

Section: Contact Information

First Name : **James**
Last Name : **Bates**
Institution : **University of Florida**
Address 1 : **2000 SW Archer Road**
Address 2 :
City : **Gainesville**
State/Province/Region : **FL**
Country : **US**
Zip/Postal Code : **32608**
Phone Number : **1-315-529-2062**
Alternate Phone Number :
Email Address : bateja@shands.ufl.edu

Section: Project Requirements and Description

Group: 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 : **Influence of Radiotherapy Dose to Cardiac Substructures on Cardiac Risk in Long-Term Survivors of Childhood Cancer**

Planned research population (eligibility criteria) :

All patients from the original and expanded cohort (as well as their siblings for absolute risk calculations) who received treatment for a primary childhood malignancy of any type for whom cardiac dose reconstructions are available as well as those who received no cardiac radiotherapy. The sibling population may be used as well to generate absolute excess risk estimates.

Proposed specific aims :

1) Develop a heart phantom to include cardiac substructures (including, but not limited to, the left ventricle, right ventricle, left atrium, right atrium, valvular structures, and coronary arteries) such that mean and maximum doses can be calculated for those substructures.

2) Describe the dose-response relationship between radiation dose to specific substructures and specific CTCAE grade 3-5 cardiac toxicities. For example, we will aim to describe the relationship between doses to the valvular structures and valvular disease.

3) Generate a multivariate model to identify the most predictive radiation

dose/volume parameters for risk of overall and specific CTCAE grade 3-5 cardiac toxicities.

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? :

It will be significantly benefited by a Conquer Cancer Foundation Young Investigator Award; the award deadline is in late September 2018 with notification in the spring of 2019. The grant period would be July 2019 - June 2020.

Group: Does this project require contact of CCSS study subjects for:

Additional self-reported information : **No**

Biological samples : **No**

Medical record data : **No**

If yes to any of the above, please briefly describe. :

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

Second Malignancy :

Chronic Disease : **Primary**

Psychology / Neuropsychology :

Genetics :

Cancer Control :

Epidemiology / Biostatistics : **Secondary**

Section: Outcomes or Correlative Factors

Late mortality : **Primary**

Second Malignancy :

Group: Health Behaviors

Tobacco : **Correlative Factors**

Alcohol : **Correlative Factors**

Physical activity : **Correlative Factors**

Medical screening :

Other :

If other, please specify :

Group: Psychosocial

Insurance :

Marriage :

Education :

Employment :

Other :

If other, please specify :

Group: Medical Conditions

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

Group: Medications

Describe medications :

Group: Psychologic/Quality of Life

BSI-18 :
SF-36 :
CCSS-NCQ :
PTS :
PTG :
Other :
If other, please specify :

Group: Other

Pregnancy and offspring :
Family history : **Correlative Factors**
Chronic conditions (CTCAE v3) : **Primary**
Health status :

Group: Demographic

Age : **Correlative Factors**
Race : **Correlative Factors**
Sex : **Correlative Factors**
Other :
If other, please specify :

Group: Cancer treatment

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

Section: Anticipated Sources of Statistical Support

CCSS Statistical Center : **Yes**
Local institutional statistician :

If local, please provide the name(s) and contact information of the statistician(s) to be involved. :

Will this project utilize CCSS biologic samples? : **No**

If yes, which of the following? :

If other, please explain :

Section: Other General Comments

Other General Comments :

Dr. Rebecca Howell will be a co-primary investigator for this analysis. Additional mentorship will be provided from Dr. Louis “Sandy” Constine and Dr. Bradford Hoppe.

I agree to share this information with St. Jude : **Yes**