

Name: Jonathan Shoag
Institution: Case Western Reserve University School of Medicine
Address: Wolstein Research Bldg. 4541
Street Address Line 2: 2103 Cornell Rd
City: Cleveland
State: OH
Zip Code: 44106
Country: United States
Email Address: jxs218@case.edu
Phone Number: 216-337-1724
Alternate Phone Number:

Project Requirements and Description

Requirements to submit AOI:

	Yes
A comprehensive review of previously published data has been completed	✓
The specific aims are clear and focused	✓
The investigator has appropriate experience and expertise to develop the concept proposal; if not, has identified a mentor or senior co-investigator.	✓
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	✓

Project Title: Leveraging High-Fidelity Sequencing to Define the Impact of Chemotherapy on Mutation in Normal Cells

Planned research population: -Childhood cancer survivor with >50ng of DNA available (or equivalent volume of blood or buccal/saliva sample available)

-Non-hematologic malignancy

Proposed specific aims: 1. To define the differential impact of chemotherapy regimens on the somatic mutation rate of normal cells.

2. To determine whether the somatic mutation rate predicts the development of secondary malignancies in childhood cancer survivors.

3. To define exogenous and endogenous modifiers of chemotherapy induced somatic mutation.

Will the project require non-CCSS funding to complete?: Yes

If yes, what would be the anticipated source(s) and timeline(s) for securing funding?: R01 (October 5th application if possible; will proceed with the project with start-up , pilot and other funds if needed)

Does this project require contact of CCSS study subjects for:

	Yes	No
Additional self-reported information	-	✓
Biological samples		✓ -
Medical record data		✓ -

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

What CCSS Working Group(s) would likely be involved?:

	Primary	Secondary
Second Malignancy	-	✓
Chronic Disease	-	
Psychology/Neuropsychology	-	-
Genetics	✓	-
Cancer Control	-	
Epidemiology/Biostatistics	-	

Outcomes or Correlative Factors

Late Mortality and Second Malignancy:

	Primary	Secondary	Correlative Factors
Late Mortality	✓	-	-
Second Malignancy	✓	-	-

Health Behaviors:

	Primary	Secondary	Correlative Factors
Tobacco	-	-	✓
Alcohol	-	-	✓
Physical Activity	-	-	✓
Medical Screening	-	-	✓
Other	-	-	-

Psychosocial:

	Primary	Secondary	Correlative Factors
Insurance	-	-	✓
Marriage	-	-	✓
Education	-	-	✓
Employment	-	-	✓
Other	-	-	✓

If other, please specify:

Medical Conditions:

	Primary	Secondary	Correlative Factors
Hearing/Vision/Speech	-	-	✓
Hormonal Systems	-	-	✓
Heart and Vascular	-	✓	-
Respiratory	-	✓	-
Digestive	-	✓	-
Surgical Procedures	-	✓	-
Brain and Nervous System	-	✓	-
Other	-	-	-

If other, please specify:

Medications

Describe medications:

Psychologic/Quality of Life:

	Primary	Secondary	Correlative Factors
BSI-18	-	-	✓
SF-36	-	-	✓
CCSS-NCQ	-	-	✓
PTS	-	-	✓
PTG	-	-	✓
Other	-	-	-

If other, please specify:

Other:

	Primary	Secondary	Correlative Factors
Pregnancy and Offspring	-	✓	-
Family History	-	✓	-
Chronic Conditions (CTCAE v3)	-	✓	-
Health Status	✓	-	-

Demographic:

	Primary	Secondary	Correlative Factors
Age	✓	-	-
Race	-	✓	-
Sex	-	✓	-
Other	-	✓	-

If other, please specify:

Cancer Treatment:

	Correlative Factors
Chemotherapy	✓
Radiation Therapy	✓
Surgery	✓

Anticipated Sources of Statistical Support:

	Yes	No
CCSS Statistical Center	✓	-
Local Institutional Statistician	✓	-

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

Will this project utilize CCSS biologic samples?: Yes

If yes, which of the following?: Buccal cell DNA and Peripheral blood

If other, please explain:

Other General Comments

General comments: