Society of Behavioral Medicine
1991	Annual Award for Outstanding Contributions to Health Psychology, Division of Health
	Psychology, APA
1992 - 1997	Research Scientist Development Award, National Institute of Mental Health
1997	Elected President, Society of Behavioral Medicine
2003	Career Service Award, Division of Health Psychology, APA
2005	Fellow Status: American Association for the Advancement of Science; American
	Psychological Association, Academy of Behavioral Medicine Research; Society of
	Behavioral Medicine; Association for Psychological Science.
2009	Distinguished Psychologist in Management Award, Society of Psychologists in Management
2013	Elected to Black College Alumni Hall of Fame
2011-2014	National Advisory Council on Aging, National Institute on Aging, NIH
2012-2015	Appointed to the National Academic Affiliations Council, Department of Veterans Affairs
	(VA)

#### C. Contributions to Science

3.

- 1. In collaboration with my former student Dr. Rodney Clark (and others), developed perhaps the first biopsycho-social model of racism as a stressor for African Americans, and continued to make contributions in collaboration with others to understanding the potential connection between racism, discrimination, and health.
  - a. Clark, R., **Anderson, N.B.**, Clark, V.R., and Williams, D.R. (1999). Racism as a stressor for African Americans: A biopsychosocial model. *American Psychologist*. 54, 805-816.
  - b. Williams, D.R., Yu, Y., Jackson, J.S., and **Anderson, N.B.** (1997). Racial differences in physical and mental health: Socioeconomic status, stress, and discrimination. *Journal of Health Psychology*, 2, 335-351
  - c. Steffen, P.R., McNeilly, M., Sherwood, A., **Anderson, N.** (2003). The effects of perceived racism and anger inhibition on ambulatory blood pressure in African Americans. *Psychosomatic Medicine*, 65, 746-750.
  - d. Hill, L., Sherwood, A., McNeilly, M., **Anderson, N.**, Blumenthal, J., and Hinderliter, A. (2018). The impact of racial discrimination and hostility on adrenergic receptor responsiveness in African Americans. *Psychosomatic Medicine*, 80(2), 208-215.
- 2. Was among the first researchers to focus on race and health from a bio-psycho-social perspective, especially as it related to hypertension in African Americans. Organized arguably the first national conference on behavioral and sociocultural aspects of health disparities, which occurred in 1992 (proceedings published in Health Psychology in 1995).
  - a. **Anderson, N.B.**, Myers, H., Pickering, T., and Jackson, J.S. (1989). Essential hypertension in Blacks: Psychosocial and biological perspectives. *Journal of Hypertension*, 7, 161-172.
  - b. **Anderson, N.B.** (Ed.). (1995). Behavioral and sociocultural perspectives on ethnicity and health. Special Issue of *Health Psychology*, 14, 589-591.
  - c. **Anderson, N.B.** and McManus, C.H. (1999). Hypertension in blacks across the life course: A biopsychosocial analysis. J. Jackson (Ed.), *The black American elderly: Research on physical and psychosocial health*. Vol. 2.
  - d. Hill, C.V., Pérez-Stable, E. J., **Anderson, N.B.**, and Bernard, M. A. (2015). The National Institute on Aging Health Disparities Research Framework. *Ethnicity & Disease*, 25(3), 245-254.

- 4. Was among the first researchers to systematically study cardiovascular responses to stress as a potential mechanism for the high rates of hypertension in African Americans. More specifically, was among the first researchers to identify heightened vascular constriction (as opposed to heightened heart rate or cardiac output) as a potentially important cardiovascular stress response pattern and potential risk factor for hypertension in African Americans.
  - a. **Anderson, N.B.**, Lane, J.D., Monou, H., Williams, R.B., and Houseworth, S.J. (1988). Racial differences in cardiovascular responses to mental arithmetic. *International Journal of Psychophysiology*, 6, 161-164.
  - b. Anderson, N.B., Lane, J.D., Muranaka, M., Williams, R.B., and Houseworth, S. (1988). Racial differences in blood pressure and forearm vascular responses to the cold face stimulus. Psychosomatic Medicine, 50, 57-63. Reprinted in 1989 Yearbook of Psychiatry and Applied Mental Health.
  - c. **Anderson, N.B.** (1989). Racial differences in stress-induced cardiovascular reactivity and hypertension: Current status and substantive issues. *Psychological Bulletin*, 105, 89-105.
  - d. **Anderson, N.B.** and Shumaker, S.A. (Eds.). (1989). Race, reactivity and blood pressure regulation. Special Issue of *Health Psychology*, 8, 483-596.
- 5. As the first director of the NIH Office of Behavioral and Social Sciences Research (OBSSR), I worked to advance behavioral and social sciences research across all of the institutes and centers at NIH. In this role I led the development of the "levels of analysis" framework to serve as the conceptual basis for advancing a transdisciplinary, bio-psycho-social, team science agenda at NIH. During this time, OBSSR organized the first NIH-wide conference to set the research agenda on social determinants of health. After leaving NIH, I was on the National Institute of Aging (NIA) Council Task Force on Minority Aging that developed the NIA research framework on health disparities and health equity across the life course.
  - a. **Anderson, N.B.** (1997). Integrating behavioral and social sciences research at the National Institutes of Health in the U.S.A. *Social Science & Medicine*, 44(7), 1069-1071.
  - Anderson, N.B. (1998). Levels of analysis in health science: A framework for integrating sociobehavioral and biomedical research. *Annals of the New York Academy of Sciences*, 840, 563-576.
  - c. Progress and Promise in Research on Social and Cultural Dimensions of Health (2001). Report from the NIH Office of Behavioral and Social Sciences Research. National Institutes of Health.
  - d. Hill, C.V., Pérez-Stable, E. J., **Anderson, N.B.**, and Bernard, M. A. (2015). The National Institute on Aging Health Disparities Research Framework. *Ethnicity & Disease*, 25(3), 245-254.

#### D. Additional Information: Research Support and/or Scholastic Performance

N/A

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.** 

NAME: Christopher Schatschneider

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Professor of Psychology and Associate Director of the Florida Center for Reading Research

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Case Western Reserve University, Cleveland, OH	B.S.	1988	Psychology
Case Western Reserve University, Cleveland, OH	M.S.	1993	Psychology
Case Western Reserve University, Cleveland, OH	Ph.D.	1995	Psychology
University of Houston, TX	Postdoctoral	1997	Quantitative Methods

#### A. Personal Statement

The overall goal of this proposal to develop novel interventions to combat racism, discrimination and bias in integrated primary health care setting serving ethnic minority and underinsured populations. As part of this grant, we will develop measures that will be reliable and valid for assessing the effects of anti-racism interventions at the provider and organizational/systems level. My role on this grant is to provide technical help in constructing these measures. I have experience in test development, item response theory modeling, and computer adaptive testing. I am a co-author of two commercially available tests (The Texas Primary Reading Inventory and the RAPID test which is licensed through Rosetta Stone) as well as one computer adaptive test used by the State of Florida (The. Florida Assessments for Instruction in Reading). I also hold a patent through the U.S. Patent and Trademark Office for a computer adaptive algorithm used to administer the items in the RAPID. I have published a number of paper using IRT modeling and differential item functioning. I am currently the Statistical Core Director on a current NICHD LD Center (P50) project, and I am the lead methodologist on a NICHD-funded multi-site trial of reading interventions for children who are co-morbid for ADHD and reading problems. In addition to over 200 articles pertaining to reading development and interventions, I have authored or co-authored 17 articles or chapters focusing exclusively on methodology and statistics (including issues with estimating item response theory models and simulations) and over 60 peerreviewed articles in which my primary role on the manuscripts was as the methodologist. Finally, I teach our department's course on ANOVA, hierarchical linear modeling, and psychometrics and have given numerous workshops on these topics.

### **B.** Positions and Honors

#### Positions and Employment

1995-1997 Postdoctoral Fellow, University of Houston

1997-2002 Research Assistant Professor, University of Houston

2002-2007 Associate Professor, Department of Psychology, Florida State University

2007-present Professor, Department of Psychology, Florida State University

2007-present Associate Director, Florida Center for Reading Research

## **Other Experience and Professional Memberships**

2002-2008 Member of the National Institute for Family Literacy

2007- 2010 Editor, Annals of Dyslexia.

2005- present Standing Panel Member on the Cognition and Student Learning Review Panel (IES)

2004- present National Center on Progress Monitoring Panel Member

#### C. Contributions to Science

- 1. Introducing new statistics and methods to a field. Many of my publications introduce new and innovative statistical modeling techniques to a field. As is often the case, different disciplines tend to use particular models and methods that have been developed in those fields, but are unaware of other potentially interesting and useful models that could be employed. To that end, I have authored or co-authored papers that use statistical modeling techniques such as dominance analysis, ROC curves, quantile regression, advancements in item response theory, and simulations. Additionally, we have also introduced a new classification statistic, the Affected-Status Agreement (ASA) index that is useful for assessing categorical agreements when the base-rates for each category are low. Finally, I was lead author on a paper that used simulations to investigate classification agreement rates.
  - a) **Schatschneider, C.**, Wagner, R.K., Hart, S.A., & Tighe, E.L. (2016). Using simulations to investigate the longitudinal stability of alternative schemes for classifying and identifying children with reading disabilities, *Scientific Studies of Reading*, 20, 34-48.
  - b) Francis, D.J., **Schatschneider, C.,** & Carlson, C.D. (2000). Introduction to individual growth curve analysis. In D. Drotar (Ed.), Handbook of Research in Pediatric and Clinical Child Psychology. New York: Plenum
  - c) Tighe, E. L., & **Schatschneider**, **C**. (2014). A dominance analysis approach to determining predictor importance in third, seventh, and tenth grade reading comprehension skills. *Reading and Writing*, 27, 101-127. doi:10.1007/s11145-013-9435-6
  - d) **Schatschneider, C.**, Lane, K. L., Oakes, W. P., & Kalberg, J. R. (2014). The Student Risk Screening Scale: Exploring Dimensionality and Differential Item Functioning. Educational Assessment, 19(3), 185-203.
- 2. I have authored numerous studies using item response theory and have previously authored tests.
  - a) Foorman, B.R., Petscher, Y., & **Schatschneider, C**. (2015). Florida Assessments for Instruction in Reading, Aligned to the Language Arts Florida Standards (FAIR-FS): Grades 3-12 Technical Manual. Tallahassee, FL: FCRR.
  - b) **Schatschneider, C.**, Lane, K. L., Oakes, W. P., & Kalberg, J. R. (2014). The Student Risk Screening Scale: Exploring Dimensionality and Differential Item Functioning. *Educational Assessment*, *19(3)*, 185-203.
  - c) **Schatschneider, C.**, Francis, D.J., Foorman, B.F., Fletcher, J.M., & Mehta, P. (1999). The dimensionality of phonological awareness: An application of item response theory. Journal of Educational Psychology, 91, 467-478.
  - d) Crawford, E.C., Petscher, Y., & **Schatschneider, C**. (2012). U.S. Patent No. 20120077173A1. Washington, DC: U.S. Patent and Trademark Office.

#### Complete List of Published Work in MyBibliography:

https://www.ncbi.nlm.nih.gov/myncbi/browse/collection/49679183/?sort=date&direction=ascending

#### D. Additional Information: Research Support and/or Scholastic Performance

### **Ongoing Research Support**

**P50 HD052120** Wagner (PI) **2017-2022** 

The Florida Learning Disabilities Research Center

This is the third cycle of the Florida Learning Disabilities Research Center, and I am a co-investigator of the entire grant which is composed of 6 research projects and 3 cores.

Role: Co-I

P50 HD052120 Schatschneider (PI) 2017-2022

**Data Analytics Core** 

This Core serves 6 projects that all focus on examining the identification, classification, and remediation of reading disabilities.

Role: PI

**R324A160193 IES** Ingvalson (PI) **2016-2020** 

Training-Induced Language and Literacy Improvement in Children with Cochlear Implants

This is a randomized control trial of the effectiveness of a phonological training program for students with cochlear implants..

Role: Co-I

**R324A130262 IES** Wanzek (PI) **2016-2020** 

Passport to Literacy: Examining the Effectiveness of the Voyager Passport Intervention for Fourth-grade Students With or At High Risk for Reading Disabilities.

This is a randomized control trial of the effectiveness of a decoding training program for struggling middle-school readers.

Role: Co-I

**R305A170203IES** Wanzek (PI) **2017 - 2020** 

The Relationship between Elementary Teachers' Language Use and Students' Language and Literacy Achievement. This individual differences study is examining the relationship between teacher's vocabulary usage and students language and literacy development

Role:Co-I

**R305A160241 IES** Lonigan (PI) **2016- 2020** 

Generating Large and Sustained Impacts On Early Language Skills: Evaluation Of Timing And Duration Of Intervention. This RCTstudy is designed to investigate the impacts of an intervention delivered in preschool, kindergarten, or both preschool and kindergarten.

Role:Co-I

R305A090169 IES Lonigan(PI) 2017 - 2021

Identifying Effective Instructional Practices and Contexts for Spanish-speaking English Learners in Florida's Universal Preschool Program.

Role:Co-I

R305A170463 IES Ganley(PI) 2017 - 2021

Examining Teacher Math Anxiety as a Malleable Factor Related to Student Outcomes. This individual differences study is designed to examine the relationship of teacher's math anxiety on student math outcomes. Role:Co-I

Provide the following information for the Senior/key personnel and other significant contributors.

Follow this format for each person. **DO NOT EXCEED FIVE PAGES**.

NAME: Pettus-Davis, Carrie

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Associate Professor of Social Work

**EDUCATION/TRAINING** 

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Kansas, Lawrence, KS	B.A., B.S.W.	05/1999	Psychology, Social Work
University of Kansas, Lawrence, KS University of North Carolina at Chapel Hill, NC	M.S.W. Ph.D.	05/2001 05/2011	Social Work Social Work

#### A. Personal Statement

I am well-suited as a MPI on the proposed study because I have over 20 years of experience with communitybased research and treatment and a research portfolio of policy and behavioral health services intervention design using mixed methods approaches. I have extensive community partnerships with complex health and behavioral health systems largely grounded in correctional facilities and other criminal justice settings. Through these partnerships I have developed trusted research-practitioner partnerships across numerous jurisdictions across the United States that have allowed for large-scale and ground breaking research leading to the development of interventions that impact behavior, policies, and practices of individuals embedded in systems and within the systems they are in embedded. My research investigates outcomes of health, well-being, and equity (across race, socioeconomic class, and behavioral health status) among one of the most vulnerable and marginalized populations in the U.S. – those involved in the criminal justice system. The dearth of anti-racism approaches in this nation's systems of care, and the prevalence of unaddressed racism interwoven through the fabric of our major institutions has led to the drastic disproportionate representation of people of color throughout our criminal justice system - especially Black and African Americans. Once involved in the criminal justice system, health and behavioral health symptoms worsen and when individuals return to the community, they find themselves locked out of the healthcare system because of numerous criminal history and poverty related barriers. Death after incarceration because of health and behavioral health symptoms risk skyrockets after release, formerly incarcerated individuals are nearly 13 times more likely to die in the 2 weeks following a prison experience when compared to other residents. Overall, formerly incarcerated individuals have a death rate 3.5 times that of individuals who have never been incarcerated. Patient-centered medical homes and federally-qualified health centers are quite literally a lifeline and ensuring that those with incarceration histories can access equitable care is essentially for their well-being.

