First Name: Darren Last Name: Mays Institution: Georgetown University Medical Center, Lombardi Comprehensive Cancer Center Address 1: 3300 Whitehaven Street NW Address 2: Suite 4100 City: Washington State/Province: DC Country: USA Zip: 20007 Phone: 202-687-8937 Alternate Phone: Email: <u>dmm239@georgetown.edu</u>

Requirements to submit AOI:

A comprehensive review of previously published data has been completed.: Yes The specific aims are clear and focused.: Yes

The investigator has appropriate experience and expertise to develop the concept proposal; if not, has identified a mentor or senior co-investigator.: Yes

The investigator agrees to develop an initial draft of the concept proposal within 6 weeks of approval of the AOI and to finalize the concept proposal within 6 months.: Yes

Project Title: Locus of Control and Survivorship Care

Planned research population (eligibility criteria): The planned study population will consist of Childhood Cancer Survivor Study participants who took part in the 2001 Health Care Needs Survey (HCNS).

Proposed specific aims: Aim 1: Examine the relationship between health locus of control and health behavior outcomes, including tobacco and alcohol use and sun safety practices Aim 2: Determine whether health locus of control moderates the relationship between psychological distress and health behaviors among pediatric cancer survivors Aim 3: Characterize changes in pediatric cancer survivors' health locus of control over time and identify associations with demographic and clinical factors and health behavior outcomes

Will the project require non-CCSS funding to complete?: No

If yes, what would be the anticipated source(s) and timeline(s) for securing funding?: This project is being submitted in November 2012 in response to the Childhood Cancer Survivor Study Career Development Award Request for Proposals.

Does this project require contact of CCSS study subjects for . . .

Additional self-reported information: Yes

Biological Samples: No

Medical record data: No

If yes to any of the above, please briefly describe.: To accomplish Aim 3, we propose to work closely CCSS investigators and personnel to conduct follow-up data collection with the 2001

HCNS sample. In close collaboration with CCSS personnel, we will develop a detailed protocol to re-contact the 978 HCNS participants through the CCSS Coordinating Center at St. Jude Children's Research Hospital. Participants will be asked to complete a follow-up assessment of health locus of control and behavioral outcomes, including tobacco and alcohol use and sun safety behaviors.

What CCSS Working Group(s) would likely be involved? (Check all that apply)

Second Malignancy: Chronic Disease: Psychology / Neuropsychology: Primary Genetics: Cancer Control: Epidemiology / Biostatistics:

To describe the anticipated scope of the study, please indicate the specific CCSS data to be included as <u>outcome</u> (primary or secondary) or <u>correlative factors</u>. (Check all that apply)

Late mortality: Second Malignancy:

## Health Behaviors

Tobacco: Primary Alcohol: Primary Physical activity: Medical screening: Other: Primary If other, please specify: Sun safety practices

## Psychosocial

Insurance: Marriage: Correlative Factors Education: Correlative Factors Employment: Correlative Factors Other: If other, please specify:

## Medical conditions

Hearing/Vision/Speech: Hormonal systems: Heart and vascular: Respiratory: Digestive: Surgical procedures: Brain and nervous system: Other: If other, please specify:

Medications

Describe medications:

Pregnancy and offspring: Family History:

Psychologic/Quality of Life

BSI-18: Correlative Factors SF-36: CCSS-NCQ: PTS: PTG: Other: Primary,Correlative Factors If other, please specify: Health locus of control (outcome for Aim 3); cancer-specific distress items (correlative factors for Aim 2 analyses)

Chronic conditions (CTCAE v3): Health status:

Demographic

Age: Correlative Factors Race: Correlative Factors Sex: Correlative Factors Others: If others, please specify:

Cancer treatment

Chemotherapy: Correlative Factors Radiation therapy: Correlative Factors Surgery: Correlative Factors

Anticipated sources of statistical support

CCSS Statistical Center: Yes

Local institutional statistician: Yes

If local, please provide the name(s) and contact information of the statistician(s) to be involved.: As a Career Development Award, we plan to work with both the statisticians at the CCSS Statistical Center, and rely as well on local statistical support resources available through Lombardi Comprehensive Cancer Center. Our biostatistician is: George Luta, PhD, Assistant Professor of Biostatistics, Department of Biostatistics, Bioinformatics, and Biomathematics, Georgetown University Medical Center. <u>gl77@georgetown.edu</u>. Will this project utilize CCSS biologic samples?: No

If yes, which of the following?

Buccal cell DNA: Peripheral blood: Lymphoblastoid cell lines: Second malignancy pathology samples: Other requiring collection of samples: If other, please explain:

Other general comments: Dr. Mays is preparing this study in response to the CCSS Career Development Award Funding Opportunity Announcement. He has communicated with Kevin Krull, PhD, Chair of the Psychology Working Group, about the preliminary idea. Dr. Mays also has local GUMC mentors who will be involved in the project. We look forward to continuing to develop the concept throughout the career development award application process.