

INTRODUCTION: This is a resubmission of K01CA190559-01. Several strengths and only minor weaknesses were noted by all three reviewers for the candidate, career development plan, mentoring team, and environment.

| <u>REVIEWER</u> | <u>CAND.</u> | <u>CAREER</u> | <u>RESEARCH</u> | <u>MENTOR(S)</u> | <u>ENV.</u> |
|-----------------|--------------|---------------|-----------------|------------------|-------------|
| One | | | | | |
| Two | | | | | |
| Three | | | | | |

While several strengths were noted for the research plan, weaknesses ranged from negligible to major. We appreciate all comments and have addressed each. Reviewers' comments are underlined below and revisions are indicated by a line in the margin in the application to facilitate review.

CANDIDATE: Bio-statistics background unclear (Reviewer 2): As an epidemiologist, Dr. Carson has completed numerous biostatistics courses which is now more fully described in the "Candidate Background" section.

CAREER DEVELOPMENT PLAN/PLAN TO PROVIDE MENTORING: Coordination of outstanding mentoring/consulting team (Reviewer 1): As suggested by the reviewers, we have reduced the mentoring team size and also addressed the coordination of the mentoring team (which will be overseen by Dr. Monica Baskin) in the "Career Development" section including a plan for how differences will be addressed. Potential projects for future grant submissions may be overly ambitious (Reviewer 2): We have removed the original table and more clearly detailed that **potential** funding mechanisms and projects have been identified to be pursued following the proposed award; Actual projects will be determined based on which will be the most competitive based on preliminary data and funders' research priorities. No apparent training in cancer epidemiology or other "omics" (Reviewer 3): Now, additional training in cancer epidemiology, genomics, proteomics, and epigenetics to increase Dr. Carson's familiarity with these areas for better integration into her overall bio-behavioral research model has been added and offset by a reduction in training in bio-specimen collection.

RESEARCH PLAN: Convenience sample of community controls (Reviewer 1): We have revised the research plan to describe controls as a convenience sample and noted potential biases in the limitations section. Define and operationalize wide range of questionnaire data (Reviewer 1): These variables, which are meant to better characterize the population and generate future hypotheses, and the operationalization plan have been more clearly defined in the "Approach" section of the research plan. Microbiota only vaguely described (Reviewer 1 and 3): Substantial detail has been added to the "Approach" section to more fully describe the experimental methods related to the microbiome. Statistical methods and analysis (Reviewer 1 and 3): Additional detail has been added to the "Approach" section to more fully describe the statistical methods and analysis plan. Research plan seems ambitious (Reviewer 2): As suggested, the application has been revised. The proposed research plans were critically examined by Dr. Carson's mentoring team and can be accomplished within the proposed timeline. Apparent lack of clear integration of bioinformatics training into data management and analysis phase (Reviewer 2): The plan to integrate bioinformatics training into data management and analysis are more clearly described throughout the proposal. Need to justify hypothesis (Reviewer 3): Data from Dr. Carson's preliminary studies and support from additional literature has been added to the research plan to justify the study hypotheses. Collect a sample of men to explore gender differences in stress and the microbiome: (Reviewer 3): We have decided to focus this study on women based on the justification described in the research plan. As noted by Reviewer 2, the current proposal borders on being ambitious. Gender questions will be considered for future studies. "Microbiome" not clearly defined (Reviewer 3): We have added an operational definition of "microbiome" and related terms in the significance section to clarify what we are referring to with microbiome, microbiota, microbes, and microflora. No estimate of recruitment rate for individuals who are prescribed surgical treatment (Reviewer 3): Revisions to visit schedule for cancer patients to coincide with oncology appointments are now described in "Approach".

MENTORING TEAM: Add mentors for several topic areas including microbiology, psychology, bioinformatics, and cancer epidemiology or GI oncology (Reviewers 1, 2, 3): We have further clarified the expertise of the proposed team of mentors/collaborators, which we believe addresses many of the mentoring suggestions without further expanding the team given concerns raised by reviewers 1 and 3. Team members include: Dr. Morrow-Microbiologist, Drs. Baskin and Epel-Licensed Psychologists, Dr. Lefkowitz-Bioinformatics, Dr. Cannon-GI Oncologist/Surgeon. Each provides valuable expertise to help strengthen Dr. Carson's proficiency in each suggested area. Meeting schedule not well described (Reviewer 3): We have added additional details/table to clarify the meeting schedule. Career advisory panel may be too large (Reviewer 3): We have reduced the team into a mentoring panel (3) and consultants (5).

ENVIRONMENT: Unclear if MHRC is being fully utilized (Reviewer 1): We have more clearly highlighted how the MHRC will be leveraged to meet the goals of in this application including utilizing MHRC recruitment assistance, funding and presentation opportunities. Few details of the interaction with Microbiome Resource, Dr. Morrow (Reviewer 1): This has been better described in the proposal and Dr. Morrow's letter of support.

TRAINING PLAN

Candidate Background

From my first experiment in biology laboratory as an undergraduate at Florida State University (FSU) where I explored color recognition in bumblebees, I was fascinated with the notion of being able to create a hypothesis and systematically test it. Though my fear of bees made my experiment a little challenging, I realized that I was very stimulated by science and discovery and wanted to pursue a career in research.

One year after obtaining my Bachelor of Science in Biological Sciences, I began graduate school at the University of Alabama at Birmingham (UAB) pursuing a Master of Public Health in Epidemiology (2003-2005). During that time, in addition to coursework with a strong emphasis on epidemiologic methods and biostatistics, I completed a 16-week Cancer Research Experiences for Students (CaRES) internship in the UAB Department of Nutrition Sciences (mentor: Jamy Ard, MD), which focused on nutrition and physical activity for prevention of cancer. After completing my internship, I remained a part of Dr. Ard's research team as a graduate research assistant and, later, a program coordinator. Though I gained a wealth of knowledge (Table 1), I realized that in order to achieve my ultimate goal of leading independent research studies, I would need additional training. In 2007, I began the PhD program in Epidemiology at UAB (mentor: Olivia Affuso, PhD 2007-2010). My dissertation, supported by a NIDDK-funded Ruth Kirschstein National Research Service Award Pre-doctoral Fellowship (F31DK08397), examined psychosocial factors related to obesity among black and white women. My findings suggested that black and white women may have different psychosocial (e.g., weight-related quality of life and body image) perspectives of weight that may influence their dietary and physical activity behaviors.

To augment my background in epidemiology at UAB, in 2011 I began a post-doctoral fellowship at the University of Arkansas for Medical Sciences (mentor: Delia Smith West, PhD) to receive additional training in behavioral interventions for weight management. I continued to explore the line of research associated with my dissertation by leading the evaluation of a stress-management augmented weight management intervention and exploring the links between stress, quality of life, and body image. During my postdoc, an additional element that peaked my interest, perhaps due to my background in biological sciences, was the collection of bio-specimen (saliva) for cortisol analysis to serve as a bio-marker of stress. For me, this experience brought to the forefront the need to incorporate biological measures into behavioral studies. This need is further evidenced by a growing body of literature revealing strong bi-directional links between biology and behavior.

In 2012, I returned to UAB as an Assistant Professor in the Division of Preventive Medicine (DOPM). DOPM is a research-focused division where my primary responsibilities are to conduct scholarly research and provide service to the institution and the profession. Thus, I am fully able to commit to 11.4 person-months to this project. I have no formal teaching load, but as a tenure-track faculty member, I am expected to demonstrate excellence in teaching as evidenced by guest lectures, grand rounds presentations and mentoring. Dr. Monica Baskin is my primary senior faculty mentor and in this role, she provides me with the intellectual support and physical resources needed to develop my research program. To build upon and extend work from my post-doctoral training, I recently completed a Diversity Supplement from the National Cancer Institute (NCI) (U54CA153719-03S2) associated with a cancer prevention study led by Dr. Baskin. The goal of the supplement study, for which data analysis and manuscript preparation is underway, is to examine whether stress is associated with weight status and weight loss among a subsample of generally healthy rural, black women participating in a behavioral intervention to improve diet and physical activity to reduce their risk of cancer. Additionally, I have collaborated with the Dr. Casey Morrow, Director of the UAB Microbiome Resource, to analyze the oral microflora of saliva samples collected as a part of the supplement study.

I have extensive training in epidemiology and behavior. In this application, I propose several training objectives to provide me with a foundation in the areas of basic science related to study of the microbiome (and other omics) and bioinformatics. **I envision tying these areas of research together to develop a bio-behavioral research program that offers a translational approach aimed at linking basic science and community based research to shift the paradigm of current cancer research and epidemiology by developing new knowledge to inform cutting edge approaches for cancer prevention.** This K01 mechanism provides an excellent opportunity for me to receive the preliminary training in microbiome research and bioinformatics needed to function as the "translator" for the integration of basic science and community based research for cancer prevention. ***My multidisciplinary training background partnered with my stellar mentoring team and research environment make me well-suited to receive the requisite training on how to integrate the basic sciences into my socio-behavioral research to become a leader in translational research as an independent bio-behavioral cancer disparities researcher.***

Table 1: Summary of research training background

| Projects | Candidate's Training Level | Role and/or Training Received | Products |
|---|----------------------------|--|--|
| Biological | | | |
| Exploring potential bio-behavioral explanations for cancer disparities (PI: Tiffany Carson) | Assistant Professor | <ul style="list-style-type: none"> Bio-specimen collection from racially diverse populations | 1 year pilot study initiated in January 2014; preliminary data included; manuscripts under development |
| Stress, weight, and microbiota (PI: Edward Partridge, Project Leader: Monica Baskin, Diversity Supplement Recipient: Tiffany Carson) | Assistant Professor | <ul style="list-style-type: none"> Recruitment of women with no cancer history from underserved groups for bio-specimen research Bio-specimen collection from healthy women, i.e, no history of cancer | 1 first-authored publication in <i>Journal of Community Genetics</i> ¹ ; additional manuscripts under development |
| Stress-management augmented behavioral weight loss intervention (PI: Delia Smith West) | Post-doctoral Fellow | <ul style="list-style-type: none"> Evaluation of cortisol as bio-marker of stress | 1 first-authored publication in <i>Health Education and Behavior</i> ² |
| Behavioral/Intervention | | | |
| Design Issues in Obesity RCTs: Building an evidence base (PIs: David Allison and Olivia Affuso) | PhD Student | <ul style="list-style-type: none"> Methodology related to meta-analytic evaluation of the weight loss intervention literature | 1 co-authored publication ³ |
| Culturally tailored worksite wellness intervention for black women (PI: Jamy Ard) | Master's/PhD Student | <ul style="list-style-type: none"> Cultural tailoring of evidence-based weight loss program Evaluation of body image and quality of life | 1 co-authored publication ⁴ |
| Long-term follow up of black and white women who participated in weight loss intervention (PI: Jamy Ard) | Master's Student | <ul style="list-style-type: none"> Collection and analysis of psychometric data on eating behaviors, self-perceived body image, quality of life Assessment of physical activity | 1 first-authored publication in <i>Obesity</i> ⁵ |
| Culturally tailored wellness intervention for black girls and their mothers (PI: Monica Baskin) | Master's Student | <ul style="list-style-type: none"> Program interventionist | 1 first-authored and 1 co-authored abstract published in <i>Obesity Supplement</i> ⁶ |
| Social/Psychological | | | |
| Dietary Intake Project (PI: Monica Baskin) | Assistant Professor | <ul style="list-style-type: none"> Secondary analysis of the effect of stress level on dietary intake of black women | 1 first-authored manuscript currently under review |
| Social Support in an internet-based behavioral weight loss program (PI: Delia Smith West) | Post-doctoral Fellow | <ul style="list-style-type: none"> Recruitment and retention of women into behavioral weight loss program Measurement of social support Social network analysis | 1 first-authored publication in <i>Journal of Obesity</i> ⁷ |
| Examining body image and quality of life in a group of black and white women (PI: Tiffany (Cox) Carson) | PhD Student | <ul style="list-style-type: none"> Recruitment of diverse populations Assessment of body image and weight related quality of life in obese women | 2 first-authored publications in <i>Journal of Women's Health</i> ⁸ and <i>Applied Research in Quality of Life</i> ⁹ |
| Physical/Environmental | | | |
| Community Action to Increase Demand for Healthy Food in African American Communities (PI: Monica Baskin) | PhD Student | <ul style="list-style-type: none"> Certified as Nutrition Environment Measures Survey (NEMS) rater | 1 co-authored abstract ¹⁰ |
| Evaluating the nutrition environment (PI: Jamy Ard) | Master's Student | <ul style="list-style-type: none"> NEMS rating of local nutrition environment | 1 co-authored publication ¹¹ |

CAREER GOALS AND OBJECTIVES

My overarching career goal is to become an independently funded investigator and develop evidence-based bio-behavioral interventions to overcome cancer disparities. Over the next 5-10 years, I have the following interim goals: 1) Establish an evidence base to elucidate bio-behavioral causes of cancer, 2) Develop an interdisciplinary research laboratory to investigate innovative bio-behavioral approaches to reduce or eliminate colorectal cancer disparities, and 3) Gain promotion and tenure in the ranks of academia. In order to achieve my overarching career goal, I have identified the following 3 training objectives for this K01 period which are synergistic with the activities of the accompanying research plan:

- a. Training Objective 1: Train in the recruitment of racially diverse populations from clinical and community populations for bio-specimen and bio-banking research**
- b. Training Objective 2: Obtain hands-on and didactic training in bioinformatics techniques and other omics technologies (e.g., microbiome, genomics, proteomics, and epigenetics)**
- c. Training Objective 3: Improve professional skills including how to coordinate and implement successful team science, networking, grant writing, mentoring, and high-impact publications**

Table 2: Timeline of complementary research and training objectives

| Year | Activity | Q1 (July-Sept) | Q2 (Oct-Dec) | Q3 (Jan-Mar) | Q4 (Apr-June) |
|---------------------|----------------|--|--|---|---|
| 2015-2016 (Yr 1) | Research (60%) | Prepare for study start-up (e.g., IRB approval, establish protocols, hire staff, finalize logistics) | | Begin recruiting participants (cases and controls), data collection and entry, bio-specimen analysis | |
| | Training (40%) | -Sodeke: bio-ethics -IRB: bio-ethics -Cannon: GI oncology -professional seminars | - Review bio-ethics materials from UAB/TU - AACR Cancer Health Disparities Conference -Cannon: GI oncology -professional seminars | - Georgetown University Bio-ethics -Sodeke: bio-ethics -Cannon: GI oncology -professional seminars | -Graduate Biomedical Sciences Bioethics core course -professional seminars |
| 2016-2017 (Yr 2) | Research (60%) | Ongoing recruitment of participants (cases and controls), data collection and entry, bio-specimen analysis | | | |
| | Training (40%) | -EPI 713 -Sodeke: bio-ethics -professional seminars -Omics workshops/seminars -Cannon: GI oncology | -COALESCE course -AACR Disparities Conference -professional seminars -Omics workshops/seminars -Cannon: GI oncology | -BST 680 -GBS 746-VT -professional seminars -Society of Behavioral Medicine (SBM) Annual Meeting -Cannon: GI oncology | -BST 680 -GBS 746-VT -Sodeke: bio-ethics -professional seminars -Omics workshops/seminars -Cannon: GI oncology |
| 2017-2018 (Yr 3) | Research (70%) | Ongoing recruitment of participants (cases and controls), data collection and entry, bio-specimen analysis | | | |
| | Training (30%) | -professional seminars -Omics workshops/seminars | -AACR Cancer Health Disparities Conference - Sodeke: bio-ethics -professional seminars- - Omics workshops/seminars | -Bioconductor course -professional seminars - Omics workshops/seminars | -Epel Lab visit -Sodeke: bio-ethics -Experimental Biology (EB) Annual Meeting -professional seminars |
| 2018-2019 (Yr 4) | Research (70%) | Ongoing recruitment of participants (cases and controls), data collection and entry, bio-specimen analysis | | | |
| | Training (30%) | -Lefkowitz: bioinformatics -Cannon: GI oncology -professional seminars | -Lefkowitz: bioinformatics -Sodeke: bio-ethics -Cannon: GI oncology -professional seminars | -Lefkowitz: bioinformatics -Cannon: GI oncology -EB or SBM annual meeting -professional seminars | -Lefkowitz: bioinformatics -Sodeke bio-ethics -Cannon: GI oncology -professional seminars |
| 2019-2020 (Yr 5) | Research (80%) | Analyze data, prepare and submit abstracts for meetings of professional societies, prepare and submit manuscripts for Specific Aims 1-3, prepare/submit grant application based on study finding | | | |
| | Training (20%) | -Hands-on training and analysis with Lefkowitz -Cannon: GI oncology -professional seminars | -Hands-on training and analysis with Lefkowitz -Cannon: GI oncology -AACR Disparities Conference -APHA annual meeting | -Hands-on training and analysis with Lefkowitz -Cannon: GI oncology -professional seminars | -Hands-on training and analysis with Lefkowitz -Cannon: GI oncology |

CAREER DEVELOPMENT AND TRAINING ACTIVITIES DURING AWARD PERIOD (entire section revised)

I have assembled an outstanding mentoring committee and a team of collaborators with complementary expertise who helped develop this training and research plan to help achieve my career goals.