For well over a decade my applied behavioral health intervention research has occurred at the intersection of well-being, behavioral health, and criminal justice involvement. Thus, my research agenda requires me to conduct rigorous research methods while understanding the complex settings and systems of care within which I am trying to develop and test interventions. I have active projects in correctional and community settings across 7 states. I am currently the principal investigator or co-principal investigator on six randomized controlled trials within community and criminal justice settings. Over the past five years, I have received over 15 million dollars in federal and private foundation support to conduct this research and the studies have ranged from feasibility to pilot studies to large multi-site randomized controlled trials (RCT). My largest multi-phased and multisite RCT is currently occurring within over 100 correctional facilities with participants continuing the trial after release from prison in one of 24 rural and urban counties (N=3000). This is a privately funded trial that is high risk and transformative and one example of several of my projects that I would not likely had been able to implement with traditional federal funding mechanisms. I have portfolio of privately funded research paired with federally funded research because it allows for me to engage in high risk and

transformative research in a field that is solely lacking an evidence base – well-being, behavioral health, and criminal justice involvement. Therefore, I am very familiar with and energized by the high risk and transformative types of research that this Transformative R01 supports. When I first launched my transformative and high-risk approaches to research, I formed a National Scientific Advisory Council that continues to expand to help to monitor and guide my research. Because my research spans bases to translational phases of behavioral and social sciences research, nearly half of my publications present my mixed methods research requiring the type of integration and contextualizing of data that we propose in this current submission. As a result of being a social worker in field settings for ten years before joining academia, I conduct all my research in partnership with correctional stakeholders and community service providers. This blend of prior field-based practitioner experience and community-engaged scholarship has allowed me to understand the depth and nuance of complications that can occur with applied, real-world research in community settings. During my years as a health intervention and services researcher, I have thus established a large bank of anticipated challenges and possible responses to them based on strategies that have worked in the past.

My role on this project will be to lead the system science team for aims 1 and 2, oversee the postdoctoral fellow activities including literature reviews and summaries for all phases of the project, ensure the research sharing plan is implemented, and ensure the dissemination timeline of data release to publication and dissemination to communities is adhered to. I will oversee the staff structuring and management related to my team and roles on the project.

I am well supported for this project because I have the infrastructure through the research center that I run and the experience in managing multi-site projects from afar. My research center is comprised of over 80 operations and field-based research staff dispersed across 10 states working on active research studies. Within my research center I have a data management and analysis core, an operations and administration core, a training and fidelity monitoring core, and a dissemination core that has the capacity to take on a study of this scope. I have trained field staff already located throughout Florida. I worked at Washington University in St. Louis (Wash U) for 7 years prior to agreeing to join FSU to launch a campus-wide research center on criminal justice and behavioral and public health. During my time in Missouri, I established productive research partner relationships with the co-investigator and research team from Wash U that we have involved in our proposal. Under the leadership of our Wash U team, I have participated in both Group Modeling Building workshops and simulation modeling. We have also prepared other research proposals together in the past.

#### **B.** Positions and Honors

2011-18	Assistant Professor, Washington University in St. Louis. Brown School
2014-18	Founding Director, Institute for Advancing Justice Research & Innovation
2014-	Grand Challenges, PSD Network Co-Lead, American Academy of Social Work & Social Welfare
2018-	Founding Co-Director, Smart Decarceration Initiative, CSD, Brown School
2018-	Founding Executive Director, Institute for Justice Research and Development
2018-	Associate Professor, College of Social Work, Florida State University

# Other Experience and Professional Memberships

2015	Conference Co-Director and Co- Host: From Mass Incarceration to Smart Decarceration
2015-	Board Member, Advisory Committee for the Center for Diversity and Social and
	Economic Justice: Council on Social Work Education
2017	Conference Co-Director and Co-Host: Tools and Tactics: Promising Solutions to Advance the
	Era of Smart Decarceration
2017-	Co-Chair, Criminal Justice Track. Society for Social Work and Research
2017	Member, National Advisory Board on Mental Health and Criminal Justice. The Equitas Project
2018-	Member, National Advisory Council, Safe Streets Second Chances Initiative
2018-	Chair, Research & Education Council, Center for Study of Communities, Families & Children

## Honors (Selected)

2009 Shaver Hitchings Award for Service in the Area of Addictions 2010 Fahs-Beck Scholar in Research and Experimentation

- 2010 Impact Award for research with high impact in North Carolina
- 2010 Royster Society of Fellows Award
- 2011 Society for Social Work and Research Dissertation Fellows Award
- 2011 Dissertation with Distinction University of North Carolina at Chapel Hill
- 2012 National Institute of Health Intervention Research Summer Institute
- 2015 Training Institute for Dissemination and Implementation Research
- 2017 William T Grant Foundation Scholars Award Finalist
- 2018 Marguerite Q. Warren & Ted B. Palmer Differential Intervention Award, American Society of Criminology
- 2020 Society for Social Work and Research (SSWR) Fellow

#### C. Contributions to Science

Conceptual Guidance & Collaborative Work with Community Partners to Create & Disseminate Models Research on the complex circumstances of incarcerated and formerly incarcerated individuals and how to best relieve symptoms and promote behavioral health and well-being is still in its infancy. And, although it is tempting to take existing empirically validated interventions conducted with other populations and impose those interventions on an incarcerated population, I have found this approach to be misguided because of the unique, and extreme, psychological and physical tolls that an incarceration experience imposes on incarcerated individuals, formerly incarcerated individuals, and the professionals that work with them. Therefore, I have sought to advance conceptual literature and methodological approaches specific to the intersection of incarceration, policy and health intervention, and behavioral health by working with corrections professionals and clients to propose empirically and theoretically grounded frameworks to guide intervention and implementation research.

**Pettus-Davis, C.,** Renn, T., & Motley, R\*. (2019). Proposing a population-specific intervention approach to treat trauma among men during and after incarceration. *Psychology of Men & Masculinity*, 3, 379-393doi: 10.1037/men0000171

**Pettus-Davis, C.**, Renn, T., Veeh, C., & Eikenberry, J. (2019). Intervention development study of the 5-Key Model for Reentry: An evidence driven prisoner reentry intervention. *Journal of Offender Rehabilitation*, 58,614-643. doi:10.1080/10509674.2019.1635242

Grady, M., Edwards, D., & **Pettus-Davis, C.** (2013). Sex offender recidivism: Does volunteering for treatment matter? An assessment using propensity score analysis. *Sexual Abuse: A Journal of Research and Treatment*, 25,319-346. doi:10.1177/1079063212459085

**Pettus, C.A**. & Severson, M. (2006). Paving the way for effective reentry practice: The critical role and function of the Boundary Spanner. *The Prison Journal*, *86*, 206 – 229. doi:10.1177/0032885506287821

### **Primary Research with Providers and Patients**

My policy and behavioral health services research has included understanding behavioral phenomenon from the perspective of both the providers and the patients receiving services. For example, using the perspectives of both corrections professionals and clients, I examined the role of social support in behavioral health outcomes. My research found that the nature and quality of social ties are highly predictive factors contributing to criminal justice involvement including criminal behavior and the recovery from, or deterioration of, behavioral health disorder symptoms. Through my phased policy and behavioral intervention research agenda I first sought to identify the prevalence and quality of social support available to individuals with substance use disorders releasing from incarceration. I contributed to research knowledge by finding that many of these individuals -despite having been removed from social networks -have positive social support available to them from providers as well as their informal networks that, under the right circumstances, can facilitate recovery from substance use disorders and promote successful reintegration to communities and promote health and well-being. I further advanced scientific knowledge by developing a behavioral health intervention that includes social support as a key mechanism of action and I tested and found that social support focused interventions are feasible. Through this inquiry, I also discovered that social support plays an important role for providers and that they experience the presence or lack of this support in the form of their coping while performing the duties of their job.

Biosketches Page 76

**Pettus-Davis, C.**, & Kennedy, S. (2020). Early lessons from the multistate study of the 5-key model for reentry. Perspectives: The Journal of the American Probation and Parole Association, Vol 44, 19-3.1

**Pettus-Davis, C.**, Howard, M.O., Murugan, V\*., Roberts-Lewis, A., Scheyett, A., Botnick, C\*.,&Vance, M.\*(2015).Acceptability of a social support intervention for reentering prisoners. *Journal for Society of Social Work and Research*,6, 51-89.doi:10.1086/680340\

**Pettus-Davis, C.**, Scheyett, A., Haley, D., Golin, C., & Wohl, D. (2009). From "Streets" to "Normal Life": Assessing the role of social support in release planning for HIV-positive and substance-involved prisoners. Journal of Offender Rehabilitation, 48, 367-387.doi:10.1080/10509670902979447

Severson, M., & **Pettus-Davis, C**. (2013). Parole officers' experiences of the symptoms of secondary trauma in the supervision of sex offenders. *International Journal of Offender Therapy and Comparative Criminology*, *57*(1), 5-24.

### Race and Behavioral Health Equity Research

Racial and behavioral health equity is almost nonexistent among criminal justice involved populations. I have conducted translational behavioral and social science research examining experiences of disparities and opportunities for promoting equity for well-over a decade. I have published proposed research agendas and co-edited the first book of its kind documenting a comprehensive view of disparities throughout the criminal justice system. To this end, I have conducted basic research as well as proposed conceptual frameworks for thinking about how to promote equity for justice-involved individuals. Each of my current studies includes an outcome variable that examines whether the interventions being tested and refined promote equity.

Veeh, C., Tripodi, S., **Pettus-Davis, C.**, Scheyett, A.M. (2016). The interaction of serious mental disorder and race on time to reincarceration. American Journal of Orthopsychiatry,88,125-131. doi: 10.1037/ort0000183

Co-edited: Epperson, M.W., & **Pettus-Davis, C**. (Eds). (2017). Smart Decarceration: Achieving criminal justice transformation in the 21stCentury. NY: Oxford University Press.

**Pettus-Davis, C**. (2012). Reverse social work's neglect of justice-involved adults: The intersection and an agenda. Social Work Research, 36, 3-7.doi:10.1093/swr/svs036

Cuddeback, G.S., Scheyett, A., **Pettus-Davis, C**., &, Morrisey, J.P. (2010). General medical problems of incarcerated persons with severe and persistent mental illness: A population-based study. Psychiatric Services, 61, 45-49.doi:10.1176/appi.ps.61.1.45.

### **Complete List of Published Work in MyBibliography:**

https://www.ncbi.nlm.nih.gov/myncbi/16i2ikvyusjgCx/bibliography/public/

D. Additional Information: Research Support and/or Scholastic Performance

### **Ongoing Research Support**

National Institute of Justice Pettus-Davis, Rogers, Aggarwal (Co-PI) 01/01/20-12/31-24

Al Enabled Community Supervision for Criminal Justice Services.

The goal of this project is to develop and test Artificial Intelligence applications to be used jointly by probation officers and individuals under community supervision.

Role: Co-PI

National Institute of Justice Pettus-Davis, Tripodi, Renn (Co-PI) 01/01/20-12/31/22

Multisite Randomized Controlled Trial of Comprehensive Trauma Informed Reentry Services for Moderate to High Risk Youth Releasing from State Prison.

The goal of this project is to design, implement, and evaluate a trauma-informed intervention delivered to young men at high risk for returning to incarceration after release. The intervention begins during custody and continues in the community after release.

Role: Co-PI

Biosketches Page 77

Arnold Ventures Pettus-Davis (PI) 01/01/20-12/31-20

Multi-Site Feasibility Evaluation of Crisis Stabilization Units across Three Jurisdictions with High Opioid Use Disorders and a Proposed Follow-Up RCT

This project examines the effectiveness of mobile aftercare for individuals releasing from crisis stabilization units in three geographically diverse regions in Florida.

Role: PI

Seminole County Sherriff's Office Pettus-Davis, Tripodi, Renn (Co-PI) 03/01/19-02/28/21 Skills Training and Affective Regulation Intervention – Pilot Trauma Treatment for Men and Women Releasing from Jail; Seminole County, Florida

This project is a pilot study of a trauma-informed intervention delivered to individuals releasing from a local jail setting in Seminole County Florida. The intervention begins during custody and continues in the community after release.

Role: Co-PI

Charles Koch Foundation Pettus-Davis (PI)

03/01/18-7/31/26

Multistate Randomized Controlled Trial of the 5 Key Model for Reentry

The goal of this project is to test a novel reentry program with individuals leaving incarceration and returning to the community. The study is currently being implemented with more than 3,000 participants in 21 rural and urban counties in seven states across the nation.

Role: PI

Arnold Ventures

Pettus-Davis, Tripodi (Co-PI)

09/01/18-06/30/26

A Low-Cost Randomized Controlled Trial of Therapeutic Communities and Interactive Journaling Substance Use Disorder Treatments: Research on Reductions in Recidivism and Social Spending.

The goal of this project is to evaluate the effectiveness of a low-cost substance use treatment program when compared to existing programs (i.e., outpatient, intensive outpatient, therapeutic communities) in prisons across Florida.

Role: Co-PI

*U.S. Department of Human Service*, Office of Minority Health **Pettus-Davis**, Mueller (Co-PI)09/01/16-06/30/21 Evaluation of the Re-Link Project.

This project is a comprehensive evaluation of the Re-Link Program.

Role: Co-PI

### **Recently Completed Research Support**

Arnold Ventures Pettus-Davis, Epperson (Co-PI) 06/01/16-12/31/18

Advancing the Implementation and Rigorous Testing of Deferred Prosecution Programs: A Multisite Study This project focused on best practices for implementation and testing of deferred prosecution programs.

Role: Co-PI

NIH Clinical & Translational Science Awards -- Sharing Partnership for Innovative Research in Translation, SPIRIT award Pettus-Davis, Epperson (Co-PI) 01/01/17-12/31/18

Promoting Behavioral Health within Communities to Reduce Criminal Justice Contact

This project explored behavioral health as a community prevention point for criminal justice system contact.

Role: Co-PI

Biosketches Page 78

#### **Transformative R01**

PI: Sylvie Naar, PhD; Florida State University

09/01/2021 - 08/31/2026

Florida State University

#### **BUDGET JUSTIFICATION**

### **Key Personnel:**

Sylvie Naar, PhD, Contact MPI (10% FTE, 1.20 Calendar Months, Y1-5) is a clinical researcher with more than two decades of studies across the translational spectrum of behavioral and organizational intervention research from early trials translating basic behavioral science into new interventions, to randomized clinical trials, to comparative effectiveness, to implementation. Her focus is on reducing health disparities in minority youth and families. And has had several large-scale trials of interventions to improve health of Black and African Americans. Dr. Naar will serve as the contact MPI for this proposal, and will be responsible for communication between the sponsor and the research team, provide scientific oversight of all components, liaison to the intervention development, community engagement, and measurement teams, and lead dissemination efforts. She will supervise the manager, coordinator, and research assistant. Additionally, Dr. Naar will oversee the financial and regulatory components of the project, including annual reporting.

