

Section: Contact Information

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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 : **Comprehensive comparative analysis of chronic health conditions, health status, social outcomes and mortality in patients with rhabdomyosarcoma by treatment era**

Planned research population (eligibility criteria) :

Rhabdomyosarcoma patients eligible for the CCSS cohort from 1970-1999

Proposed specific aims :

1) To compare the burden of chronic health conditions and overall health status in childhood survivors of rhabdomyosarcoma treated between 1970-1991 (IRS-I to IRS-III) and those treated between 1991-1999 (IRS-IV). 2) To compare the impact of chronic conditions and health status on social outcomes in the above two cohorts. 3) To compare cumulative mortality and standardized mortality ratios (all cause and cause-specific) between the two cohorts and 4) To determine the impact of changes in therapy over time on chronic health conditions and mortality if significant differences are elicited between the two cohorts.

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? :

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 : **Secondary**

Epidemiology / Biostatistics : **Secondary**

Section: Outcomes or Correlative Factors

Late mortality : **Primary**

Second Malignancy : **Secondary**

Group: Health Behaviors

Tobacco :

Alcohol :

Physical activity : **Correlative Factors**

Medical screening : **Correlative Factors**

Other :

If other, please specify :

Group: Psychosocial

Insurance : **Correlative Factors**

Marriage : **Primary**

Education : **Primary**

Employment : **Primary**

Other :

If other, please specify :

Group: Medical Conditions

Hearing/Vision/Speech : **Secondary**

Hormonal systems : **Secondary**

Heart and vascular : **Secondary**

Respiratory : **Secondary**

Digestive : **Secondary**

Surgical procedures : **Secondary**

Brain and nervous system : **Secondary**

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 : **Secondary**

Family history : **Correlative Factors**

Chronic conditions (CTCAE v3) : **Primary**

Health status : **Primary**

Group: Demographic

Age : **Secondary**

Race : **Secondary**

Sex : **Secondary**

Other :

If other, please specify :

Group: Cancer treatment

Chemotherapy : **Correlative Factors**

Radiation therapy : **Correlative Factors**

Surgery : **Correlative Factors**

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 :

The objectives of this AOI have been reviewed and approved by Dr. Ness and Dr. Marina who have kindly agreed to mentor me on this project. Upon discussions with them and Dr. Douglas Hawkins, we have chosen to compare cohorts of RMS treated on IRS-I to III versus those treated on IRS-IV. The first Cohort (IRS-I to III)

ran between 1972-1991. The second cohort (IRS-IV) ran between 1991-1997. We have included patients between 1997-1999 in cohort 2 as IRS V did not open until 1999 for majority of patients except low risk. We have also included 1970-1972 in cohort I as we believe the treatment of those patients was somewhat similar to IRS-I. Thank you for reviewing our AOI.