| Name | Expertise | Role on Project | Regular Meetings |
|-----------------------|---|--|--|
| Monica Baskin, PhD | Psychology, recruitment /retention of minorities, health disparities, social determinants of health, team science | Primary Mentor | Bi-weekly |
| Upender Manne, PhD | CRC, racial health disparities, pathology | Co-Mentor | Monthly |
| Elissa Epel, PhD | Psychology, social and psychobiological stress mechanisms | Contributing Team Member | Bi-annually |
| Casey Morrow, PhD | Microbiology, bio-specimen collection, microbiome analysis and interpretation | Collaborator; provide training opportunity (objective 2) | Monthly years 2-5 |
| Elliot Lefkowitz, PhD | Bioinformatics and computational tools | Collaborator; provide training opportunity (objective 2) | Bi-weekly years 4-5 |
| Jamie Cannon, MD | GI oncology | Collaborator; provide training opportunity (objective 1) | Monthly years 1-2 Quarterly years 4-5 |
| Stephen Sodeke, PhD | Bioethics | Collaborator; provide training opportunity (objective 1) | Bi-annually |
| Gary Cutter, PhD | Biostatistics | Collaborator | Monthly years 4-5 |

Mentoring Committee (Dr. Monica Baskin: Primary Mentor; Dr. Upender Manne: Co-Mentor; Dr. Elissa Epel: Contributing Member); **Mentors** will provide overall guidance, intellectual support, and resources to ensure the successful completion of the proposed research and training objectives. **Contributing member** will provide feedback and guidance regarding my overall career development and offer a more nationally representative perspective for my career development and provide opportunities for continued expansion of my professional network nationally. Dr. Monica Baskin, Professor in the UAB Division of Preventive Medicine and licensed psychologist, has numerous NIH-funded research projects related to cancer prevention and control. She is PI of an RCT (R01CA160313) testing a multi-level weight management program in breast, colorectal, and prostate cancer survivors. She has mentored numerous graduate students, post-doctoral trainees, and junior faculty members. Dr. Baskin helped with the development of this application and will continue to oversee research activities and career development through scheduled bi-weekly meetings. Further, due to the physical proximity of our offices, Dr. Baskin is available daily to offer advice and assistance. Dr. Upender Manne is a Professor of Pathology in UAB's Department of Pathology. Dr. Manne is PI for the NCI-funded Morehouse School of Medicine/Tuskegee University/UAB Comprehensive Cancer Center Partnership (U54CA118948-08) designed to reduce and eliminate cancer disparities through education, training, outreach, bioethics and biostatistics. He has mentored over 50 individuals from undergraduate students to junior faculty members. Dr. Manne will offer expertise on CRC biology/pathology and general career development during regularly scheduled monthly meetings and will be available for additional meetings as needed. Drs. Baskin and Manne will connect **monthly** to coordinate mentoring. **Quarterly meetings** of Drs. Baskin, Manne, and Carson together will occur. Dr. Elissa Epel is an Associate Professor and licensed psychologist with longstanding interests in social and psychobiological stress mechanisms and the impact of stress physiology on food intake. She is the PI of multiple NIH grants. Dr. Epel will provide guidance on developing an interdisciplinary research program through bi-annual conference calls and an in-person visit to Dr. Epel's laboratory during which she and Dr. Carson will discuss progress towards short- and long-term career goals; troubleshoot potential barriers; and set goals for the next 6 months. **Collaborators** will provide specific expertise key to the proposed research project and my overall career development (letters of support included). Dr. Casey Morrow, Professor in the Department of Cell Biology and Director of the Microbiome Core facility, has expertise in microbiology, bio-specimen collection, microbiome analysis, and interpretation. Dr. Morrow will provide training experiences in microbiology with emphasis on the study of the microbiome. His lab will also lead the microbiome analysis during which time Dr. Carson will complete a rotation to gain more proficiency in this topic area. Dr. Elliot J. Leftkowitz, Professor in the Department of Microbiology and manager of the Bioinformatics Core Facility, has extensive expertise in the development and utilization of computational tools and bioinformatics techniques. Currently, he also

applies bioinformatics techniques to multiple microbiome studies at UAB including work described by Muzny et al¹². Dr. Lefkowitz's lab will lead the bioinformatics effort related to this proposal during which time Dr. Carson will complete a rotation to gain more exposure and hands-on training in these topic areas. Dr. Carson will shadow the Bioinformatics team and complete bioinformatics activities related to the data for her study. **Dr. Jamie Cannon**, Assistant Professor of Surgery in the Section on Gastrointestinal Surgery, is a gastrointestinal oncologist and colorectal surgeon at UAB. In addition to Dr. Cannon's clinical duties, she has longstanding interests in CRC research and served as the PI for a CRC-focused pilot study supported by the NCI-funded Deep South Network for Cancer Control (U54CA153719). In addition to providing the patient population for Dr. Carson's study, Dr. Cannon will provide training to Dr. Carson in topics related GI oncology including the etiology and treatment of CRC and the clinical relevance of the proposed research. **Dr. Gary Cutter** is a Professor in the Department of Biostatistics and Head of the Section on Research Methods and Clinical Trials. Recently, his work has included exploration of the microbiome of HIV patients. Dr. Cutter will bring biostatistical expertise on the design, analysis and interpretation of study findings and provide training on appropriate computational methods for combining biological and behavioral data to address key research questions in the proposed project. **Dr. Stephen Sodeke**, a bioethicist and Professor of Allied Health at Tuskegee University, holds an appointment at the National Center for Bioethics in Research and Health Care at Tuskegee University. He will provide consultation on bioethics related to the collection and storage of bio-specimens.

We are confident that the esteemed mentoring and collaborative team will operate synergistically to facilitate the research and training activities proposed under the leadership of Dr. Baskin who will coordinate the team's input. Evidence of our ability to coordinate the team's input includes the development of this application which includes the input of each team member. Additionally, the previous interaction of team members for activities including shared mentorship of other trainees documents the team's ability to operate in concert. In the event that differences arise, Dr. Carson will seek the council of other senior scientist outside of this team to whom she has access through her Comprehensive Cancer Center (CCC) affiliation such as Dr. Edward Partridge, Director of UAB CCC (see letter of support).

The team has helped develop the following plan to address the proposed **training objectives:**

Objective 1: Training in the recruitment of racially diverse populations from clinical and community populations for bio-specimen and bio-banking research; I currently have no experience in the collection of more invasive bio-specimens (e.g., blood, stool, tissue) from racial/ethnic minorities or the recruitment of cancer patients. To realize my goals of ongoing cancer disparities research, additional training is needed related to bioethical considerations and cultural concerns related to bio-specimen and bio-banking research.

Formal coursework: **The Georgetown University Kennedy Institute of Ethics Online Course: Introduction to Bioethics (Year 1; Spring 2016)**-This course explores the fundamental moral issues that arise in medicine, health, and biotechnology including how they intersect with racial and gender equality. **Graduate Biomedical Sciences (GBS) Bioethics Core Course (Year 1; Summer 2016)** – The GBS Bioethics course at UAB covers training in the responsible conduct of research, as required by the NIH. **EPI 713 – Cancer Epidemiology and Control (Year 1; Summer 2016)** - This course addresses methodology and substantive issues in cancer epidemiology, definitions, biological origins and pathological and clinical aspects of cancer; the global burden of cancer; descriptive epidemiology and major risk factors for various cancers; strategies for cancer prevention and the role of epidemiology developing and evaluating strategies.

Consultations and individual activities: I will have bi-annual meetings via video conference or in-person with Dr. Stephen Sodeke, bioethicist to review activities for the previous and upcoming 6-months in the context of bioethics and additional relevant topics. I will review training materials available from the UAB Center for Ethics and Values in the Sciences and the Tuskegee University National Center for Bioethics in Research and Health Care. Meetings with Dr. Baskin will include discussions of cultural considerations for bio-specimen research.

Objective 2: Obtain hands-on and didactic training in bioinformatics techniques and other "omics" technologies (e.g., microbiome, genomics, proteomics, and epigenetics); To achieve my overall research goal of understanding and developing bio-behavioral approaches for cancer prevention, it is critical that I am able to analyze, summarize, and interpret my biological data in the context of other factors under consideration (e.g., race and stress level). Bioinformatics techniques will allow me to synthesize the findings of lab analysis into population-level outcomes which is a cornerstone of translational and bio-behavioral research. Familiarity with additional omics technology will provide me with a better understanding of the omics research landscape.