NIH Salary Cap applied (\$197,300) x Effort (10%) + Fringe ( x Years (5) =

Carrie Pettus-Davis, PhD., MSW, MPI (10% FTE, 1.20 Calendar Months, Y1-5) Associate Professor at Florida State University, College of Social Work, Founder and Executive Director for the Institute for Justice Research and Development (IJRD) will serve as MPI for the study. Dr. Pettus-Davis be responsible for coordinating the systems science team for aims 1 and 2a. She will oversee the recruitment for these aims, and will supervise the postdoctoral fellow.

NIH Salary Cap applied ( x Years (5) = x Years (5) = x Years (5) = x Years (5) = x Years (5)

Norman Anderson, PhD, MPI (10% FTE, 1.20 Calendar Months, Y1-5) is a trained clinical psychologist, who has held a variety of researcher, professor, and other leadership experience in the area of health disparities and mind/body health. This experience spans higher education, government, and nonprofit sectors. Dr. Anderson is a current Assistant Vice President for Research and Academic Affairs and Research Professor of Social Work and Nursing at Florida State University. He was founding director of the Office of Behavioral and Social Science research at the NIH. Prior to Florida State University, Dr. Anderson has served as a tenured associate professor at Duke University and as a professor at the Harvard School of Public Health and is well known for his research and writing on health and behavior and racial and economic health disparities. Dr. Anderson is also a Certified Professional Coach, with nearly two decades of experience providing leadership training to senior executives, with a special interest in using mindfulness, emotional intelligence, and positive psychology techniques. It is Dr. Anderson's wealth of experience and expertise that will serve his role as MPI well, providing guidance and leadership to the study team related to the evaluation of community partner organizational systems, and defining and simulating anti-racism provider and organizational interventions. Further, Dr. Anderson will serve as the liaison to the Scientific Advisory Committee and provide scientific input into all phases of the project. As such, Dr. Anderson will participate as MPI at 10% FTE, from initial planning and evaluation to analysis and dissemination.

NIH Salary Cap applied ( x Years (5) =

**Heather Flynn, PhD, Co-Investigator (5% FTE, 0.60 Calendar Months, Y1-5)** is a clinical psychologist and Professor and Vice Chair of Research at the Florida State University (FSU), College of Medicine in the

Department of Behavioral Sciences and Social Medicine. She is an expert in integrated primary care and is the Director of the FSU Center for Behavioral Health Integration and the Center of Excellence for Anxiety and Depression. Dr. Flynn conducting projects focused on advancing the field of integrated physical and mental health care both nationally and in the State of Florida and facilitates collaborative research networks to enhance synergy among experts in depression and medical care. She is the Co-Chair of the Florida Maternal Mental Health Collaborative (www.flmomsmatter.org), and the Chair of the Women & Mood Disorders Task Group within the National Network of Depression Centers (www.nndc.org). Dr. Flynn is a member of the Motivational Interviewing Network of Trainers (MINT) and has been conducting training and supervision in this behavioral intervention with various settings and professionals for over 15 years. She trains medical students and physicians in this approach at FSU. She is also a trainer and supervisor in other behavioral interventions such as Interpersonal Psychotherapy for Depression and serves on the Executive Board of the International Society for Interpersonal Psychotherapy. She will lead the intervention development team in collaboration with MPI Naar.

NIH Salary Cap applied ( x Years (5) = x Years (5) = x Years (5) = x Years (5) = x Years (5)

Penny Ralston, PhD, Co-Investigator (10% FTE, 1.20 Calendar Months, Y1-5) is a Professor, Dean Emeritus, and Director of the Center on Better Health & Life for Underserved Populations at Florida State University. Dr. Ralston's research focuses on evaluation and programmatic development of community-based organizations and higher education programs with the goal of improving health across the lifespan. She has extensive background in community-engaged health disparities research and will lead the community engagement team. She will outreach to key stakeholders for participation in model development, intervention development, and measurement development and coordinate these activities with the Project Manager.

NIH Salary Cap applied ( x Effort (10%) + Fringe ( x Years (5) =

Calendar Months Y4-5) is a professor in the Department of Psychology at Florida State University, and an Associate Director of the Florida Center for Reading Research. He is an expert in scientific methodology and statistical modeling including item response theory methods. He has significant experience in developing measures for minority populations in his work to improve reading among persons at high risk for low literacy. Dr. Schatsneider has also provided methodological support for Dr. Naar's CTSA KI2 program. He is also an expert in computer adaptive measures. He will lead the measurement development team in collaboration with MPI Naar.

NIH Salary Cap applied x Effort (5%) + Fringe (x x Years (3) = X Years (3) = X Years (2) = X Years (2) = X Years (2) = X Years (3) = X Years (3) = X Years (4) = X Years (5%) + Fringe (

#### Other Personnel:

**TBD, Post-Doctoral Fellow.** (100% FTE, 12.0 Calendar Months, Y1-5). One post-doctoral fellow will specialize in literature reviews and summaries and qualitative research methods, and will support Dr. Pettus-Davis and the systems science team. The fellow will also participate in dissemination efforts.

**TBD, Project Manager** (100% FTE, 12.0 Calendar Months, Y1-5) from the Center for Translational Science, will assist the contact MPI with all aspects of project management related to related to coordination, communication and regulatory functions. This position will also oversee the project coordinator and research assistant related to day-to-day administrative project tasks, support the MPI with site communication and stakeholder engagement, technology and resource support, dissemination of research findings and coordinating and facilitating study meetings and applicable regulatory reporting.

**Sara Green, MSW, Project Coordinator (10% FTE, 1.20 Calendar Months, Y1-5)** will assist the Project Manager and MPIs with all aspects of regulatory management and reporting, for all years of the project.

Kerensa Lockwood, PhD. Study Coordinator. (5% FTE, 0.60 Calendar Months, Y1-5). Dr. Lockwood will assist Dr. Pettus-Davis in administrative operations related to her activities and those within the Department of

Social Work including personnel services, expenditure and procurement activities, travel documentation, and project related factors.

TBD, Research Assistant (100% FTE, 12 Calendar Months, Y1-5) will assist with all research activities, including but not limited to IRB application, amendments and renewals, study recruitment, data collection activities and intervention monitoring. The research assistant will oversee all study related activities at the research study sites. S/he will participate in weekly research team meetings. RA – assist the PM in all areas of the project with particular focus on meeting coordination, meeting minutes, organizing literature reviews and summaries, and preparing dissemination materials. This will be a project dedicated, part time position (20 hours per week at \_\_\_\_\_\_, fully funded throughout the life of the project. **Fringe Benefits:** Fringe benefits may consist of Retirement ( Social Security. Medicare, Workers/Unemployment Compensation and Terminal Leave Pool, plus appropriate health insurance yearly for individual; yearly for family; and yearly if both employee and spouse are full-time State of Florida employees). The cost of health and/or life insurance should be added to the fringe benefit cost, if applicable. The following rates should be used in calculating fringe benefits: Faculty/A&P/USPS under FSRP and FSRI is Faculty/A&P/USPS under ORP is Faculty/A&P/USPS under DROP is COPS Students is COPS Non-students and Postdocs is ■. A scost-of-living increase was assumed for all benefits eligible salaries. **Other Direct Costs** Travel: Stakeholder and Community Engagement Travel: in years 1-3 of the project is requested to support travel to model building focus group inperson meetings for study leads. Costs include travel to a minimum of 3 in person stakeholder engagement meetings for 2 travelers annually. Associated costs are estimated to include rental car transportation when appropriate (per day for 2 days = per night), lodging for 1 night (per night), and other allowable per day for 2 days = (a) for a total per person cost of person x 2 travelers incidentals ( x 3 times per year x 3 years = Investigator Conference Travel: Support for each MPI to travel to 1 national or international conference to disseminate study findings in years 4 and 5 of the project. Associated costs are estimated to include conference registration ( lodging ( , ground transportation (\$120), and other allowable incidental expenses ( ) for 3 MPIs for a per trip, per year. In the event there are travel restrictions in these years, the MPIs will make every effort to register for and participate in virtual conferences/symposiums. Publication costs: A total of is requested his will cover publications fees to publish findings in Years 4 and 5 in prominent academic journals, such as PLoS Medicine and PLoS ONE. Materials & Supplies: 2 Laptops and accessories will be purchased for the project manager, postdoctoral fellow, and research assistant. The laptops are estimated at least leach ), 6 monitors at /each , and 3 docking stations at ). Additionally, software and associated licenses each and other technology components will be purchased for for project management, data management, and analysis and dissemination efforts on each device. per year is requested to support consumable supplies, such as paper, printer ink,

binders, and other materials utilized for stakeholder engagement and other study activities.

Consultants:
, <b>Consultant</b> will participate in the scientific advisory council and assist Dr. Anderson in recruiting members. extensive experience in clinical trial research, community outreach, and policy, will further facilitate the system science approach through providing expertise on translating stakeholder engagement findings into intervention development, practice and policy recommendations. In this role, will compensated for 10 hours per year at per hour for a total of every over the life of the project.
Scientific Advisory Council will consist of 4 additional subject matter experts who will play an integral role in the participatory stakeholder systems science approach, by participating in efforts to identify intervention points for disruptive anti-racism innovations. This team of experts will advise the study team on stakeholder engagement and retention in the study, the development of model building for phased behavioral and social science interventions, achievement of project goals and dissemination efforts. These external consultants will be compensated at a rate of per hour, 10 hours per year for each member, for a total of per year; total throughout the life of the project.
<b>Consultant</b> will provide consultation on measurement development methods with extensive experience in provider and organizational measures. This consultation will consist of up to 10 hours in Years 3 - 5 at a rate of record or a total record.
Participant Support Costs:
Over the course of the project, 150 participants will attend 10 group model building meetings and be compensated a gift card per session, for an individual stakeholder total of . We are estimating only 50 percent of stakeholders will be compensated per their organizational guidelines (e.g. public health officials) for a total requested amount of gift card incentives between years 1-5.
Additionally, a subset of 10 stakeholders will participate in a stakeholder advisory council for four meetings per year at per session for a total request of across all years (10 stakeholders x 4 meetings x x 5 years).
Overall, stakeholder participant incentives are requested at project over the life of the project.
For in-person sessions, food and drink will be provided to the community-based participants for an estimated total of across all years.
SUBAWARDS
Washington University in Saint Louis
For a detailed explanation of subaward costs, please refer to the subaward budget justification.
Total subaward costs:
total direct costs
indirect costs
total subaward costs, Years 1-5
Annual subaward costs:
Year 1: Year 2: Year 3: Year 4: Year 5:

The federally negotiated indirect cost rate for the Washington University in St. Louis is 57.50% of all Modified Total Direct Costs.

### **Indirect Cost Rate**

for the period July 1, 2019 through June 30, 2021 as per Florida State University F&A rate agreement effective 79/2018. MTDC consists of all salaries and wages, fringe benefits, materials, supplies, services, travel, and subgrants and subcontracts up to the first of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). MTDC shall exclude equipment costing or more, capital expenditures, charges for patient care, student tuition remission, rental costs of off-site facilities, scholarships, fellowships, and participant support costs, as well as the portion of each subgrant and subcontract in excess of

### **Washington University**

### **Budget Justification**

#### Introduction

A 3% cost-of-living increase was assumed for all benefits eligible salaries. Washington University does not have a standard fringe rate but instead calculates fringe benefits based on the role of the individual. To comply with the Department of Health and Human Services' Office of the Inspector General's recommendation, effective July 1, 1993 Washington University began including as direct costs on grants and contracts those fringe benefits previously included in the University's indirect cost rate.

\* Fringe benefits include FICA, annuity, health allowance and other fringe benefits. Other fringe benefits include: tuition remission, workmen's compensation, disability insurance, group life insurance, non-dependent tuition, metrolink and unemployment compensation and will be a direct cost at a flat rate per employee, per month, times the employee's percent of salary on the grant.

## A. Senior/Key Personnel

**Douglas Luke, PhD., Subaward Principal Investigator, (5% FTE, 0.60 Calendar Months, Y1-5).** Dr. Luke is a Professor at Washington University's (WUSTL) Brown School and the Director of the Center for Public Health System Science (CPHSS) at Washington University. Dr. Luke brings over 20 years of experience as a public health scientist with expertise in implementation science, sustainability research, systems science, and measurement development and was responsible for the development of the Clinical Sustainability Assessment Tool. Dr. Luke will serve as the Sub-Award PI and will primarily oversee development and execution of the computational model for Aim 2. He will also collaborate with project PIs and other personnel to assist with activities for Aim 1 and in dissemination of project results.

Voor 1.	
Year 1:	
Year 2:	
Year 3:	
Year 4:	
Year 5:	

Todd Combs, PhD., Co-Investigator (5% FTE, 0.60 Calendar Months, Y1 and 5; 20% FTE, 2.40 Calendar Months, Y2-4). Dr. Combs is an Assistant Research Professor and Assistant Director of Research at CPHSS. Dr. Combs has expertise in the collection, assessment, translation, and dissemination of retail tobacco policy activity in the US and in statistical and agent-based modeling of the impacts of public health policy strategies. In his role, he will lead development of the computational model for Aim 2 and collaborate with other key personnel to incorporate findings from Aim 1 into the model development. He will also provide input to the measurement team and will collaborate for dissemination of project results.

Year 1:	
Year 2:	
Year 3:	
Year 4:	
Year 5:	

Ellis Ballard, MSW, MPH, Co-Investigator (30% FTE, 3.60 Calendar Months, Y1; 10% FTE, 1.20 Calendar Months, Y2; 5% FTE, 0.60 Calendar Months, Y5). Mr. Ballard is the Director of the Social System Design Lab and an Assistant Professor of Practice at the Brown School at Washington University in St. Louis. He will lead systems mapping activities for Aim 1 as a system dynamics modeler and community-based researcher, provide input in aims 2 and 3 and collaborate in dissemination of project results.

Year 1:	
Year 2:	
Year 3:	
Year 4:	
Year 5:	

Veronica Chaitan, MPH, Data Analyst (5% FTE, 0.60 Calendar Months Y1 and 5; 20% FTE, 2.40 Calendar Months Y2-4). Ms. Chaitan will work closely with PIs to develop and implement an analysis plan for modeling. Her responsibilities will include data collection and preparation for informing model development as well as assistance with analysis, interpretation, and reporting of the study results.

Year 1:	
Year 2:	
Year 3:	
Year 4:	
Year 5:	

#### C. Materials and Services

None

## D. Travel

None

### **E. Other Direct Costs**

None

The federally negotiated indirect cost rate for the Washington University in St. Louis is \_\_\_\_\_% of all Modified Total Direct Costs.

**Significance, Innovation and Impact.** Increased media attention regarding COVID-related health disparities combined with horrific institutionalized violence against Black/African Americans have revitalized the call to action to address systemic racism in health care (e.g., <sup>1-4</sup>). Among the consequences of systemic racism in health care are significant health disparities in prevalence, diagnosis, and treatment of comorbid physical and mental health conditions, inequities that synergistically result in poor physical and mental health outcomes. <sup>5, 6</sup> Black/African Americans' health inequities are further increased by the significant overrepresentation of Black/African Americans in prisons and jail, experiences that are related to poor mental and physical health outcomes both prior to and after incarceration. <sup>7</sup> Despite decades of studies acknowledging racial health disparities and an increased awareness of the social determinants of health, we seem to be light-years away from significant change. Racism still very much impacts the health care delivery system even in systems designed for low income and minority populations that strive to integrate physical and mental health treatment in primary care such as Patient Centered Medical Homes. <sup>8</sup>

As noted in *Lancet*, racism kills, 9 and there are shockingly few evidence-based interventions to change racist attitudes, behaviors, and practices at the provider and organizational/systems level. Beyond one-time, brief training modules, which have minimal impact on behavior 10 little has been done to combat racism and discrimination in the context of primary care in the US. New paradigms are needed to transform, and not just document, racism in health care systems. We propose to develop and test a transformative paradigm for translating basic behavioral and social science into new anti-racism interventions for primary care settings. The paradigm is the first of its kind to integrate community-based participatory research, systems science, individual and organizational behavior management, diffusion of innovation theory and measurement theory. The paradigm leverages an established framework of early phase translational behavioral and social science to rigorously define and refine new anti-racism interventions within complex health systems and rigorously develop measures to assess impact with community engagement formalized at every step. Without such a transformative paradigm, anti-racism provider and organizational intervention research will remain stagnant and have minimal impact on redressing mental and physical health inequities because of such a fragile evidence-base. By establishing a process of rigorous translational research in community-engaged anti-racism intervention development and testing, this transformative project will produce a replicable, innovative, efficient and effective community-engaged model for addressing health care racism and transform efforts to improve integrated primary health and mental health care services.

Insight and Rationale. Science-informed anti-racism is a disruptive innovation in the United States that will have profound systems-level consequences in health care. A disruptive innovation in health systems is one that creates new networks and new organizational cultures to diffuse new practices to improve health outcomes and the value of health care. 11. Such a disruptive innovation within an integrated health care system can be rigorously mapped using community-engaged systems science methods. 12, 13 This map identifies "leverage points" likely to result in the most impactful intervention targets and to support the diffusion of such innovations within complex systems. 14 Once leverage points are identified, basic behavioral and social science can be rigorously translated into new interventions, policies and practices to target these points and can be simulated in systems science models (e.g. communication science translated improve the patient-provider interactions; diffusion of innovation theory translated to ensure the adoption of anti-racism policies and practices), resulting in screening the most potent interventions with mathematical standards for intervention efficacy in future trials. 15 Potential interventions will need to be measured by efficient and effective measurement tools (e.g., computerized adaptive tests) to rigorously monitor outcomes and develop a foundation for future health care anti-racism intervention research. 16 Thus, this project will transform health equity research in integrated primary care and provide a foundational community-engaged process model for developing an evidence base in anti-racism policies and practices within other systems and against other marginalized groups with the following aims:

**Primary Aim 1:** Using group model building (i.e., a participatory stakeholder systems science approach), identify the leverage points where disruptive innovations in anti-racism behaviors, policies, and practices can improve health equity.

**Primary Aim 2:** Design a simulation system to demonstrate the impact of such anti-racism interventions. **Secondary Aim:** Using Item Response Theory, initiate the process of developing core measures for assessing the effects of anti-racism interventions at the provider and organizational-systems level as specified in the primary aims.

Specific Aims Page 122

#### **OVERVIEW OF RESEARCH PROJECT**

Racism in Health Care is a Public Health Crisis. The significant health disparities in the prevalence, diagnosis, and treatment of comorbid physical and mental health conditions among Black/African Americans has been well established.<sup>3, 5, 17-20</sup> These inequities synergistically result in poor physical and mental health outcomes, including increased mortality in Black/African Americans.<sup>21, 22</sup> The overrepresentation of Black/African Americans in the criminal justice system and the associated mental and physical health consequences of this experience intensify health inequities.<sup>23-25</sup> Integrating mental health and primary health care for underinsured populations, as in the patient-centered medical home (PCMH) model, was expected to improve these disparities (ref).<sup>26-28</sup> Yet such hopes have not been realized. As noted in Health People 2020, disparities persist and access and engagement in primary care is still inadequate among persons of color.<sup>29-31</sup>

The PCMH model dictates that each patient has a personal primary care physician who directs a team of health care professionals in order to provide accessible, patient-centered, and coordinated mental and physical health care to maximize health outcomes. <sup>32, 33</sup> PCMH is a designation and accreditation status that includes incentives for meeting core standards of care. <sup>34</sup> PCMH has five core principles and functions: comprehensive care, patient-centered approach, coordination of care, accessibility of services, and quality and safety. The PCMH primary care model has earned the support from every major physician organization in the U.S., major consumer groups, and most Fortune 500 companies<sup>35</sup> with over 13000 practices qualifying for PCMH recognition from National Committee for Quality Assurance, the main accrediting body. <sup>28</sup> Despite evidence of business model success, outcomes of PCMHs are mixed, particularly for persons of color are mixed. For example, one meta-analysis suggested limited effects of PCMHs the majority of measures of cost, utilization, and quality. <sup>36</sup> Findings from the Medical Expenditures Panel Survey found low overall access and significant racial/ethnic variations in experiences of PCMH with persons of color having lower odds of receiving each of the five core principles of the PCMH functions. <sup>37</sup>

Such disparities and poor health outcomes can, in part, be explained by racism in health care.<sup>38-40</sup> Health care racism against Black/African Americans in particular has been recently declared a public health emergency.<sup>4</sup> The literature has captured a great deal of evidence about racism among health care providers in the US. In one systematic review alone, 26 out of 37 studies showed "statistically significant evidence of racist beliefs, and an assessment of implicit and explicit bias against persons of color among primary care providers and community members revealed substantial implicit bias against both Latinos and Black/African Americans among both providers and community members, while explicit bias was absent or difficult to detect for both.<sup>41</sup> Not surprisingly, clinicians' implicit bias negatively affects patients' perceptions of their care and reluctance to engage in primary care and follow-up with recommendations<sup>42,39,43,44</sup>

Anti-racism interventions are necessary for achieving health equity but there are few rigorously tested anti-racism interventions and few measures appropriate for health care settings. Several systematic reviews capture the current state of interventions to reduce racism in health care settings, but few are antiracism specifically and instead focus on prejudices, stereotypes, cultural competency, and cultural appropriateness. These are, of course, ways of targeting racism, albeit in a more indirect way. One review covered 30 peer-reviewed studies conducted between 2005 and 2015 on interventions designed to reduce implicit prejudices and implicit stereotypes in real world contexts. Few studies reported robust data, and among the conclusions of the review reported to presumably reduce bias but their effectiveness is questionable: many interventions showed no effect or actually increased implicit bias. 10 For example, interventions such as engaging with others' perspective had little impact but some techniques such as exposure to counterstereotypical exemplars were more promising but still lacking rigor. In a systematic review of reviews of articles published between 2000 and 2012 on interventions to improve cultural competency in health care, 19 published reviews consisting of between 5 and 38 studies were identified. Among the conclusions of the review of reviews: many of the studies relied on self-report, many studies lacked methodological rigor, and few studies included evidence of intervention effectiveness. 45 Finally, in a systematic review to establish whether cultural competency training of health professionals improves patient outcomes the conclusion is similar to other studies: High-quality research on interventions designed to improve cultural competency and reduce various race-related biases is lacking. Similarly, the literature does not often contain studies revealing a positive

relationship between cultural competency training and improved patient outcomes<sup>46</sup> and instead shows limited impact. These reviews paint a rather unfortunate picture of anti-racism interventions appropriate for health care settings, though the demand for such interventions is high and necessary to achieve health equity.

**Fundamental New Insight Needed.** Racism in health care is woven throughout a complex system that can be disrupted by diffusing anti-racism innovations at critical points in the system. A new transformative paradigm is needed to ignite the stagnate field of anti-racism health care interventions to change behavior, policies and practices in order to fully realize the potential of integrated primary care models such as PCMHs for achieving health equity for Black/African Americans. This project aims to transform this field by combining scientifically proven social and behavioral science approaches and methods and applying them to behavior, policies, and practices of individual providers and organizational-systems.

**Novel Application and Integration of Proven Methods.** Newly established methods of translational behavioral and social science have not been leveraged to rigorously develop and test the most potent antiracism health care interventions to change provider behavior and organizational-systems policies and practices. The ORBIT model of translational behavioral and social science, an established phased approach with associated research questions and methods, capitalizes on new approaches such as systems science to define critical leverage points ripe for disruptive innovations within complex systems.<sup>47</sup> Community-based participatory research has recently aligned with systems science to ensure community engagement at every step of the translational process, <sup>12, 13</sup> which maximizes the likelihood of intervention relevance and future adoption, but has not been utilized for anti-racism interventions in health care or other systems. Implementation science has shed new light on the contribution of organizational theories for the diffusion of new innovations, but again such basic science has not been translated into anti-racism interventions, policies, and practices within health care systems.

Creating Transformative and Paradigm Shifting Strategies. Guided by the established ORBIT model, this project will create and test a transformative community-engaged paradigm for developing anti-racism interventions in real world integrated health care systems serving Black/African Americans. Using systems science methods, this project will map racism in provider behavior and organizational-systems practices, identify disruptive anti-racism interventions, simulate the impact of intervention models on provider behavior and organizational-systems' policies and practices, and begin to develop related outcome measures for anti-racism provider and organizational-systems interventions. This study will take place within a —a state-wide PCMH network. The ultimate goal is to create paradigm shifting strategies and a manualized process model for developing evidence-based anti-racism interventions, policies, and practices that can be replicated for other marginalized groups and in other health care systems and beyond.

### **APPROACH RATIONALE**

Per the FOA instructions, a significantly detailed plan and substantial preliminary data are not recommended. We provide the underlying logic, rationale, and process model for the approach we are pursuing in this project and the step-by-step manner in which will apply the proposed methods.

The proposed project entails two primary aims and one secondary aim.

**Primary Aim 1:** Use group model building (i.e., a participatory stakeholder systems science approach) to identify the leverage points where disruptive innovations in anti-racism behaviors, policies, and practices can improve health equity.

**Primary Aim 2:** Design a simulation system to demonstrate the impact of such anti-racism interventions.

**Secondary Aim:** Using Item Response Theory, initiate the process of developing core measures for assessing the effects of interventions at the provider and organizational-systems level as specified in the primary aims.

**ORBIT as A Guiding Framework.** To promote disruptive translational innovation, the NIH created the National Center for Advancing Translational Science (NCATS) to reengineer the process of developing diagnostics, devices, and therapeutics. Because the focus of NCATS has been largely biomedical, the Office of Behavioral and Social Science (OBSSR) held a conference to propose guidelines for developing behavioral

and social systems interventions to improve health.<sup>14</sup> The resulting model (ORBIT) specified activities and methods for early phase translation in the behavioral and social sciences. This a rigorous translational process ensures that only the most potent interventions move along the translational spectrum. Using this model, we increase the likelihood that carefully defined, refined, community-engaged, and scalable interventions, programs and policies, developed from a strong foundation of basic behavioral and social science research, are successful in full scale trials. Our approach leverages the ORBIT model by rigorously translating community-engaged systems science findings into new anti-racism interventions to change behaviors, policies and practices and then refining the interventions with systems science simulations while beginning the measurement development process.<sup>48</sup>

The proposed approach follows ORBIT's detailed process for early phase translation in behavioral and social science (Figure 1). Phase 1, the design phase, includes two subphases, *Define and Refine*. In the ORBIT model, the following activities occur in **Phase 1a-Define**: Develop hypothesized pathways by which the intervention can solve an important clinical problem, provide scientific basis for behavioral milestones, and provide basic behavioral and social science basis for treatment components and their respective targets. Following this approach, our project will use community engaged systems science (i.e., group model building) to identify critical leverage points in the PCMH system for anti-racism interventions and use expert stakeholders to suggest possible intervention strategies. In the ORBIT model, **Phase 1b-Refine:** Activities include identifying independent and interacting treatment strategies, optimizing and tailoring for specific populations or systems, and ensuring appropriate measures to assess effects in future trials. In this project, we will apply ORBIT approaches by and testing and refining the intervention strategies by consulting the literature and preliminary studies to specify components of the anti-racism behavioral/policy/practice-interventions identified in Aim 1. Then, we will simulate the anti-racism interventions to assess for potential impact on provider behavior and organizational-systems policies and practices.

With an eye toward future trials, we will begin the process of identifying core measures to assess anti-racism interventions developed and simulated in Aims 1 and 2.

# Primary Scientific Method – Systems Science. We propose to use systems science approaches because they are

Figure 1 ORBIT Model Applied to Anti-racism Interventions SYSTEM SCIENCE METHODS (C) Significant Aim 2 Effectiveness Aim 1 Clinical **Efficacy Trial** Research PHASE III PHASE IV PHASE I PHASE II DISCOVERY EFFICACY PRELIMINARY TESTING DESIGN **EFFECTIVENESS** 

particularly useful for understanding public health problems that result from the interplay between individuals, providers, organizations, and society. Systems science has been applied to a variety of public health issues, 1c, 50-55 including cardiovascular risk, addiction, 56, 57 domestic violence, 58-61 and mental health. 1c, 62, 63 In a novel application of systems sciences methods, we are harnessing the power of their full potential by combining the qualitative systems sciences methods (i.e., group model building) with quantitative methods (simulation modeling) to develop a comprehensive view of both the drivers of racism and the potential impact of anti-racism interventions.

First, as delineated in *Primary Aim 1*, systems science utilizes qualitative methods for group model building (GMB), including problem structuring and systems mapping to visualize and specify the complex and dynamic characteristics of problems such as health care racism in an integrated care system. As can be seen in this obesity example, such a causal map identifies potential leverage points where a system (or agents in the system) can change from one phase (health care racism) to another (anti-racism behaviors, policies, and practices). Leverage points are utilized to define and refine the most potent interventions at the behavioral, podlicy, and practice levels. Consistent with a community-based participatory systems science approach, key stakeholders partner with investigators to develop the system map using structured group facilitation and visual diagramming techniques. Key stakeholders include practitioners, administrators, regulators, patients, researchers and others.

In *Primary Aim 2*, we will apply systems science quantitative methods (e.g., prospective agent-based modeling) to simulate exemplary anti-racism interventions.<sup>64</sup> During this process, dintervention strategies are

refined by specifying intervention components based on available literature and existing data on changing provider behavior and changing the policies and practices of organizational-systems. In this way, the simulation model (see example above) becomes a laboratory to explore the effects of anti-racism interventions on the outcomes of provider behavior and organizational-systems policies and practices (see Figure 3 for a simulation example).