Formal coursework: **GBS 746-VT – Introduction to Scientific Computing (Year 2; Spring 2017):** This is a hands-on training for graduate students, staff scientists and faculty dedicated to the installation/configuration of Linux operating system, scripting language (Python and/or Perl), and understanding the basic data structure types and build-in functions available. An introduction to the R Project for Statistical Computing will be provided

in part 2. **BST 680 - Statistical Computing with R (Year 2; Spring 2017):** This course is focused on R, a statistical program, and how to use R to conduct basic statistical computing. The course contains three themes: R programming, introduction to high performance computing, and basics of statistical computing. **Bioconductor Course; Analysis of High-Throughput Sequencing Data (Year 3; Spring 2018):** This course, offered by the Fred Hutchinson Cancer Research Center (Seattle, Washington), covers essential topics in the analysis of next-generation sequencing data.

Laboratory training Dr. Lefkowitz will **provide training in computational biology and bioinformatics** by overseeing and assisting with analysis and data interpretation from my study. **I will be very actively involved.** I will also participate in weekly meetings with Dr. Lefkowitz's lab to review NexGen sequencing issues.

Consultation and individual activities: **UAB Heflin Center for Genomic Science:** I will utilize the education/outreach resources available to UAB faculty through this University Wide Interdisciplinary Research Center. To help educate UAB faculty about the use of genomics and proteomics in their research, the Heflin Center offers traditional and nontraditional approaches to education and outreach including: grand rounds, departmental seminars; newsletters; seminars, workshops, symposia; academic and professional development courses; and a genomics immersion course.

Objective 3: Improve professional skills including how to coordinate and implement successful team science, networking, grant writing, mentoring, and high-impact publications

- **Team Science:** UAB's research environment is highly supportive of collaborative endeavors as evidenced by numerous interdisciplinary centers and grants including the Mid-South Transdisciplinary Collaborative Center for Health Disparities Research (U54MD008176) of which Dr. Baskin currently leads a full research project with clinical research collaborators. Given my goal of establishing an interdisciplinary research lab to investigate cancer health disparities, it is important that I am trained in the principles of team science.

Formal Coursework: **COALESCE: CTSA Online Assistance for Leveraging the Science of Collaborative Effort (Year 2; Fall 2016):** This course offers tools designed to help envision how transdisciplinary collaborations work and how to overcome communication challenges. Content in the modules is grounded in empirical research and theory about the science of team science (SciTS). Modules are intended to help researchers acquire and apply basic knowledge of team science and participate through experiential learning.

Consultations and individual activities: I will read the NIH Publication "Collaboration and Team Science: A Field Guide" by Bennett, et al.; I will meet with Dr. Elissa Epel twice per year to discuss topics related to developing an interdisciplinary research lab. I will also visit Dr. Epel's research lab at UCSF in Year 3 to observe the operation of her lab, interact with her research team and to evaluate what activities I should undertake in the final years of my career development award to prepare to lead and engage in interdisciplinary research efforts.

- **Conferences:** Annually, I will attend 1-2 scientific meetings from national societies related to my research area (e.g., American Association for Cancer Research, Behavioral Medicine, Experimental Biology, or APHA). Attendance will foster networking and improve visibility as an independent investigator.
- **Professional skills workshops:** The Comprehensive Cancer Center (CCC), Center for Clinical and Translational Science (CCTS), Nutrition Obesity Research Center (NORC), Diabetes Research and Training Center (DRTC), and Minority Health Research Center (MHRC) provide opportunities for further training in skills needed for academic research success. I will continue to attend a minimum of 4 seminars/workshops annually, particularly those focused on scientific writing, grantsmanship, effective presentations, networking, team building, leadership, laboratory management, interviewing, and attainment of promotion and tenure.
- **Presentations:** I will make scientific presentations to local and national audiences. Local opportunities include, but are not limited to, Division and Department Grand Rounds, NORC weekly seminar series, and the MHRC and Department of Epidemiology seminar series. I will also submit abstracts for scientific presentations at national meetings of professional organizations or other academic institutions.
- **High-impact publications:** In order to bring the findings of this important work to the scientific forefront, I will focus on obtaining the needed data and senior advising to achieve publications in high-impact journals. I will continue to contribute to the body of knowledge in health disparities and microbiome research by submitting at least 2 first-authored publications each year. I have identified several planned manuscripts from the work proposed in this application and additional ongoing studies that will be completed during the project period.
- **Grant-writing:** I will continue to submit proposals for both intra- and extramural funding opportunities to augment the planned research study and expand preliminary work into a robust research program. Potential funding opportunities and projects have been identified. The final determination of projects will be guided by the findings of my current and upcoming research and ongoing mentoring. With the assistance of my mentoring team, I will select the most competitive 1-2 projects based on preliminary data, the strategic plan of the institute, and new developments in the scientific literature.

SUMMARY STATEMENT
(Privileged Communication)

Release Date: 07/08/2014

PROGRAM CONTACT:
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Application Number: 1 K01 CA190559-01

Principal Investigator

CARSON, TIFFANY LASHAUN PHD

Applicant Organization: **UNIVERSITY OF ALABAMA AT BIRMINGHAM**

Review Group: NCI-I
Subcommittee I - Transition to Independence

Meeting Date: 06/17/2014
Council: OCT 2014
Requested Start: 09/01/2014

RFA/PA: PAR12-050
PCC: W2MB

Project Title: The interplay of behavior, environment, and microbiota in colorectal cancer risk

SRG Action: ++

Next Steps: Visit http://grants.nih.gov/grants/next_steps.htm

Human Subjects: 30-Human subjects involved - Certified, no SRG concerns

Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Gender: 2A-Only women, scientifically acceptable

Minority: 1A-Minorities and non-minorities, scientifically acceptable

Children: 1A-Both Children and Adults, scientifically acceptable

| Project Year | Direct Costs Requested |
|-----------------|---------------------------|
| 1 | |
| 2 | |
| 3 | |
| 4 | |
| 5 | |
| <hr/> | |
| TOTAL | |

++NOTE TO APPLICANT: Members of the Scientific Review Group (SRG) were asked to identify those applications with the highest scientific merit, generally the top half. Written comments, criterion scores, and preliminary impact scores were submitted by the assigned reviewers prior to the SRG meeting. At the meeting, the more meritorious applications were discussed and given final impact scores; by concurrence of the full SRG, the remaining applications, including this application, were not discussed or scored. The reviewers' comments (largely unedited by NIH staff) and criterion scores for this application are provided below. Because applications deemed by the SRG to have the highest scientific merit generally are considered for funding first, it is highly unlikely that an application with an ND recommendation will be funded. Each applicant should read the written critiques carefully and, if there are questions about the review or future options for the project, discuss them with the Program Contact listed above.

1K01CA190559-01 Carson, Tiffany

DESCRIPTION (provided by applicant): Dr. Tiffany Carson is an applied epidemiologist with a background in studying health disparities of black and white women. Dr. Carson's early work focused on behaviors related to diet, physical activity, obesity and related health outcomes. Recently, Dr. Carson has focused on applying her research efforts to better understand cancer disparities of black and white women. Dr. Carson's overarching career goal is to become an independently funded investigator and develop evidence-based bio-behavioral interventions to reduce cancer health disparities. To that end, this application proposes a rigorous research project and training plan focused on investigating the microbiota as a novel potential contributor to colorectal cancer (CRC) disparities between black and white women. CRC is the 2nd leading cause of cancer death in the United States accounting for 9% of cancer deaths. Known risk factors for CRC include increasing age, male sex, family history, inflammatory bowel disease, type 2 diabetes, alcohol consumption, smoking, physical inactivity, high consumption of red and processed meats and high fat diet, and obesity. Among women, even after accounting for differences in the distribution of risk factors, black women remain at 48% greater risk for CRC than white women. There is a growing body of research suggesting that the influence of diet on CRC risk is mediated through the microbiota and that microbial perturbations caused by diet, lifestyle, and antibiotics can lead to increased risk for CRC and other chronic diseases. Stress is one factor that has been shown to lead to alterations in the microbiota. Our research has shown that black women report moderate to high stress levels and additional published literature indicates that black women report higher stress levels than their white counterparts. These observations have led to our hypothesis that a greater proportion of black women have a perturbed microbiota as a result of higher stress levels compared to white women, putting black women at greater risk for developing CRC. In the present proposal, we plan to explore this hypothesis employing a case-control study design comparing the following groups: 1) black and white women with incident CRC from the Kirklin Clinic at UAB and 2) age-matched cancer-free black and white female community controls. Specifically, we will first characterize the oral and gut microbiota of black and white women with CRC and compare by race with particular focus on microbes known to be either positively or negatively associated with CRC. Because all cases will have CRC, we hypothesize that there will be no significant racial differences in the microbiota or other known risk factors for CRC such as diet. In contrast, when we repeat this experiment in cancer-free black and white female community controls, we expect to observe racial differences in the microbiota, with black women having less health-promoting bacteria and more pathogenic bacteria than white women, which would put black women at increased risk for CRC. We anticipate that a greater proportion of black females in the control group will have microbiota that resembles the microbiota of participants with CRC. Additionally, if our hypothesis is supported, psychological stress will be inversely associated with health-promoting bacteria and positively associated with pathogenic bacteria. Our findings will provide insight into how lifestyle factors that have not been fully explored to date such as stress may be associated with risk for CRC as a result of how stress perturbs the microbiota. If we determine that stress contributes to CRC risk via microbial perturbations, future bio-behavioral interventions that incorporate stress management and dietary/supplemental recommendations to promote mucosal health, and therefore reduce CRC risk, can be developed and implemented which could lead to diminished health care costs related to diagnosis and treatment and reduce CRC disparities between black and white women. In addition to providing valuable data, the proposed research project will also provide the opportunity for the additional training needed for Dr. Carson's development as an independently funded bio-behavioral cancer disparities researcher. Dr. Carson will engage in an intensive, structured training experience to develop expertise by completing the following: 1) Training in the recruitment of racially diverse clinical and community populations for bio-specimen and bio-banking research, 2) Obtaining hands-on and didactic training in bioinformatics techniques, and 3) Improving professional skills such as team science, networking, grant writing, mentoring, and high-impact publications. Under the guidance of an esteemed panel of mentors and collaborators and the high quality research and training environment that the University of Alabama

at Birmingham offers, Dr. Carson's research and training experiences will make a significant contribution to the scientific community and Dr. Carson's overall career development.

PUBLIC HEALTH RELEVANCE: Colorectal cancer is the second leading cause of cancer death in the USA, and the disparity between black and white women remains unexplained. This study will evaluate novel biological, behavioral and environmental factors that may contribute to this disparity. Findings from this study will provide insight into whether stress and the microbiota contribute to risk for CRC and possibly lead to innovative interventions to reduce CRC incidence and disparities.

The written critiques of individual reviewers are provided in essentially unedited form in the section below.

CRITIQUE 1:

Candidate:

Career Development Plan/Career Goals /Plan to Provide Mentoring:

Research Plan:

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Environment and Institutional Commitment to the Candidate:

Overall Impact: This K01 application proposes a strong training program addressing the applicant's career goals to focus on women's health disparities, particularly white-black differences in colorectal cancer and its risk factors. The proposed development plan includes hands-on involvement in recruiting subjects, training in bioinformatics, and a range of professional development goals include grant writing, team science, networking, and high impact publications. The candidate is well trained and has been conducting and publishing research on this topic. The mentor has a strong track record of mentoring junior scientists, and the team of collaborators provides expertise in the relevant disciplines required for this potentially transformative research on the role of the microbiome on colorectal cancer risk; however, a more major mentoring role is needed to provide overall guidance on microbiology. This lack of mentoring was also evident in the research plan that, while strong in other respects, offered only a cursory description of the important experimental techniques and assays to discover and validate associations of cancer risk with specific organisms.

1. Candidate:

Strengths

- Currently Assistant Professor of Preventive Medicine at the University of Alabama (UAB) School of Medicine, Dr. Carson trained at UAB and received both and MPH and PhD in Epidemiology. She also completed post-doctoral training in Health Behavior and Health Education.
- Is currently funded by a U54 NCI Diversity supplement award to examine relationships between stress and weight among black women enrolled in a cancer prevention study, and by an institutional pilot fund to investigate microbiotic influences. These formative studies are directly relevant to the proposed K award.
- The CV lists 15 total peer-reviewed publications, among which Dr. Carson is the first author on three recent papers (one of which is a review) on diet, weight loss, quality of life, and biospecimens collection.

Weaknesses

- None noted.

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:

Strengths

- Proposed development plan includes hands-on involvement in recruiting subjects to the study (Objective 1), with a mix of didactic and applied experiences and activities.
- Proposed training in bioinformatics will be very important and relevant to future work on this topic, (Objective 2), with a mix of didactic and applied experiences and activities.
- Other professional development goals include enhancing skills in grant writing, team science, networking, and high impact publications (Objective 3).
- Proposes a team of four scientific collaborators and an advisory panel of three scientists in addition to the two mentors.

Weaknesses

- Although the proposed team of mentors, collaborators, and advisors is outstanding, in practice this could be unwieldy. The plans to coordinate their input are not well detailed. How will differences in advice be handled, and who specifically will help to prioritize input and sort out differences?

3. Research Plan:

Strengths

- Strong focus on women's health disparities, particularly white-black differences in colorectal cancer and its risk factors.
- Innovative focus on the gut microbiota, a rapidly evolving area of new knowledge that is not yet well integrated into cancer prevention.
- High potential for future interventions to improve the cancer-protective microbiota and diminish the harm from cancer-associated microbiota.
- The applicant and mentors have a track record of successfully recruiting subjects and obtaining biospecimens for epidemiological research. Preliminary results from those studies establish the feasibility of the proposed scope of research.
- The use of community-based controls for the study has many advantages over hospital-based and other types of controls, avoiding some forms of bias in this case-control design.

Weaknesses

- The community controls are referred to as a random sample, but this does not seem to be the case; rather, they appear to be a convenience sample recruited through churches and various partner networks in the community. The advantages of this strategy to meeting recruitment goals are clear, but the possible effects of such sampling on bias and measurement error were not clearly elaborated.
- A very wide range of data will be collected from questionnaires. It is not clear how all these data will be used. In particular, measures of diet intake, diet quality, tobacco smoking, alcohol drinking, and neighborhood attributes (based in zip codes) were neither defined nor operationalized.
- The major innovative domain in this research plan, the microbiota, is only vaguely described in the research plan. The experimental methods of analysis are missing, along with any QC/QA plans, and there is no mention of how the major proposed categories of microorganisms (i.e. those that form short chain fatty acids vs. those that promote the formation of secondary bile acids) will be defined and validated. It is unclear if this categorization will be done at the species

level or higher taxonomic levels, and how this could introduce any biases, co-linear effects, or other problems into the statistical analysis. Also, the statistical power section mentions “quantity of organisms” as a key variable, but this is not defined and it does not seem to be related to the proposed hypotheses.

- Similarly, given the proposed importance of stress as an independent or modifying factor in the proposed associations of colorectal cancer risk, race, and microbiota, there is little or no mention of any specific statistical methods to examine those effects and disentangle the potentially complex relationships between the many domains of biology and behavior.
- The statistical analysis plan is rather generic and does not directly address the hypotheses proposed in the Specific Aims, nor does it adequately address the proposed theoretic model.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- Letters from the mentors are richly detailed and provide evidence of firm support and commitment to the applicant.
- Dr. Baskin (primary mentor) is a tenured full professor at UAB’s Department of Medicine, Division of Preventive Medicine, with a track record of NCI-funded grants in health disparities research, and a strong record of mentoring junior scientists. Her research is primarily in diet, exercise and weight loss in minority populations. She specifically mentions using her national network of collaborators and professional contacts to help further the career of the applicant. The letter also mentions having protected time for mentoring, which also reveals the institution’s commitment to developing productive junior faculty.
- The second mentor, Dr. Manne, is a tenured professor of Pathology at UAB, and an expert in cancer biomarkers and bioinformatics. His research spans several types of cancer but he has expertise, peer-reviewed publications, and research grant funding in colorectal cancer and its disparities in the population. His letter documents his overall commitment to and experience in mentoring and specific plans to mentor the applicant.
- Frequency of contacts between mentors and mentee will be adequate and conducive to progress and any needed course corrections.
- The two mentors offer a highly complementary blend of expertise in the biological and behavioral sciences as applied to cancer and its disparities.

Weaknesses

- Given the importance of the microbiological aspects of the proposed K award, it is not clear that sufficient mentoring is in place to guide that part of the research, and to help promote the design of future interventions.
- Similarly, as stress is proposed as a major modifying factor in the research plan, a more central mentoring role for a psychologist may be a missed opportunity.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- University of Alabama (UAB) School of Medicine will be a highly supportive and conducive research environment; the facilities and resources include a well-respected health disparities research center, a center for outcomes and effectiveness research, and clinical facilities for study subject recruitment and phlebotomy.

- The UAB's Comprehensive Cancer Center has several Programs of note, directly relevant to this application: the Women's Cancer Program, Chemoprevention Program, and Cancer Control and Population Science Program. Interactions with faculty in these programs should greatly enhance the candidate's successful transition to career independence.
- There is a Microbiome Resource within the Department of Cell Biology.
- The Minority Health and Health Disparities Research Center has Programs for Faculty Training and Development, and for Community Outreach, and emphasizes culturally competent research methods and community-based participatory research.