## Group Model Building Rationale (Aim 1).

Although intervening on racial bias in health care settings is not new, an underlying reason that these interventions have not been effective is because the field has not taken approach that allows for the systematic documentation of the drivers of racism practices (e.g., stigmatizing provider communication, poor diffusion of anti-

racism leadership values) and how they interact in a complex system. In addition, interventions that have proven effectiveness in changing organizational practices and behaviors, such as Organizational Behavioral Management, have not been employed.

To address health equity through anti-racism interventions, multiple stakeholders must play

significant roles throughout the process. Group model building (GMB), a community-engaged approach to inform system dynamics models, is an effective way to involve key stakeholders in the process of conceptualizing and formulating disruptive and innovative models for anti-racism interventions.<sup>65, 66</sup> Stakeholder participation is essential to building useful systems science models to understand racism in integrated health care because seeing the entirety of the process of achieving anti-racism behaviors and practices may be challenging as each stakeholder engages in only a facet of the overall system. A participatory stakeholder systems sciences approach – like GMB<sup>67, 68</sup> – that help people visualize the interconnections and critique the process boundaries can aid in the development of innovative approaches to anti-racism and health equity. Furthermore, involving stakeholders in the process include developing deeper system insights and increasing the likelihood that disruptive innovations based on the system insights will be implemented.<sup>66</sup>

**Simulation Model Rationale (Aim 2).** Methodological advances in computational modeling have yielded new tools to assess the viability and sustainability of anti-racism interventions and dynamic interactions between provider behavior and organizational-system policies and practices. Computational simulation models equip researchers with new tools that have the potential to transform the traditional methods of intervention refinement (e.g., small N studies) prior to funding expensive pilots and full-scale trials. In their seminal text on clinical trials design, Powell et al. <sup>69</sup> delineate the key questions and activities of early phase translation of behavioral and social science within the ORBIT model. These include: What are the treatment components and level of implementation necessary to change the targeted behavior or practice? What is the optimum number of components and mode of delivery? What is the impact of the intervention on the complex system within which it is embedded?

Computational simulation modeling allows us to build a 'virtual laboratory' to study the disruptive effects of multi-level intervention strategies over long periods of time, accounting for adaptation and environmental-person interactions that give rise to racism and disparities across different contexts. To Such simulations can demonstrate intervention potential, delineate how much change is necessary to affect the system and the ultimate outcome of improving the presence of anti-racism in integrated health care settings (similar to clinical targets such how much weight loss is necessary to improve health). Simulation models help to clarify the effects on the total system and requirements for sustainability.

Research Strategy

Though the specific approach and development of the computational model will depend on results of the GMB in Aim 1 as well as a thorough review of the social science and organizational behavior literatures, one possibility is an agent-based model (ABM) that focuses on individuals within PCMHs in a larger context of the organizational policy and practice environment as well as state and federal regulations. In such a model, individuals (agents) would be staff within the organization and patients, each with demographic characteristics. In addition, staff would have professional (e.g., experience) and organizational (e.g., role, position) characteristics, patients would have varying health histories, and all these would reflect real-world PCMH data from the state of XXX. Individual behaviors at baseline or status quo would be informed through GMB and the literature and guided by regulations and current organizational policies and practices.

Examples of interventions that could be simulated are a) financial incentives – of varying amounts – for reduced disparities and b) randomized computer-generated screening prompts. These interventions would be implemented in the virtual environment and behavioral and policy/practice changes post-intervention would be measured and compared across individuals and then aggregated to estimate potential systems-level changes. Possible emergent behaviors – those arising from different combinations of agents and their reactions or

changed practices after introducing the interventions – such as diffusion of norm changes or potential unintended consequences would also be measured. Varying intervention levels, implementation strategies (e.g., simultaneous implementation across an institution or to specific individuals) and combining interventions could reveal thresholds for change, multiplicative effects, or relatively ideal or problematic approaches. In this way, the virtual laboratory will be guided by existing theory, empirical data, and expert data generated from Aim 1 about feedback loop mechanisms related to provider behavior, provider-patient interactions, and organizational-systems/provider/patient /policy/practice interactions. Accounting for interactional complexity

Figure 3. Simulation Example Applied to Other Public Health Issues



is important for understanding the long-term effects of disruptive anti-racism interventions on health equity.<sup>49</sup>

Early Stage Measurement Development Rationale (Secondary Aim). The combined work of Aims 1 and 2 will generate disruptive anti-racism interventions to be adopted in PCMH integrated health care settings. In anticipation of future trials to adopted by this research team and many other investigators, we propose to capitalize on the extensive qualitative methods in Aim1 and the substantial community engagement throughout both aims, and begin to the early stages of item bank development for core measures of these novel interventions. This aim is an important component of early phase translation, not only to assess intervention efficacy but also to ignite future research stimulated by this transformative project with a common measures approach encouraged by NIH (e.g., PROMIS, Toolbox, PhenX). 16, 71 To that end, we will utilize state of the art measurement development methods informed by Item Response Theory (IRT) to begin to address the dearth of measures of racism and anti-racism behaviors, policies, and practices at the provider and organizational-systems level.

IRT models have distinct advantages over measures developed using classical test theory (CTT)<sup>73</sup> because CTT only provides a single estimate of average reliability. Whereas IRT allows us to see exactly when a test is giving more or less precise estimates of the attribute being measured. Additionally, IRT provides an estimate of "reliability" where single test can have a range of reliability depending upon how much of the attribute is present. Thus, the advantage is that, if the model fits well, the information obtained for an individual is not dependent on the particular choice of test items used in the assessment. An additional benefit to IRT modeling is that it more readily allows for the development of computer adaptive tests. Computer adaptive tests have many advantages over standard pencil-and-paper tests. Computer adaptive tests are designed to only deliver as many items as needed to estimate a person's level of attribute with a prespecified level of precision. Because the items chosen to be delivered are targeted at a person's estimated level of attribute, fewer items need to be delivered to get the same (or better) estimates for each person. A second benefit is that these assessments can be given to the same person over time using largely a different set of items so that the person being assessed experiences less boredom or fatigue associated with being asked the same questions over and over. Because health care intervention studies typically require repeat assessments in

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busy practice environments, computer adaptive testing can increase the feasibility and reliability of such measurements, can significantly improve study retention, and can limit desirability bias. Computer adaptive tests rely on the development of a large item bank where the properties of each item are known through IRT modeling, and such an item bank will be developed by the end of the project.

**Study Team.** We have structured the study team (See MPI plan; Structure of the Study Team) so that the activities are organized by their innovative methods and associated expertise: Community Engagement, Systems Science, Intervention Design, and Measurement Development. Each team will be led by a coinvestigator expert but will be assigned an MPI liaison. There are three advisory groups for the activities. First, the Scientific Advisory Council will be led by our named consultant and will consist of five experts in health equity research in primary care. This group will report directly to the MPIs for all phases of the project. Second, the Community Advisory Council will consist of 10 leaders (two from each stakeholder group). This council will report to the Community Engagement Team to guide all phases of the project. Third, the Core Modeling Group will report to the systems science team and facilitate the activities for Aim 1.

#### INNOVATION

Innovation in Translational Behavioral Science to Address Health Care Racism. There is a paucity of literature to combat health care racism, and even less in integrated primary care where mental and physical health needs of underserved populations are addressed. It is well-established that the current practice of short, one-time training modules on implicit bias and cultural competence do not change provider or leader behavior<sup>74</sup> nor organizational-systems policies and practices. We will not improve health inequities without directly targeting, instead of describing, health care racism. Utilizing an established model of translational behavioral and social science - typically applied to changing patient behavior - to address health care racism is novel. We utilize the specified translational model to uniquely address provider behaviors and organizational-system policies and practices (e.g., simulate the impact of pairing coaching, plus financial incentives, plus organizational culture practices). Utilizing systems science, we move beyond the traditional pathway of brainstorming interventions from the literature, typically targeting a single system, and then piloting them. Instead, this transformative project will systematically identify the most impactful leverage points at multiple levels within a complex health care system.

Innovation in Systems Science. Systems science has only just begun to address public health problems, primarily in the policy arena, and has not been sufficiently translated into new behavioral and organizational interventions. To our knowledge, systems science approaches have not been utilized to address health care racism. Systems science approaches have typically utilized group model building or computational modeling, but rarely are both integrated in a single project. This project is innovative in the integration of systems science qualitative and quantitative methods, community-based participatory research, translational behavioral science, and organizational theory like diffusion of innovation to develop novel leverage points within an integrated health care system (i.e., PCMHs) to improve health equity.

Transforming Translational Behavioral and Social Science Methods. The first stage of traditional intervention development is to identify a clinically significant target. In the biomedical sphere, these targets are more readily available (e.g.,5% weight loss, .5% change in A1C, one log drop in viral load), but there are rarely guidelines for such changes in the behavioral and social sciences. Simulations can provide a comparable benchmark at the provider and systems level by determining how much change is mathematically needed to affect the system. Similarly, the simulation models can develop benchmarks for the percentage staff that need to change to influence the system. Such benchmarks can transform the determination of what interventions, policies and practices should move forward to more costly comparative trials and may transform methods for estimating sample sizes for such trials. Furthermore, this paradigm integrates measurement development by utilizing the same qualitative findings to simultaneously specify interventions, policies and practices while developing item banks to measure such innovations.

**Innovation in Community-based Participatory Research.** This project specifies methods for community engagement beyond the traditional community advisory group model. GMB engages a wide spectrum and relatively large number of stakeholders in an intensive qualitative process to ensure sufficient community engagement at the foundation of intervention development, testing and outcomes measurement.

#### **APPROACH ACTIVITIES**

**Primary Aim 1 Activities.** Use group model building (i.e., a participatory stakeholder systems science approach) to identify the leverage points where disruptive innovations in anti-racism behaviors, policies, and practices can improve health equity.

**Overview.** In the first phase of the study, Aim 1, we will map the complex dynamic systems driving racism practices in PCMHs and identify leverage points for disruptive anti-racism innovations. We will focus on leverage points that would allow for disruptive and transformative shifts in individual provider behavior and organizational-systems policies and practices to sustain effective and sustainable adoption of anti-racism approaches. Stakeholders from across an integrated primary health care system – PCMHs – will engage in group model building (GMB) workshops with researchers. Participants will describe and map the system driving racism practices, identify points for disruptive interventions, policies and practices, and then prioritize a list of possible intervention strategies.

Setting – PCMHs in the State of XXX. The state of xxx has the second largest number of NCQA accredited PCMH's in the nation (n=1,023) making this PCMH system a particularly compelling study site for developing transformative interventions. This project will enroll PCMH practices throughout the state of Florida capitalizing on the statewide clinical network of over 3,000 primary care clinicians affiliated with the primary study site in addition to providers affiliated with the health department. Leveraging this longstanding collaboration and their own stakeholder groups, integrated health care stakeholders from PCMHs throughout

the state of Florida will be invited to participate in the GMB study activities (see letters of support). Figure 5 demonstrates the process flow of activities for Aim 1.



Aim 1 Step 1a-c. In **Step 1a**, the research team will draw from this collaboration to develop a "participatory core modeling team" that will include that will include top administrators from the state's health department and two specific offices within that department (see letters of support). **In Step 1b**, the core modeling team will convene an initial meeting to review the overall project including an introduction to group model building techniques, complete a session schedule for the group model building workshops, and identify prospective participants to represent stakeholder groups that will participate in the GMB workshops.

In Step 1c, we will identify and recruit stakeholders. Because this process will be developmental and collaborative, we cannot indicate an exhaustive list of stakeholder groups in this proposal. However, we anticipate stakeholders will at a minimum represent a) administrators of PCMHs; b) providers (including physicians, physicians aids, nurses, residents, and interns) at PCMHs; c) patients of PCMHs; d) research team members; e) state administrators; f) medical students; h) legislators; i) ancillary provider settings (e.g., inpatient substance abuse or mental health treatment facilities). To accommodate statewide sampling and current COVID-19 restrictions, GMB sessions will be conducted in-person and virtually as needed. The research team will request from the core modeling team comprehensive and statewide lists of names and contact information for potential study participants representing all of the stakeholder groups listed above. Then, the research team will first stratify (by age, gender, race) and then randomly select from the lists potential participants to reach out to oversampling by 15% to anticipate ineligibility or refusal to participate (this rate was determined based on the teams prior research with varied stakeholder groups). The only exception to the recruitment strategy are for the recruitment of patients. Leveraging the deep collaborative relationships between two faculty investigator team members, patient recruitment will be done through patient advisory boards, flyers, and patient portal messages at randomly selected PCMHs throughout the state. Potential patient participants will be provided phone numbers, emails, and social media contacts for the research project. All other potential study participants will be contacted via email and phone by a research team member requesting their participation. In total we anticipate a minimum 150 stakeholder participants, divided into groups of no more than 15, to

participate in the group model building workshops. *Study eligibility, exclusion, consent.* Stakeholders will be eligible if they are 18 or older and have been a member of their stakeholder category for at least a year. Stakeholders will be excluded if they are assessed to have cognitive impairment that would interfere with their ability to participate in GMB workshops. Patient stakeholders will be excluded if they do not identify as Black/African American. We plan to include English speaking at the conversational level as an eligibility criterion; however, the core modeling team believe that this will rule out a significant number of participants, we will consider a translator. We will monitor study enrollment to ensure equitable representation by gender and age as well. Human Subjects approval will be obtained from the institution of the contact PI in advance of participant recruitment and enrollment; and electronic or verbal consent will be obtained from stakeholder participants using an informed consent information sheet/script approved by university's Human Subjects Board. The Human Subjects attachment details the incentive structure.

Aim 1 Step 2: GMB Workshops. Drawing on earlier published work on GBM scripts and workshop techniques from participatory rural appraisal, 65, 76-78 community operations research, 79 and soft systems methodology, 80 the core modeling team will develop a set of GMB scripts to identify racism practices (provider and organizational-systems level) within and across the PCMH system. In Step 3, the team will complete a session schedule for the group model building workshops. GMB sessions will be organized around the use of "scripts"—structured group exercises designed to elicit information and engage participants. Each script defines the purpose of exercise, duration, preparation needed, activities, and outcomes. Group model building sessions are then organized around these sequenced scripts. Script based approaches have

#### **EXAMPLE**

Leverage points identified:

- In-office patient/provider interactions
- Financial incentive practices

Potential intervention strategies:

- Random prompts for screening and prevention psychoeducation
- Financial incentive for 100% compliance to prompts

Stakeholder Prioritize from List of Possible Intervention Strategies by:

- Impact
- Feasibility
- Acceptability

the advantages of standardized protocols that can be combined in various ways to meet the specific needs for an otherwise unique project.