Weaknesses

- It is not clear that the candidate is taking full advantage of the resources of the Minority Health and Health Disparities Research Center.
- There are few details of the interaction proposed with the Dr. Morrow of the Microbiome Resource, which seems to be a missed opportunity to better understand the microbiological aspects of the proposed exposures.

Protections for Human Subjects: Acceptable Risks and Adequate Protections

- Plans to protect human subjects are well detailed and appropriate.

Inclusion of Women, Minorities and Children:

G2A - Only Women, Acceptable

M1A - Minority and Non-minority, Acceptable

C1A – Children (over 19) and Adults, Acceptable

Vertebrate Animals: Not Applicable (No Vertebrate Animals)

Biohazards: Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research:

Comments on Format (Required):

- The format of the proposed training is appropriate.

Comments on Subject Matter (Required):

- Excellent, including in depth course work in bioethics.

Comments on Faculty Participation (Required; not applicable for mid- and senior-career awards):

- Senior faculty will be participating in this training.

Comments on Duration (Required):

- Duration extends for the full five years of the K award.

Comments on Frequency (Required):

- Frequency is appropriate, including both annual and biennial components.

Select Agents: Not Applicable (No Select Agents)

Resource Sharing Plans: Acceptable

Budget and Period of Support: Recommend as Requested

CRITIQUE 2:

Candidate:

Career Development Plan/Career Goals /Plan to Provide Mentoring:

Research Plan:

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Environment and Institutional to the Candidate:

Overall Impact: This K01 submission is focused on the candidate receiving training in development of bio-specimen and bio-banking research, bioinformatics techniques, and further development in grant writing, mentoring, manuscript writing, and team-building/networking. The research proposal is focused on collection of biospecimens and survey data to evaluate whether stress mediates the association between gut microbiota and colorectal cancer, and whether there are differences between African American and non-Hispanic White women. There are a number of strengths of this project including a clearly formulated career development plan and research plan, strong supportive letters, and evidence from both candidate and mentors that strongly indicate a path to independent researcher capability. There are few significant weaknesses with this application.

1. Candidate:

Strengths

- MPH in 2005, PhD in Epidemiology in 2010, 1-year Postdoctoral traineeship at University of Arkansas, 2011-2012
- Currently an Assistant Professor in the Division of Preventive Medicine at UAB
- Project Leader on NCI-funded Diversity Supplement to examine relationship between stress, salivary cortisol, and weight among African American women participating in a study of diet and physical activity
- PI of study through UAB cancer center on association between race, weight, stress, oral and gut microbiome
- 15 publications; 9 as first-author
- Understanding and some experience with incorporation of biological measures into behavioral studies

Weaknesses

- Unclear as to how strong the candidate's background is in biostatistics

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:

Strengths

- Clear and detailed plan for development of skills in recruiting racially diverse populations, training in bioinformatics, and enhancement of professional skills with attention to how proposed activities will provide new and different skills or enhance previous training and experience

- Summary table of research and career development activities by year and quarter stratified by research and training activity
- Interaction with mentors appears to be via regularly scheduled meetings

Weaknesses

- The career development plan may be overly ambitious in terms of potential projects that are outlined for grant submissions

3. Research Plan:

Strengths

- A focus on ethnic differences between African American and non-Hispanic White women
- Generation of pilot data on biological, behavioral, social, and environmental factors in relation to increased risk of colorectal cancer
- Clearly stated research aims in relation to the interaction of stress with diet and specific gut microbes
- Inclusion of proof of concept data for microbiome sample collection and analysis

Weaknesses

- The research plan seems ambitious but it is also noted in both the candidate's research description and confirmed in the mentor's letter of support that a number of aspects of the project will be covered by the primary mentor's resources
- Although one of the aims is to increase the level of knowledge on bioinformatics and there is evidence that this area will be covered through didactic coursework and it is noted that 'hands-on' experience will be included, there does not appear to be a clear integration of how this will be incorporated in the data management and analysis phase

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- A strong team composed of a mentor, co-mentor, advisory committee members and supportive community collaborators, all of which have provided very supportive letters of commitment
- Dr. Monica Baskin, a behavioral scientist, is the primary mentor, and has served as Dr. Carson's mentor in the past. She is well-funded and has a strong background in clinical psychology and experience in the recruitment and retention of minorities into research studies. She has been a primary mentor to 13 trainees or junior faculty.
- Dr. Upendar Manne is well-suited as a co-mentor with a research focus on tumor molecular biology and validation of cancer biomarkers of colorectal cancer
- Four collaborators are identified to provide expertise in bio-specimen and microbiome analysis, bioinformatics, biostatistics, and bioethics related to bio-specimen collection and storage
- Career Advisory Panel to aid in establishing network and collaboration
- Clear statement that pilot data will belong to the candidate

Weaknesses

- Although Dr. Manne has a certificate in bioinformatics, given that the candidate seeks a solid understanding in this area, it would greatly strengthen the application to have the inclusion of a

third mentor in this area. The application would be strengthened with the addition of a formal mentor for the bioinformatics component

5. Environment and Institutional Commitment to the Candidate:

Strengths

- The University of Alabama provides a wealth of resources for cancer researchers having Centers for Clinical and Translational Science, Minority Health and Health Disparities, and a Comprehensive Cancer Center, as well as a microbiome laboratory, and a bioinformatics core
- Previous collaboration between the candidate and the Director of the microbiome laboratory on analyses of saliva samples

Weaknesses

- No major weaknesses noted

Protections for Human Subjects: Acceptable Risks and Adequate Protections

- A detailed description is provided.

Inclusion of Women, Minorities and Children:

G2A - Only Women, Acceptable

M2A - Only Minority, Acceptable

C3A - No Children Included, Acceptable

- Focus is on women (336 women; 168 African American; 168 non-Hispanic white)

Vertebrate Animals: Not Applicable (No Vertebrate Animals)

Biohazards: Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research: Acceptable

Comments on Format (Required):

- Adequate

Comments on Subject Matter (Required):

- Adequate

Comments on Faculty Participation (Required; not applicable for mid- and senior-career awards):

- Adequate

Comments on Duration (Required):

- Adequate

Comments on Frequency (Required):

- Adequate

Select Agents: Not Applicable (No Select Agents)

Resource Sharing Plans: Acceptable

Budget and Period of Support: Recommend as Requested

CRITIQUE 3:

Candidate:

Career Development Plan/Career Goals /Plan to Provide Mentoring:

Research Plan:

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Environment and Institutional to the Candidate:

Overall Impact: This is a new application for a K01 award from a candidate trained as a cancer epidemiologist who seeks training to do work on stress, obesity and microbiota in regard to racial disparities. The candidate has substantial training, an excellent publication record, and an outstanding mentoring team. The research plan is well described, but would benefit from better justification of the hypothesis, justification of the sample size, and clarification of the subject recruitment timing. Mentoring in cancer and cancer epidemiology would probably also be of benefit.

1. Candidate:

Strengths

- The PI is well trained as an epidemiologist and has good postdoctoral training to prepare her for this Award.
- Recommendation letters are very good and supportive.
- PI has a reasonable number of publications on obesity and race/ethnicity in her background.

Weaknesses

- No significant weaknesses noted.

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:

Strengths

- Most of the plans appear to be well thought out and appropriate to Dr. Carson's career plans.
- The courses are good.

Weaknesses

- There is no apparent training in cancer or cancer epidemiology in Dr. Carson's background. Some mentoring in that would be beneficial.
- While there is training planned for the microbiome, it is clear that the candidate lacks training in the other "omics" as well. Training should be expanded to genomics, proteomics, and epigenetics. Training in specimen collection can probably be reduced.

3. Research Plan:

Strengths

- The plan is nicely detailed and described.
- Racial disparities in obesity and colon cancer is a worthwhile goal.

Weaknesses

- Section C.2 describes a number of small pilot studies underway on stress and race, the microbiome and race which have been analyzed and for which data are available but the data are not shown. These data would be helpful in justifying the hypotheses put forth in this proposal.
- As above, there is virtually no basis put forward for the hypothesis linking stress and the microbiome and racial disparities. Thus, funding a large study on the subject and devoting 5 years of a person's career on the subject seems difficult to justify.
- The most salient fact about racial disparities and colon cancer is that they only apply to women. The PI puts this forward without any comment and does not suggest how stress or the microbiome may differ between men and women to account for this difference. Perhaps a sample of men should be collected to see how the microbiome and how stress differ between the two genders.
- The proposal uses the term microbiome repeatedly, yet is ambiguous as to what it refers to. Apparently it refers to both oral and fecal microflora. It is not clearly defined.
- No description is provided as to how the microbiome analyses will be conducted. Nor are the number of potential microflora to be ascertained (both from the oral cavity and from feces) suggested and thus an estimate for sample size given.
- Given the fact that there is no a priori hypothesis with regard to which microflora play a role, nor with regard to the role of stress nor with regard to the multiple other risk factors being measured, it seems inappropriate that no correction is being made for the p-value. This would seem a good circumstance in which to utilize Bonferroni or other corrections.
- The protocol states that consent, interviews and all biological specimens will be collected before any treatment occurs. It is not clear if this refers to surgery as well as radiotherapy and chemotherapy. There is usually very little time between diagnosis and surgery, so it is likely that there will be not be an excellent recruitment rate. It is very difficult to believe a large number of patients will be willing to make 2 visits to the clinic for study purposes prior to cancer surgery. No estimate is given of the recruitment rate under these circumstances.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- Drs. Baskin and Manne are outstanding and well qualified choices as co-mentors and complementary.
- The other mentors are also well selected.

Weaknesses

- The schedule for meetings with the mentors and consultants is not well described.
- The career advisory panel may be too large.
- As mentioned above, it may be useful to add a mentor who can assist with knowledge about cancer and cancer epidemiology, perhaps a GI oncologist.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- UAB is an outstanding environment for the proposed research.
- The Cancer Center is one of the best in the country and particularly strong in disparities research, especially with Dr. Partridge and Dr. Fouad.

Weaknesses

- None noted.

Protections for Human Subjects: Acceptable Risks and Adequate Protections

- Acceptable

Inclusion of Women, Minorities and Children:

G2A - Only Women, Acceptable

M1A - Minority and Non-minority, Acceptable

C3A - No Children Included, Acceptable

Vertebrate Animals: Not Applicable (No Vertebrate Animals)

Biohazards: Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research: Unacceptable

Comments on Format (Required):

- Acceptable

Comments on Subject Matter (Required):

- Acceptable

Comments on Faculty Participation (Required; not applicable for mid- and senior-career awards):

- Not clear

Comments on Duration (Required):

- Not clear if it meets 8 hrs. requirement

Comments on Frequency (Required):

- Acceptable

Select Agents: Not Applicable (No Select Agents)

Budget and Period of Support: Recommend as Requested

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html>. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

Subcommittee I - Transition to Independence National Cancer Institute Initial Review Group NATIONAL CANCER INSTITUTE NCI-I June 17, 2014 - June 18, 2014

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* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.

1K01CA190559-01A1 Carson, Tiffany

TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH UNACCEPTABLE

RESUME AND SUMMARY OF DISCUSSION: In this resubmitted application for the NCI mentored Research Scientist Development Award to Promote Diversity (K01), Dr. Carson proposes to elucidate potential relationships between demographic, biological, and behavioral factors in order to explain differences in colorectal cancer risk among black and white women living in Birmingham, Alabama. Dr. Carson is an excellent and well-trained candidate, a recipient of numerous awards and fellowships, including a competitive F31 award from the NIH. She has an extensive publication track record. The application is supported by uniformly strong and enthusiastic letters of reference. Dr. Carson has thoughtfully addressed weaknesses identified in the previous review, as a result the application has been significantly improved in all aspects. The career development plan is in general well written and comprehensive. The candidate will be supported by an outstanding team of established investigators with all the necessary expertise required for the successful completion of the proposed studies. The environment is exceptional for the proposed studies with all the required resources available to the candidate. The institutional commitment to the candidate is very strong. The research plan addresses potentially impactful question and is in general well described. However, several weaknesses still remain in the application, predominantly in the research plan. For example, some concerns regarding the proposed sample size and statistical analyses were expressed by the review panel. The proposed sample size may be too small to address the proposed hypotheses, and the statistical analyses are relatively simple and do not take advantage of the wealth of information in the data to address the hypotheses. In addition, some of the potential confounding factors are not adequately addressed.

DESCRIPTION (provided by applicant): Dr. Tiffany Carson is an applied epidemiologist with a background in studying health disparities of black and white women. Dr. Carson's early work focused on behaviors related to diet, physical activity, obesity and related health outcomes. Recently, Dr. Carson has focused on applying her research efforts to better understand cancer disparities of black and white women. Dr. Carson's overarching career goal is to become an independently funded investigator and develop evidence-based bio-behavioral interventions to reduce cancer health disparities. To that end, this application proposes a rigorous research project and training plan focused on investigating the microbiota as a novel potential contributor to colorectal cancer (CRC) disparities between black and white women. CRC is the 2nd leading cause of cancer death in the United States accounting for 9% of cancer deaths. Known risk factors for CRC include increasing age, male sex, family history, inflammatory bowel disease, type 2 diabetes, alcohol consumption, smoking, physical inactivity, high consumption of red and processed meats and high fat diet, and obesity. Among women, even after accounting for differences in the distribution of risk factors, black women remain at 48% greater risk for CRC than white women. There is a growing body of research suggesting that the influence of diet on CRC risk is mediated through the microbiota and that microbial perturbations caused by diet, lifestyle, and antibiotics can lead to increased risk for CRC and other chronic diseases. Stress is one factor that has been shown to lead to alterations in the microbiota. Our research has shown that black women report moderate to high stress levels and additional published literature indicates that black women report higher stress levels than their white counterparts. These observations have led to our hypothesis that a greater proportion of black women have a perturbed microbiota as a result of higher stress levels compared to white women, putting black women at greater risk for developing CRC. In the present proposal, we plan to explore this hypothesis employing a case control study design comparing the following groups: 1) black and white women with incident CRC from the Kirklin Clinic at UAB and 2) age-matched cancer-free black and white female community controls. Specifically, we will first characterize the oral and gut microbiota of black and white women with CRC and compare by race with particular focus on microbes known to be either positively or negatively associated with CRC. Because all cases will have CRC, we hypothesize that there will be no significant

racial differences in the microbiota or other known risk factors for CRC such as diet. In contrast, when we repeat this experiment in cancer-free black and white female community controls, we expect to observe racial differences in the microbiota, with black women having less health-promoting bacteria and more pathogenic bacteria than white women, which would put black women at increased risk for CRC. We anticipate that a greater proportion of black females in the control group will have microbiota that resembles the microbiota of participants with CRC. Additionally, if our hypothesis is supported, psychological stress will be inversely associated with health-promoting bacteria and positively associated with pathogenic bacteria. Our findings will provide insight into how lifestyle factors that have not been fully explored to date such as stress may be associated with risk for CRC as a result of how stress perturbs the microbiota. If we determine that stress contributes to CRC risk via microbial perturbations, future bio-behavioral interventions that incorporate stress management and dietary/supplemental recommendations to promote mucosal health, and therefore reduce CRC risk, can be developed and implemented which could lead to diminished health care costs related to diagnosis and treatment and reduce CRC disparities between black and white women. In addition to providing valuable data, the proposed research project will also provide the opportunity for the additional training needed for Dr. Carson's development as an independently funded bio-behavioral cancer disparities researcher. Dr. Carson will engage in an intensive, structured training experience to develop expertise by completing the following: 1) Training in the recruitment of racially diverse clinical and community populations for bio-specimen and bio-banking research, 2) Obtaining hands-on and didactic training in bioinformatics techniques, and 3) Improving professional skills such as team science, networking, grant writing, mentoring, and high-impact publications. Under the guidance of an esteemed panel of mentors and collaborators and the high quality research and training environment that the University of Alabama at Birmingham offers, Dr. Carson's research and training experiences will make a significant contribution to the scientific community and Dr. Carson's overall career development.

PUBLIC HEALTH RELEVANCE: Colorectal cancer is the second leading cause of cancer death in the USA, and the disparity between black and white women remains unexplained. This study will evaluate novel biological, behavioral and environmental factors that may contribute to this disparity. Findings from this study will provide insight into whether stress and the microbiota contribute to risk for CRC and possibly lead to innovative interventions to reduce CRC incidence and disparities.

The written critiques of individual reviewers are provided in essentially unedited form in this section. Please note that these critiques and criteria scores were prepared prior to the meeting and may not have been revised subsequent to any discussions at the review meeting. The "Resume and Summary of Discussion" section above summarizes the final opinions of the committee.