Members of the Participatory Core Modeling Team will host a series of GMB workshops with no more than 15 participants in any given workshop. The workshops will be led by a modeler/facilitator with expertise in GMB, a facilitator with substantive expertise in health equity research and PCMH community and patient leader. Two Systems Science team members with training in system dynamics will function as recorders/note takers in the session, and one process coach familiar with group facilitation will be present. The GMB workshops will be organized around the modeling process moving from initial problem conceptualization. elicitation of key variables, defining the problem in terms of several key indicators and their behavior over time (reference modes), eliciting structural relationships, and formulating key relationships. GMB workshops will include a series of hands on exercises designed to clarify key concepts in systems science (e.g., the distinction between stocks and flows and structure-behavior relationship). The Participatory Core Modeling Team, which includes community stakeholders, will take primary responsibility for setting the agenda, reviewing the work, and making adjustments to the session content and process. We utilize in vivo note taking and photographs of artifacts created during the session instead of audio-recordings which can suppress responses. These observers will note key concepts that participants identify and describe any departures from the GMB scripts. The scripts from aim 1 will help to inform the outcome measure development of aim 3, thus noting any deviations will be important for subsequent stages of the study.

Aim 1. Step 3: Review Leverage Points and Prioritize Possible Intervention Strategies. Following completion of the GMB workshops, the 10<sup>th</sup> and final session will be convened with the core modeling team and all stakeholder study participants to provide detailed feedback and present back synthesized causal maps of structural drivers of racism practices as well as a provisional set of potential leverage points for anti-racism interventions targeting provider behavior, and organizational-system policies and practices. The stakeholder participants – all of whom – participated in the GMB, will review and prioritize possible intervention strategies based on their perception of impact, feasibility, and acceptability. For example, in a case scenario in which

leverage points of a) in-office patient/provider interactions and b) financial incentive policies; the stakeholder participants might propose two intervention strategies: a) random prompts to screen for behavioral health disorders and do brief psychoeducation on preventing heart disease for example and b) implement a financial incentive for 100% compliance with the prompts. In this scenario once the menu of leverage points and the menu of intervention strategies (behavioral, policy, practice) are identified, the stakeholder participants would prioritize the potential intervention strategies by: impact, feasibility, and acceptability (to the implementing stakeholder – e.g., the provider). To inform their decision making, participants will be asked to reflect on the feedback and pathways within the causal maps when considering the leverage points and identify possible intervention strategies.

**Primary Activities Aim 2**. Design a simulation system to demonstrate the impact of such anti-racism interventions.

The following are the steps to achieve Aim 2 based on best practices<sup>81</sup> for building and testing computational models of complex social and organizational systems

Aim 2 Step 1: Pre-Simulation Model – Specifying Interventions and Intercepts. Building on the prioritized intervention strategies selected by the GMB participants in Aim 1, the first step is to review the extant literature on potential anti-racism intervention components (i..., provider behavior change strategies, policy approaches, and organizational practices) from multiple disciplines and fields. Intervention components will help to operationalize the potential intervention strategies prioritized in Aim 1. More narrowly focusing in on the components of interventions, the scientific advisory and community advisory councils will follow a similar

process as the participatory core modeling team and screen the potential intervention components for potential impact, feasibility, and acceptability and identify gaps for further exploration.

SPECIFY intervention components with scientific and community advisory

DESIGN CALIBRATE, AND REFINE model until parameters are established

RUN SIMULATIONS and conduct sensitivity analsysi DISSEMINATE RESULTS to scientific, policy, and public stakeholders

As noted by NIH developers of early phase behavioral translation models,<sup>82</sup> instead of forcing square pegs of interventions into the round holes of the delivery system,

Figure 6. Process Flow for Aim 2

interventions must be "more round" utilizing these stakeholder engaged processes. The following are examples of intervention specification. If patient-provider relationship or communication is identified as a leverage point, a review of the basic behavioral communication and social science of stigma may be a source of intervention component specification. Overtly communicating acceptance is a key component of stigma reduction<sup>83</sup> and communication of autonomy support is a major facilitator of ownership of stigmatized identities.<sup>84</sup> Based on the work of humanistic psychology, Miller and Rollnick<sup>85</sup> define four aspects of acceptance: 1) respect for the absolute worth of the individual or unconditional positive regard; 2) accurate empathy; 3) affirmation; and 4) autonomy support. Thus, coaching providers during simulated encounters in specific skills that demonstrate these components of acceptance may reduce the experience of racism in the health care setting.

At the organizational level, if the map identifies that lack of adoption of anti-racism policies or practices within an organization is a leverage point, diffusion of innovation theory constructs can be translated into policy or organizational culture interventions to accelerate the rate of adoption. The diffusion of innovations is a social process, a bi-directional communication of influence, usually from informal opinion leaders within social networks to top leadership. Diffusion of innovation theory sets to accelerate the adoption of new policies and practices and dictates a dual-process approach that addresses information provision and channels of influence. Examples include identifying opinion leaders and/or internal champions whose attitudes are favorable towards the new practice and who others identify positively; or implementing interventions that demonstrate the innovation along with environmental support such as hands-on approach by leaders and managers or an incentive structure. Additional examples at the systems level could be to financially incentivize providers or implement computer generated cues to reduce disparities in mental health screening.

Aim 2 Step 2: Model design, Calibrate, and Refine. The proposed model will be influenced by agents (i.e., individuals) and contextual factors. Agents: The model will have two sets of agents, one representing a population of providers in PCMHs and one representing patients that attend PCMHs. The characteristics of the agents will vary by age, race/ethnicity, status within the organization (e.g., patient or what type of provider),

and patient health characteristics of the PCMH. The agent characteristics will be drawn from PCHM data specific to the state of XXX so that it represents the actual PCMH system. The contextual factors will include varying sizes of PCMH, rural vs urban nature of the PCMH, and resource availability in the community in which the PCMH is imbedded (e.g., inpatient substance abuse treatment availability). The contextual factors in this simulation model will be generated from PCMH state data as well as factors identified in the causal map of racism generated in Aim 1. The exploration of contextual factors generated from the causal map of racism allows the simulation model to capitalize on its ability to examine heterogeneity and adaptation of different external factors in the outcomes related to healthy equity via changes in behaviors, policies, and practices and use the impact of changing different factors (e.g., provider or organizational characteristics) on patterns of antiracism intervention viability and sustainability in PCMHs. For the simulation model to be applied, a computational architecture of the model will be established and each piece will undergo testing to ensure appropriate representation of concepts and relationships. The initial model will be revised based on partial model testing. Once the model is complete, the generative explanatory power of the model is to reproduce observations about anti-racism interventions at provider and organizational-systems levels to be tested under a variety of conditions. For example, across varying contextual factors and agent characteristics, does role playing and coaching change provider behavior? Or do strategies to change organizational culture have the same level of influence on anti-racism practices across context factors? These findings will be used to calibrate the model and establish the parameters for sensitivity analysis.

Aim 2 Step 3: Conduct sensitivity analyses. Systematic exploration of model behavior is undertaken as key parameters and assumptions are varied. During this step, we will hold the contextual factors constant and explore the sensitivity and dependency of outcomes (i.e., impact of anti-racism interventions on provider behavior and organizational-systems practices) to changes in assumptions about agent behavior or intervention implementation strategies. We will utilize computational power to build a robust statistical portrait of model dynamics and parameters, where assumptions are systematically varied to allow for appropriate interpretation of model results about interactions between individual characteristics and organizational contextual factors.

Aim 2 Step 4: Disseminate model results. In addition to the overall dissemination of models and manuals for the entire proposal, in this step model outputs such as datasets will be shared using standard file formats. In addition to peer-reviewed articles, translational products will include materials such as one page research briefs and community newsletters as well as interactive dashboards of model results via the R package Shiny. Results from the potential ABM described above would lend themselves to an interactive dashboard or web app that Shiny could accommodate. Such a platform would allow different types of stakeholders to experiment with intervention levels and implementation strategies firsthand and help to increase engagement with model and project results.

**Secondary Aim Activities.** Using Item Response Theory, initiate the process of developing core measures for assessing the effects of anti-racism interventions at the provider and organizational-systems level specified in the primary aims.

The secondary aim for this proposal is considered very preliminary while also acknowledging the need for outcome measures as new anti-racism interventions are specified and implemented. We will use this Aim to capitalize on the qualitative work in Aim 1 and the extensive involvement of Community and Scientific expert stakeholders throughout the proposal. Following IRT driven processes, qualitative methods are utilized to develop the assessments needed to examine the effectiveness and mediators of interventions. Thus, we will leverage qualitative data collected in Aim 1 to understand the contextual factors, varying perspectives and the complex issues that influence them, as well as the attitudes, and beliefs of key stakeholders. Understanding these various issues will allow the team to generate potential items that will measure the malleable components of disruptive anti-racism interventions. The second strategy in IRT driven measure development is typically to assemble an expert panel to achieve consensus. Thus, we will leverage the literature review work of the community and scientific advisory panels in Aim 2 and include in that literature review an extensive review of existing measures that examine the intervention components selected by this group. In the third step, the research team along with the scientific advisory council will propose items that are assumed to assess the constructs underlying the intervention components. The items will be composed with two goals in mind: depth and construct coverage. These items will subjected to a rating system where the team will rate the

items on how well they accomplish this task. This item bank will be used to develop assessments that can be evaluated using Item Response Theory models and transformed into computerized adaptive test (CAT) mechanisms in in subsequent studies.

## Major Challenges or Risks of the Project and Alternative Approaches

There are several challenges inherent in systems science methods and intervention design phases for which we are prepared and have planned alternative timelines. First, suboptimal retention in GMB activities may result from staff turnover and patient drop out in Aim 1. We will develop replacement procedures, which may result in extending the time needed for GMB. Similarly, the specificity of the model and the identified leverage points developed in Aim 1 is critical for Aim 2 of the study. If further specification and stakeholder consensus is needed, then we will delay Aim 2 and supplement GMB with in depth interviews, focus groups and surveys with key stakeholders. This alternative approach is noted in the timeline.

Second, although unlikely based on our previous studies, it is possible that there are inadequate data sources to simulate model components in aim 2. The likelihood of inadequate data from our partners and publicly available sources is quite small, but there are simulation model methods that do not require such data (REF Gilbert Agent Based Model book) and rely on literature reviews and stakeholder perspectives. Furthermore, we have strong connections to the state department of health as noted in our resources and letters of support, and they have committed to facilitating data sharing per their letters of support. Furthermore, simulation models at times yield infeasible findings (for example, a simulation of changing tobacco availability initially resulted in smokers walking multiple miles for hours to purchase one pack of cigarettes, and others purchasing thousands of cartons at a time; ref). Through revisiting assumptions and decision rules during calibration, these behaviors can be curtailed for the final model. By starting simulations in Year 3, we allow sufficient time to address these challenges. Finally, it is possible that some of the proposed interventions do not sufficiently disrupt the entire system in simulations. These interventions would be judged lower in priority than ones that have the greatest impact. We allow sufficient time in the timeline for intervention specification to simulate multiple intervention strategies.

Third, it is critical that key stakeholders trust the simulations so that we can continue the translational process and ultimately improve health equity in real world settings. By ensuring community engagement in the GMB, we will increase the likelihood of relevance of the models and trust in their development. We will utilize diffusion of innovation theory derived strategies not only to diffuse anti-racism interventions but also to diffuse our model findings to translate into practice (e.g., identifying stakeholder champions). These approaches are important not only for public health and patient communities but also for the academic community to leverage this transformative model into anti-racism intervention trials.

### **Appropriateness for the Transformative Research Award**

Uniquely Suited to the Goals of the TR01. By definition, the aims of this project are exploratory and consistent with early phase translation. As Dr. Michael Lauer, Deputy Director for Extramural Research, declared at an NIH translational science conference, 91 "Fail early and often." Furthermore, the project proceeds in a step-wise fashion, requiring the refinement of early steps to ensure success and the flexibility of later steps consistent with the TR01 mission

Community Engaged Transformative Paradigm
To Define & Refine Anti-racism Interventions

Identify Leverage Points Development Secondary Aim

Specify Components & Identify Intervention Effects
Simulation Model Aim 2

Figure 7. Transformative Paradigm

but counter to a successful traditional R01. Yet the result should be a paradigm shift in health equity research by developing a transformative model of translating community-engaged systems science into new action steps for systems (not merely interventions) to address the complex problem of health care racism that causes increased morbidity and mortality for Black/African Americans. This transformative paradigm (Figure 7) will result in a process manual not only for future research to improve health equity for Black/Americans in PCMHs but also other marginalized populations in other systems.

### How does the proposed research significantly differ from mainstream science?

The anti-racism in health care intervention efficacy literature is very limited, and thus the focus of the proposal differs from mainstream science by moving

beyond describing racist behaviors, policies and practices and beyond testing interventions within a single layer of the system. Instead, we propose to use rigorous methods to disrupt a complex system of racism in health are. Our methods also differ from mainstream science in the following ways:

Traditional systems science typically 1) utilizes qualitative OR quantitative methods, but this project utilizes mixed methods by integrating these two approaches. T

2) Traditional translational behavioral

The proposal addresses all three priority areas of the organizing Office of Behavioral and Social Science Research (OBSSR) for the NIH:

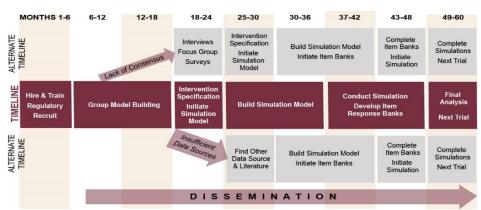
OBSSR Priority	Transformative Proposal
Facilitate the adoption of behavioral and social science research findings in health research and in practice	This proposal creates a transformative paradigm of early phase translation within complex systems in real world settings to address health inequities. This proposal conducts this early phase translation with a foundation of rigorous community-engagement methods to increase the likelihood of future adoption and sustainability
Improve the synergy of basic and applied behavioral and social science	The proposal integrates systems science with early phase translational methods The proposal translates not only behavioral science but also basic science around organizational and systems change
Enhance and promote research infrastructure, methods, and measures	The proposal integrates different systems science methods The proposal integrates systems science, item response theory, and community-based participatory approaches The proposal will result in a model and manual for the integration of these methods to address complex problems in health care

- science typically defines interventions from the research literature, refines the interventions based on a feasibility study or expert opinion, and then tests the intervention in small proof-of-concept studies. Separate studies are needed for measurement development. This proposal utilizes qualitative methods for group model building and developing an item bank and utilizes simulation models to rigorously refine and begin to test proof of concept. These methods will produce a more efficient and rigorous approach to intervention development within complex systems.
- Traditional anti-racism interventions address provider implicit bias with training approaches. Such training approaches do not result in sustained behavior or system change. This project will address provider and system level factors with multi-faceted interventions (e.g., communication coaching, incentives, leadership).
- Traditional intervention development approaches do not always include stakeholders in the earliest translational phases, or do so at a surface level with a small community advisory group. This project is founded on stakeholder engagement in group model building, ensuring that interventions are developed and refined with extensive community input from diverse stakeholders across the system. Communitybased participatory research methods are at the core of this transformative paradigm.