CRITIQUE 1:

Candidate:

Career Development Plan/Career Goals /Plan to Provide Mentoring:

Research Plan:

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Environment and Institutional Commitment to the Candidate:

Overall Impact:

This revised K01 application to Promote Diversity is from Tiffany LaShaun Carson, Ph.D., an epidemiologist, who is currently an Assistant Professor in the Department of Preventive Medicine, University of Alabama (UAB), and who also holds the post of Associate Scientist at the Comprehensive

Cancer Center. Proposed studies are designed to test the hypothesis that differences in gut microbiota of generally healthy black and white women contribute to differences in risk factor for colorectal cancer (CRC). The proposed studies are focused on collection of biospecimens and analysis of survey data to evaluate whether the relationship between the gut microbiota and CRC could partly be attributable to stress, and whether this could partly be explained for the racial disparity in CRC observed between African Americans and non-Hispanic White women. Strengths of the proposal are that **(a)** it is well-written on a subject matter that has not been investigated in detail, **(b)** the hypothesis is novel, **(c)** the current version is greatly improved by addressing the concerns raised by the previous study section and **(d)** the candidate provides detailed career development plan, research plan and strong supportive data. Proposed studies, if carefully carried out, are likely to generate some interesting and meaningful information. Weakness are that **(i)** in general, the proposal, as presented, is somewhat descriptive in nature, and **(ii)** little information is provided about the underlying regulatory mechanisms for the gut microbiota-mediated changes in CRC and also the disparity in CRC observed between African American and Non-Hispanic White women. Despite these shortcomings strengths of the application outweigh weaknesses and the application is likely to have very good impact in the field.

1. Candidate:

Strengths

- Well-trained investigator, who possesses the necessary experience and expertise to carry out the proposed studies.
- Authored 15 manuscripts.
- Recipient of pre-doctoral fellowship from the NIH/NIDDK (Ruth Kirschstein National Research Service Award) in 2010.

Weaknesses

- No significant weaknesses noted.

2. Career Development Plan/Career Goals & Objectives:

Strengths

- Detailed training plan is provided and also the plan for R01 submission.

Weaknesses

- No significant weaknesses noted.

3. Research Plan:

Strengths

- The subject matter of the proposal is interesting, which has not been investigated in detail earlier
- Novel hypothesis
- Research plan is well described

Weaknesses

- In general, the proposal, as presented, is descriptive in nature.

- The application does not adequately describe future plans to elucidate the underlying regulatory mechanisms for the gut microbiota-mediated differences in CRC between African American and Non-Hispanic women.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- Excellent collaborators and supporting letters.

Weaknesses

- No weaknesses noted

5. Environment and Institutional Commitment to the Candidate:

Strengths

- Excellent training and institutional support.
- Promoted to the rank of Assistant Professor.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Including ages < 21 justified scientifically

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Training in the Responsible Conduct of Research:

Unacceptable. Adequate details not provided.

Format:

- acceptable

Subject Matter:

- not clear

Faculty Participation:

- not clear

Duration:

- not clear if 8 hours requirement is met

Frequency:

- not clear

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2:

Candidate:

Career Development Plan/Career Goals /Plan to Provide Mentoring:

Research Plan:

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Environment and Institutional Commitment to the Candidate:

Overall impact

This is a resubmission from an epidemiologist, Dr. Carson, who is trained in biology and is now an assistant professor at UAB. This award would allow her to transition to independence to continue to pursue her research interests in behavioral research, biomarkers, and cancer risk. Mentors are appropriate and enthusiastic. The research area is of great interest at this time, and although the proposed study is small it is likely to add to the current understanding of the microbiome. The main drawback is the complexity of the research plan and the challenges of having multiple measures on a relatively small number of participants.

1. Candidate:

Strengths

- Dr. Carson is an epidemiologist who is an assistant professor at UAB, having completed her degree in 2010 and completed a post-doc in health behavior and health education at the University of Arkansas.
- The candidate has good training and experience in behavioral measures, minority health, weight loss interventions, and measures of stress but little work in cancer to date.
- She is interested in gaining further training in bio-banking, use of bioinformatics and other omics techniques.

Weaknesses

- None noted.

2. Career Development Plan/Career Goals & Objectives:

Strengths

- The training goals and specific plans are clearly described and cover a wide range of activities that should serve the candidate well.
- Training in recruiting racially diverse populations, and in bioinformatics and the microbiome, is directly related to the research project.

- The plans include a course in cancer epidemiology as well as bioethics.

Weaknesses

- None noted.

3. Research Plan:

Strengths:

- Interesting research questions linking stress, the microbiome, and colorectal cancer.
- Cases will be enrolled and measurements taken before treatment.
- The study will evaluate the prevalence of 8 taxa previously found to be associated with risk of CRC.
- Both self-report and salivary cortisol will be used to measure stress.
- Information about other potentially important variables will be collected by interviews.
- The applicant and her mentors have completed a variety of studies that indicate that the study is feasible, particularly with regard to recruitment of controls through the Deep South Network.

Weaknesses

- The sample is relatively small (84 in each cell – black, white, case, control); the project will be largely exploratory in nature
- As Dr. Carson acknowledges, it will be difficult to account for the possible confounding variables related to both CRC and the microbiome.
- It appears that general measures of the microbiome will be obtained but the analysis plan involves mainly the candidate taxa. It is not clear whether other aspects of the microbiome (e.g., overall diversity) will also be evaluated in addition to the candidate taxa.
- It will be quite a challenge to recruit newly diagnosed patients with CRC before surgery.
- What will be done with blood samples? Serum CRP analysis is mentioned in a couple of places but how this will be used is not adequately described.
- Measurement of toxins and air quality according to zip code seems beyond the scope of the study.
- Use of several scales may be too burdensome for women particularly those with a new cancer diagnosis.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths:

- Dr. Baskin, primary mentor, is a psychologist at UAB whose research focus is on health disparities. She currently holds an R01 on weight loss in cancer survivors. This is an extension of their current mentoring relationship.
- Dr. Manne is trained in both biochemistry and bioinformatics and is the co-mentor. His expertise is in pathology, molecular biology, cancer genetics, and biomarkers of breast and colorectal cancer. He will advise on mucosal health. He is the PI of the U54 with Morehouse, Tuskegee and UAB cancer center.
- Dr. Casey Morrow is a microbiologist who is collaborating on a study of the oral microbiome within the supplement study on stress and weight loss.
- Other collaborators include those with expertise in psychology (Dr. Epel), bioinformatics (Dr. Lefkowitz), CRC (Dr. Cannon, oncologist/ surgeon), Bioethics (Dr. Sodeke), biostatistics (Dr. Cutter), and the microbiome laboratory (Dr. Morrow).

Weaknesses

- Dr. Baskin's main focus has not been in cancer.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- UAB is an excellent environment for the candidate and her proposed project; there is a large focus on research in minorities.
- Institutional commitment to the candidate is strong.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Including ages < 21 justified scientifically

Training in the Responsible Conduct of Research:

Unacceptable, not described in sufficient detail.

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3:

Candidate:

Career Development Plan/Career Goals /Plan to Provide Mentoring:

Research Plan:

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Environment and Institutional Commitment to the Candidate:

Overall Impact:

This is a resubmission of a K01 application to Promote Diversity. Dr. Tiffany Carson is an Epidemiologist in the Department of Preventive Medicine at the University of Alabama and her research focuses on examining the interaction between diet and the microbiota that determines the risk for CRC and the role stress may contribute to this interaction. Dr. Carson is an outstanding candidate who has assembled an excellent mentoring team and comprehensive training plan. She has been very responsive to reviewers' comments and concerns. She proposes research in an understudied area, using novel hypotheses.

1. Candidate:

Strengths

- Outstanding candidate with over 13 publications.
- Dr. Carson has an impressive research trajectory, which builds from her pre-doctoral F31 fellowship and she recently completed her post-doctoral fellowship (an NCI diversity supplement).

- Clarified reviewers' comments about her statistical training.

Weaknesses

- None noted.

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:

Strengths

- Dr. Carson was very responsive to reviewers' comments. Career Development Plan has been improved.

Weaknesses

- The use of bioinformatics is not clear.

3. Research Plan:

Strengths

- Dr. Carson was very responsive to reviewers' comments, including justifying the target sample of women only.
- Additionally, the proposed study highlights the need for research in the area of stress and microbiome research in a racially diverse population.

Weaknesses

- The use of bioinformatics was not clear in the proposed project.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- Dr. Carson included additional mentors in specific topic areas of microbiology, psychology and bioinformatics and strategically reduced the mentoring team.

Weaknesses

- None noted.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- University of Alabama at Birmingham is an excellent environment with the required resources, including letter of commitment and support from Dr. Morrow.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Including ages < 21 justified scientifically

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resubmission:

- Dr. Carson was very responsive to reviewers' comments.

Training in the Responsible Conduct of Research:

Acceptable

Format:

- Acceptable

Subject Matter:

- Acceptable

Faculty Participation:

- Acceptable

Duration:

- Acceptable

Frequency:

- Acceptable

Select Agents:

Not Applicable (No Select Agents)

Resource Sharing Plans:

Acceptable

Budget and Period of Support:

Recommend as Requested

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWER'S WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH: UNACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html>. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

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February 24, 2015 - February 25, 2015

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