#### TIMELINE AND DELIVERABLES

The following are the key deliverables and timeline with alternative plans:

Year 1: Literature reviews to inform the mapping process; Formation of modeling core, scientific advisory council, and community advisory council



Year 2: Community-engaged Systems Science Map

Year 3: Intervention/Policy/Practice Specification

Year 4: Simulation Model and Item Banks

Year 5: Manual for Transformative Paradigm for Anti-racism Interventions in Health Care, Specification of subsequent R01 proposals to test successfully simulated interventions and item response theory testing of item banks for computerized adaptive measure

Figure 8: Timeline and Alternative Plans

# PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 02/28/2023

Use of Human Specimens and/or	Data
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Does any of the proposed research in the application involve human specimens and/or data \*

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

Are Human Subjects Involved

Is the Project Exempt from Federal regulations?

**Exemption Number** 

Other Requested Information

Yes O No

Yes O No

**4** 

No

□ 5 □ 6 7

## **Human Subject Studies**

Study#	Study Title	Clinical Trial?
1	Transforming Health Equity Research in Integrated Primary Care: Antiracism as a Disruptive Innovation	No

## Section 1 - Basic Information (Study 1)

OMB Number: 0925-0001 Expiration Date: 02/28/2023

1.1. Study Title \*

Transforming Health Ed	tiut	v Research in I	Integrated	Primary	Care:	Antiracism	as a Dis	ruptive	Innovat	ion

1.2. Is this study exempt from Federal Regulations *	O Y	'es	• 1	lo				
1.3. Exemption Number	□ 1	□ 2	□ 3	<b>4</b>	□ 5	□ 6	<b></b> 7	□ 8
1.4. Clinical Trial Questionnaire *								
1.4.a. Does the study involve human participants	?			•	Yes		O No	
1.4.b. Are the participants prospectively assigned	d to an inte	rvention?		О	Yes		<ul><li>No</li></ul>	
1.4.c. Is the study designed to evaluate the effect participants?	t of the inte	ervention	on the	О	Yes		• No	
1.4.d. Is the effect that will be evaluated a health behavioral outcome?	-related bio	medical o	or	0	Yes		• No	

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

### Section 2 - Study Population Characteristics (Study 1)

- 2.1. Conditions or Focus of Study
  - Racism
  - Stigma
- 2.2. Eligibility Criteria

Stakeholders will be eligible if they are 18 or older and have been a member of their stakeholder category for at least a year. Stakeholders will be excluded if they are assessed to have cognitive impairment that would interfere with their ability to participate in GMB workshops or does not speak/understand English at conversational level.

2.3. Age Limits Min Age: 18 Years Max Age: 67 Years

2.3.a. Inclusion of Individuals Across the Lifespan Naar\_TR01\_Inclusion\_Across\_the\_Lifespan.pdf

2.4. Inclusion of Women and Minorities
 2.5. Recruitment and Retention Plan
 Naar\_TR01\_Inclusion\_of\_Women\_and\_Minorities.pdf
 Naar\_TR01\_Recruitment\_and\_Retention\_Plan\_Draft.pdf

2.6. Recruitment Status Not yet recruiting

2.7. Study Timeline Naar\_TR01\_Study\_Timeline\_Draft.pdf
2.8. Enrollment of First Participant 01/01/2022 Anticipated

### **INCLUSION ACROSS THE LIFESPAN**

Stakeholder Participants enrolled in this study will be over the age of 18 and have held their respective stakeholder position for longer than 1 year. Patient Participants enrolled in this study will be over the age of 18 and provide informed consent for participation. Due to the nature of the study, individuals under the age of 18 or over the legal age of retirement will not be included.

#### **INCLUSION OF WOMEN AND MINORITIES**

Women included in this study will be recruited through both the stakeholder and patient recruitment populations. Gender is not a specifier for study enrollment, however, inclusion of at least 50% male to 50% female ratio of participants will allow the project to achieve necessary gender diversity to achieve the study aims.

Inclusion of minorities in this study is paramount to addressing the aims of the study. In order to ensure the inclusion of minorities and achieve a diverse participant pool, basic demographic information collected at the time of study enrollment will include questions specific to race and ethnic background, however, participants will not be excluded based on race or ethnicity. We will recruit 30 participants from each of the five stakeholder groups: patients, public health officials, providers, agency/clinic/practice leaders, broader PCMH organizational leaders. The patients will be all Black or African American. The additional recruited participants will be reflective of the diversity of Florida, based on 2018 US Census Bureau estimates (74.7% White (53.3% Non-Hispanic White), 16.0% Black or African American, 2.8% Asian, 0.3% Native American and Alaskan Native, 0.1% Pacific Islander, 3.3% Some Other Race, and 2.9% from two or more races).

#### **Recruitment and Retention Plan**

#### Recruitment:

The participants in this study will be key stakeholders, including practitioners, administrators, regulators, patients, researchers, and others, as part of the community-based participatory systems science approach. Participants will be recruited from a central location (Tallahassee, FL) with the assistance of lead project collaborators (the Florida Department of Health, Office of Minority Health and Health Equity, the Bureau of Chronic Disease Prevention at FDC, and the Florida State University College of Medicine's satellite campus locations) to recruit the various stakeholders from Florida based Patient-Centered Medical Homes (PCMHs).

The participants will be identified through collaborative efforts by the projects Core Modeling Team, and as such, an exhaustive list of stakeholder groups cannot be determined at the proposal stage. However, these participants will at a minimum represent a) administrators or PCMHs; b) providers (physicians, physician assistants and aids, nurses, residents, interns, and other clinical staff); c) PCMH patients; d) research team members; e) state administrators and other public health officials (health equity, behavioral health, and corrections); f) medical students; h) legislators; i) ancillary provider settings (inpatient substance abuse or mental health treatment facilities). It is among these populations that a total of 150 stakeholders will be recruited.

The research team will request from the core modeling team comprehensive and statewide lists of names and contact information for potential study participants representing all of the stakeholder groups listed above. Then, the research team will randomly select from the lists potential participants to reach out to oversampling by 35% to anticipate ineligibility or refusal to participate (this rate was determined based on the team's prior research with varied stakeholder groups). The only exception to the recruitment strategy is for the recruitment of patients. Leveraging the deep collaborative relationships between two faculty investigator team members, patient recruitment will be done through patient advisory boards, flyers, and patient portal messages at randomly selected PCMHs throughout the state. Potential patient participants will be provided phone numbers, emails, and social media contacts for the research project. All other potential study participants will be contacted via email and phone by a research team member requesting their participation.

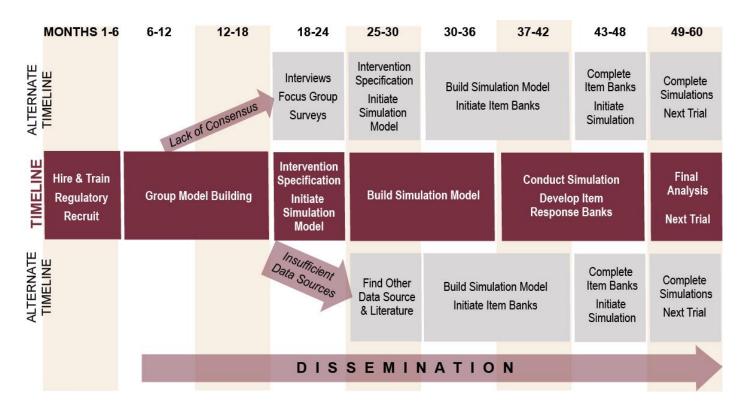
<u>Study eligibility, exclusion, consent.</u> Stakeholders will be eligible if they are 18 or older and have been a member of their stakeholder category for at least a year. Stakeholders will be excluded if they are assessed to have cognitive impairment that would interfere with their ability to participate in GMB workshops. Patient stakeholders will be excluded if they do not identify as Black/African American. We plan to include English speaking at the conversational level as an eligibility criterion; however, the core modeling team believe that this will rule out a significant number of participants, we will consider a translator. We will monitor study enrollment to ensure equitable representation by gender and age as well. Human subjects' approval will be obtained from Florida State University in advance of participant recruitment and enrollment; and electronic or verbal consent will be obtained from stakeholder participants using an informed consent information sheet/script approved by FSU Human Subjects Board.

#### Retention:

As part of the Group Model Building approach, a total of 150 stakeholders will be recruited from these populations. We will recruit 30 participants from each of the five stakeholder groups: patients, public health officials, providers, agency/clinic/practice leaders, broader PCMH organizational leaders. The patient participants will be all Black or African American. The additional recruited participants will be reflective of the diversity of Florida, based on 2018 US Census Bureau estimates (74.7% White (53.3% Non-Hispanic White), 16.0% Black or African American, 2.8% Asian, 0.3% Native American and Alaskan Native, 0.1% Pacific Islander, 3.3% Some Other Race, and 2.9% from two or more races).

These 150 stakeholder participants will each participate in a total of 10 GMB sessions each over the course of the project. These stakeholders may participate in separate, stakeholder group-specific GMB sessions or may be clustered as determined by the core modeling team. To accommodate statewide sampling and current COVID-19 restrictions, GMB sessions will be conducted in-person and virtually as needed.

#### STUDY TIMELINE



Study Timeline Page 142

### 2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	Tallahassee, FL

## **Inclusion Enrollment Report 1**

1. Inclusion Enrollment Report Title\*: Project Participant Enrollment Table

2. Using an Existing Dataset or Resource\*: ○ Yes • No

3. Enrollment Location Type<sup>⋆</sup>: • Domestic ○ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Tallahassee, FL

6. Comments:

#### **Planned**

Racial Categories	Not Hispan	ic or Latino	Hispanic	Total	
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	2	2	0	0	4
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	20	20	6	8	54
White	37	44	3	5	89
More than One Race	1	1	1	0	3
Total	60	67	10	13	150

### **Cumulative (Actual)**

	Ethnic Categories									
Racial Categories	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

# Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects	Naar_TR01_ProtectionHuman_Subjects_093020.pdf					
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	O Yes ● No O N/A					
If yes, describe the single IRB plan						
3.3. Data and Safety Monitoring Plan	Naar_TR01_Data_Safety_and_Monitoring_Plan.pdf					
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	O Yes ● No					
3.5. Overall structure of the study team	Naar_TR01_Overall_Structure_of_Study_Team.pdf					

### **PROTECTION OF HUMAN SUBJECTS**

### Human Subjects involvement, and overall design.

To address the study Aims, the proposed project intends to leverage existing collaborations with Florida-wide provider and patient networks in order to develop a systems science approach toward the development of science-informed antiracism as a disruptive innovation. In order to achieve the goals of the proposed study, organizational and provider stakeholders, as well as patients, will be recruited to participate in Group Model Building (GBM) focus group sessions, conducted both in-person and virtually. These sessions will inform the study team's efforts toward the development of a simulation model that will further define, test, and refine antiracism innovations, that will be replicable in the integrated primary health and mental healthcare organizational environments, and will be transformative toward improving integreated primary care services to the most underserved populations.

### Study Procedures, Materials.

Study Procedures. All study personnel who participate in the development of the study design, conduct, and oversight will be required to complete the web-based Collaborative IRB Training Initiative (CITI) course prior to involvement. All study procedures will have already been approved by the Florida State University Institutional Review Board (IRB) prior to the start of the study. For virtual GMB sessions, the Zoom HIPAA compliant platform will be utilized to ensure participant confidentiality. In-person sessions that are recorded, audio files will be stored in a secure file location within the Florida State University College of Medicine secure servers and access will be given only to project staff who are listed as IRB approved key personnel. Recordings will be deleted after six months and all identifiable patient data will be redacted from stored records.

Enrollment and Inclusion. Individuals will be recruited through a collaborative effort between the MPI's/Investigators and the Florida Department of Health (Office of Minority Health Equity, Bureua of Chronic Disease Prevention), Florida State University satellite campuses across the state of Florida, at Florida based Patient Centered Medical Homes (PCMHs). Patients will be recruited by the study investigators and collaborators through existing patient advisory boards, flyers, and patient-portal messages at randomly selected PCMH's, and will be provided the contact information of the study team should they choose to participate. Stakeholders will be excluded if they are assessed to have cognitive impairment that would interfere with their ability to participate in GMB workshops or does not speak/understand English at conversational level. A total of 150 stakeholder and patient participants will be recruited in the state of Florida.

Stakeholders will be eligible if they are 18 or older and have been a member of their stakeholder category for at least a year. Stakeholders will be excluded if they are assessed to have cognitive impairment that would interfere with their ability to participate in GMB workshops. Patient stakeholders will be excluded if they do not identify as Black/African American. We plan to include English speaking at the conversational level as an eligibility criterion; however, the core modeling team believe that this will rule out a significant number of participants, we will consider a translator. We will monitor study enrollment to ensure equitable representation by gender and age as well (see Inclusion Enrollment Report). We will recruit 30 participants from each of the five stakeholder groups: patients, public health officials, providers, agency/clinic/practice leaders, broader PCMH organizational leaders. The patients will be all Black or African American. The additional recruited participants will be reflective of the diversity of Florida, based on 2018 US Census Bureau (see Inclusion Enrollment Report).

Of these 150 stakeholder and patient participants, a subset of 10 will be recruited to participate in a stakeholder advisory council, who will meet 4 times per year of the project. These stakeholders may participate in separate, stakeholder group-specific GMB sessions or may be clustered as determined by the core modeling team. To accommodate statewide sampling and current COVID-19 restrictions, GMB sessions will be conducted in-person and virtually as needed.

<u>Study materials</u>. Participants involved in this study will provide quantitative and qualitative data to include basic demographic information (contact information, age, race, ethnicity, employment). Each participant will be provided a unique participant ID number that will be used on relevant study documents, correspondence, and applicable databases, to ensure that information collected is de-identified at the time of analysis.

#### Potential Risks.

Every effort will be made to ensure that study participants are protected from risks. Identified minimal risks of participation are 1) breach of confidentiality; 2) emotional stress or discomfort during GMB sessions, and; 3) concerns regarding potential consequences related to participation in the study.

Breach of Confidentiality. To mitigate these risks, the study team will take extensive measures to ensure that all patient data will be kept confidential and patients will be informed of their right to privacy and confidentiality. In addition to the required CITI training for research study personnel, privacy and confidentiality will be protected through the use of unique participant identifiers, and all study data (quantitative, qualitative, recordings, etc.) will be securely stored at the Center for Translational Behavioral Science under lock and key, or on Florida State University secure servers, with access granted only to authorized study personnel.

Emotional Discomfort. Study participants may be subject to discomfort and unpleasant emotions related to negative experiences of stigma and/or racism in their respective roles. Participants will be reminded often that they may refuse to answer any question and that they may end their participation at any point during the interview. While every step wil be taken to minimize risk, if at any time during the study a participant divulges that s/he is at risk for harm, any expressed psychological discomfort will be addressed by trained members of the study team to adequately assess and be prepared to halt participation and/or provide the participant with resources/referrals that adequately address their unique circumstances.

Protecting against concerns for consequences of partication. Further risks include the possibility that stakeholder participants may potentially be impacted by divulging experiences within their professional environment and could potentially be subject to additional stigma or career-related consequences, as well as potentially negative impacts on existing patient/provider relationships and care delivery. While every possible step will be taken to minimize such risk, if participants have any concerns about any aspect of the study, we will make it clear that they may choose to stop participating at any time without penalty. Participant stakeholders are under no obligation to participate, nor will their employment or medical care be compromised because based on their decision to consent or not. Interviews will be conducted to ensure protection of privacy, so that any potential employers or providers will not have knowledge of other participants.

### Adequacy Of Protection Against Risks.

Informed Consent. Participants will undergo an informed consent process prior to enrollment, following the procedures outlined in the Code of Federal Regulations (45 CFR 46.102). Informed consent will be collected at the time of study enrollment, and will be obtained electronically or verbally using an informed consent information sheet/script approved by the Florida State University IRB. All study participants will be afforded the opportunity to ask questions regarding the project prior to providing consent, will be given an adequate amount of time to decide whether they want to participate, informed that participation is voluntary and that they have the option to end their participation at any time without risk of penalty.

<u>Vulnerable Subjects</u>. Any patient participants who enroll in the study and are considered a member of a vulnerable population, additional measures will be implemented to ensure informed consent is properly obtained and monitoring procedures are adapted accordingly.

<u>Protection and Monitoring Plan.</u> The FSU IRB will review all activities involving humans to be conducted as part of this proposed research study. The FSU IRB complies with all requirements of Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46). After the study is approved, the FSU IRB will oversee activities, study modifications, and reporting of adverse events, in addition to providing the required annual continuing.

### Potential Benefits Of The Proposed Research To The Subjects And Others.

<u>Potential Benefits Weighed Against Risk.</u> The risk to individual participants is minimal in relation to the overall benefit to society, as the proposed project goals of developing innovative interventions to address racist attitudes and behaviors in integrated primary care settings has the potential to improve minority patient outcomes. Benefits to society in general are anticipated through the dissemination of our findings. Methods for dissemination of study findings and other materials will occur in a variety of forms (see Resource Sharing Plan) and will contribute to new insights and interventions that will greatly benefit future patients. All stakeholder participants who are eligible for compensation will be provided a \$50 gift card for

each GMB session. Those stakeholders with organizational rules prohitibing compensation will be determined by the study team prior to participation in GMB sessions and thus, will be ineligible for compensation.

## Importance Of The Knowledge To Be Gained.

The proposed study aims to be innovative in addressing racism in healthcare settings by utilizing a systems science approach to community-based participatory research. Our study is expected to result in a benefit to society as it will provide a basis of knowledge on which new and innovative evidence-based interventions can be developed to address racist attitudes, behaviors, and practices at the provider and organizational/systems level. We believe that the risk to participants are reasonable in relation to the anticipated expansion of knowledge and far-reaching implications for organizational change.

#### DATA SAFETY AND MONITORING PLAN

The study team has developed the following plan to monitor the data safety of the proposal study. This plan, in addition to the required human subjects' components, will be reviewed by the Florida State University (FSU) Institutional Review Board (IRB) prior to initiating study activities, with these approvals provided to the appropriate NIH institute overseeing the project.

# **Data Safety**

<u>Confidentiality</u>: Prior to involvement, all study personnel will complete the required web-based Collaborative IRB Training Initiative (CITI) course. All study personnel facilitating enrollment will adhere to the study protocols for obtaining informed consent from participants. Further, confidentiality will be protected through the use of unique participant identifiers, and all study data (quantitative, qualitative, recordings, etc.) will be securely stored at the Center for Translational Behavioral Science under lock and key, or on Florida State University password-protected secure servers, with access granted only to authorized study personnel.

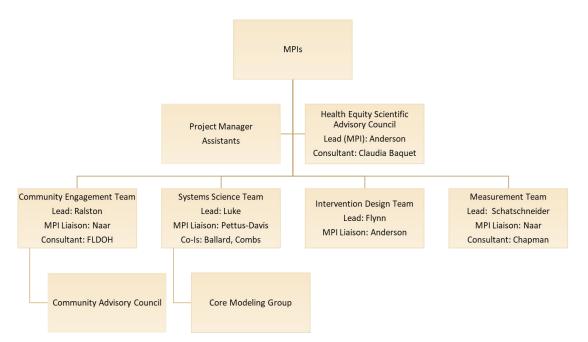
<u>Data Management</u>: All study data will be kept confidential in accordance with Florida state laws and Federal law. When study activities with participants are conducted virtually, the Zoom HIPAA compliant platform will be utilized to ensure participant confidentiality. All virtual and in-person session recordings will be stored in a secure file location within the FSU College of Medicine (CoM) secure server and access will be given only to authorized study personnel. Participants will be assigned a unique ID and all other identifiable participant data will be redacted from study records. Audio recordings will be deleted after six months.

#### Monitoring

<u>Protection of Human Subjects.</u> The FSU IRB will review all study materials, forms, and activities involving human subjects to be conducted as part of this project. The FSU IRB complies with all requirements of Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46). After the study is approved, the FSU IRB will oversee activities, including study modifications, key personnel, recruitment and enrollment, data collection and management, and other appropriate study activities. The contact MPI for this project, with assistance of the project manager and project coordinator, will be responsible for the oversight of all human subject related study activities and applicable reporting, and will schedule both monthly and ad-hoc meetings with the study team to provide routine guidance and monitoring and review any potential adverse events.

Monitoring and Reporting of Adverse Events: The contact PI will monitor and report any adverse events to the IRB. Adverse events include any reaction, side effect, or untoward event that may occur during the course of the proposed study. The categorization of adverse events as serious or non-serious, related or unrelated to study activities, expected or unexpected will be continuously monitored, documented, and reported as required. In the event of an adverse occurrence, the MPIs will meet to review the event and address any potential study changes to mitigate any further risk for harm up to and including halting study activities.

# **OVERALL STRUCTURE OF THE STUDY TEAM**



# Section 4 - Protocol Synopsis (Study 1)

4.1	. Study De	Study Design							
	4.1.a. De	etailed Des	cription						
4.1.b. Primary Purpose									
	4.1.c. Int	erventions							
	Туре		Name		Description				
4.1.d. Study Phase									
Is this an NIH-defined Phase III Clinical Trial? O Yes						<ul><li>No</li></ul>			
	4.1.e. Intervention Model								
	4.1.f. Ma	sking			O Yes	O No			
			☐ Participant	t	☐ Care Provider	☐ Investigator	Outcomes Assessor		
	4.1.g. All	ocation							
4.2	. Outcome	e Measures	S						
Ту	ре	Name		Time Fr	ame	Brief Description			
4.3	. Statistica	al Design a	nd Power						
4.4	. Statistical Design and Power . Subject Participation Duration								
4.5	4.5. Will the study use an FDA-regulated intervention?			) Yes	<ul><li>No</li></ul>				
	4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status								
4.6	4.6. Is this an applicable clinical trial under FDAAA?			O Yes	<ul><li>No</li></ul>				
<u>4</u> 7	Dissemin	nation Plan							

Funding Opportunity Number: RFA-RM-20-013 Received Date: 2020-09-30T12:40:21.000-04:00

Contact PD/PI: NAAR, SYLVIE

Tracking Number: GRANT13212400

## **Delayed Onset Studies**

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification		
The form does not have any delayed onset studies					

#### **MULTIPLE PI LEADERSHIP PLAN**

Our application takes advantage of the extensive experience and diverse but complimentary backgrounds of three multidisciplinary Principal Investigators: Sylvie Naar, PhD, Carrie Pettus-Davis, PhD, and Norman Anderson, PhD. All three Pls share a vast experience in leading complex, transdisciplinary teams, which have resulted in a robust and thriving research units with high levels of productivity. The MPls have each spent their careers addressing health equity in varying domains. Naar has focused her career in improving health equity in adolescent and emerging adult disease prevention and management utilizing models of translational behavioral science. Pettus-Davis' centers have addressed mental and physical health in corrections, and she has collaborated with the systems science team when formerly at Washington University. Dr Anderson has a legacy of addressing health equity in primary care but also in broader professional organizations such as the NIH Office of Behavioral and Social Sciences, the American Psychological Association, and the National Academy of Medicine. All three have addressed behavior change in the context of organizations, Naar patient-provider communication and diffusion of behavioral innovations in medical settings, Pettus-Davis in randomized clinical trials of transformative models of care in corrections, and Anderson in leadership transformation. As outlined below, the three MPls will serve distinctive roles, all with an emphasis on collaboration, mentorship and collegiality.

# Dr. Sylvie Naar (MPI) will be contact PI and will assume the lead in the following areas:

- Contact PI:
  - o Communication point for NIH, and
  - Submission of annual progress reports;
- Overall study implementation and integration:
  - Develop protocols and Standard Operating Procedures
  - o Oversee the recruitment of stakeholder participants for all aims
  - o Ensure integrative team processes
- Provide translational behavioral and social science expertise for all phases of the project;
- Regulatory oversight at FSU IRB.
- Communication:
  - o Facilitate the direct and indirect interactions within and between the subgroups including progress reports and other documents, emails, and conference calls and in-person meetings;
  - Setting short-term and long-term goals, and seeing that they are met;
- Financial Oversight:
  - o Responsible for financial performance including budget preparation, financial monitoring, identification of financial issues and processes for resolution;
  - Liaison to the community engagement and measurement teams.

#### Dr. Pettus-Davis (MPI) will assume the lead in the following areas:

- Coordinate the system science team for aims 1 and 2;
- Oversee the postdoctoral fellow activities including literature reviews and summaries for all phases of the project;
- Ensure that resource sharing plan is implemented;
- Dissemination:
  - o Ensure timeline adherence from data release to publication
  - Ensure dissemination to communities

## Dr. Anderson (MPI) will assume the lead in the following areas:

- Develop and oversee the scientific advisory council
- Participate in model development and measurement development meetings and focus groups
- Liaison to the intervention development team for provider and systems/organizational intervention development

## Together, the MPIs will oversee the following:

- Capitalize on the partnerships between academic and the community which they have spent years developing and nurturing in their domains.
- Leverage new partnerships between academia and the community to optimize impact on antiracism interventions in health care systems.
- Disseminate findings via community/health service providers, presentations at national and international conferences, and publication in top-tier peer reviewed journals.
- The MPIs will have weekly meetings to ensure adherence to aims and timeline and facilitate quarterly meetings across all the investigators and consultants.
- The MPIs will be jointly responsible for the determination of publication authorship which will be made prior to manuscript preparation and will be based on the relative scientific contributions of the PIs and key personnel.

#### Conflict Resolution

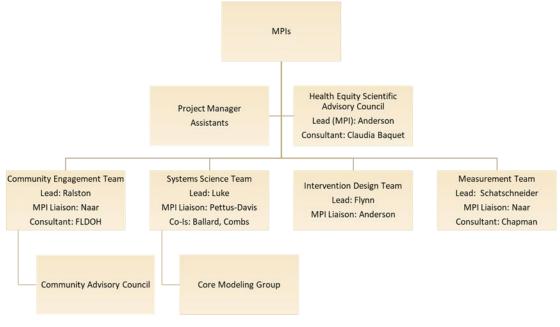
If a potential conflict develops, the PIs shall meet and attempt to resolve the dispute. If they fail to resolve the dispute, the issue will be raised with the investigators who will help make the decision. If the dispute cannot be resolved through consultation with key personnel, the disagreement shall be referred to an arbitration committee consisting of impartial senior faculty officials from FSU. No members of the arbitration committee will be directly involved in the research grant or disagreement.

#### Change in PI Location

If a PI moves to a new institution, every attempt will be made to transfer the relevant portion of the grant to the new institution. In the event that a PI cannot carry out his/her duties, a new PI will be recruited from key personnel; however, given the virtual nature of the current work environment this is unlikely.

#### STRUCTURE OF THE STUDY TEAM

We have structured the study team so that the activities are organized by their innovative methods and associated expertise: Community Engagement, Systems Science, Intervention Design Team, and Measurement Development. Each team will be led by the relevant co-investigator expert but will be assigned an MPI liaison per the MPI plan. There are three advisory groups for the activities. First, the Scientific Advisory Council will be led by our named consultant and will consist of five experts in health equity research in primary care. This group will report directly to the MPIs for all phases of the project. Second, the Community Advisory Council will consist of 10 leaders (two from each stakeholder group – patients, public health officials, providers, agency leaders, and leaders in the broader PCMH state initiative). This council will report to the Community Engagement Team to guide all phases of the project. Third, the Core Modeling Group will report to the system science teams and facilitate the activities for Aim 1.



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#### **Resource Sharing Plan**

#### **Data Sharing**

The dissemination of any and all data collected under the NIH data sharing agreement will be released: a) In a timely manner following the timeline of the project provide; and b) To the broader community, in accordance with NIH guidelines. Active dissemination to collaborators, community groups and through peer-reviewed articles will facilitate access to the data.

Beyond NIH policy, we view sharing of data generated by this proposal to be a moral obligation and essential part of our proposed activities. Our team is committed to collaboration with researchers, health and social services colleagues, our community partners and other entities for rapid dissemination of data and sharing of implementation process materials. Our plan includes the following:

- 1. Formal academic dissemination in the form of journal articles and abstracts: The MPI's and study leads for this project will work collaboratively to ensure rapid dissemination of study findings to the scientific community through submitting abstracts and manuscripts to peer reviewed journals in a timely fashion, as data and other information becomes available throughout the course of the study.
- 2. Presentations at regional, national and international scientific meetings: The goal to disseminate innovative findings is vital to ensure a wider awareness of the study's conclusions and facilitate future directions for research. In order to achieve this, the MPIs and other project leads will present data at regional, national and international conferences, including but not limited to the Society of Behavioral Medicine, and the American Public Health Association. In the event travel to conferences is not possible, the researchers will plan to present these findings in applicable virtual conferences.
- 3. Data sharing with scientific and health service community: It is the intent of the study team to ensure that all de-identified study data complies with NIH data sharing procedures, and be made readily available to other investigators upon request, and without limits or conditions beyond that of existing data sharing policies and procedures held by both the sponsor and the institution.
- 4. Existing community partnerships. Through ongoing community engagement efforts as part of their respective research centers, community collaborations, and other internal and external roles, the MPI's of this study will plan to present findings online to disseminate results as soon as they are available to other researchers, providers and health specialists, and other community stakeholders. The study MPI's also intend to utilize their existing community engagement strategies, both print and media, to further enhance community dissemination.
- 5. Newsletter. We will also publish a newsletter to disseminate study findings and information online only to increase awareness among the community and for general audiences. We will also include study materials that may be useful to other teams pursuing similar work, including study protocols, intervention manuals, factsheets, and implementation manual and procedural guides. As part of this newsletter, the study team will develop and disseminate fact sheets that will summarize study findings in lay terms so that community members can directly benefit from this project.