

## **Section: Contact Information**

First Name : **Michael**

Last Name : **Roth**

Institution : **Children's Hospital at Montefiore/ Albert Einstein College of Medicine**

Address 1 : **3415 Bainbridge Avenue**

Address 2 :

City : **Bronx**

State/Province/Region : **NY**

Country : **US**

Zip/Postal Code : **10467**

Phone Number : **718 741-2342**

Alternate Phone Number :

Email Address : [mroth@montefiore.org](mailto:mroth@montefiore.org)

## **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 : **Health Related Outcomes for Children and Adolescents Diagnosed with Chronic Myeloid Leukemia**

Planned research population (eligibility criteria) :

**Children and adolescents diagnosed with chronic myeloid leukemia prior to age 18.**

Proposed specific aims :

**1. To describe the health-related quality of life (HRQOL) and medical late effects in a large cohort of children and adolescents treated for CML (Chronic Myeloid Leukemia).**

**2. To compare the HRQOL and medical late effects in children and adolescents with CML treated in the Tyrosine Kinase Inhibitor (TKI) era (after the year 2001) versus children and adolescents with CML treated in the pre-TKI era (prior to the year 2001).**

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? :

**A proposal has been submitted to Novartis for potential funding. We anticipate funding to commence 1/2017. Other potential funding sources include the St. Baldrick's Foundation.**

***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 : **Secondary**

Chronic Disease : **Primary**

Psychology / Neuropsychology : **Secondary**

Genetics :

Cancer Control :

Epidemiology / Biostatistics :

**Section: Outcomes or Correlative Factors**

Late mortality : **Secondary**

Second Malignancy : **Secondary**

***Group: Health Behaviors***

Tobacco : **Correlative Factors**

Alcohol : **Correlative Factors**

Physical activity : **Secondary**

Medical screening : **Correlative Factors**

Other :

If other, please specify :

***Group: Psychosocial***

Insurance : **Secondary**

Marriage : **Secondary**

Education : **Secondary**

Employment : **Secondary**

Other :

If other, please specify :

***Group: Medical Conditions***

Hearing/Vision/Speech : **Primary**

Hormonal systems : **Primary**

Heart and vascular : **Primary**

Respiratory : **Primary**

Digestive : **Primary**

Surgical procedures : **Primary**

Brain and nervous system : **Primary**

Other : **Primary**

If other, please specify : **Growth**

**Group: Medications**

Describe medications :

**Group: Psychologic/Quality of Life**

BSI-18 : **Secondary**

SF-36 : **Secondary**

CCSS-NCQ :

PTS : **Secondary**

PTG :

Other :

If other, please specify :

**Group: Other**

Pregnancy and offspring : **Primary**

Family history : **Correlative Factors**

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

Health status : **Primary**

**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 : **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 :

**Three patient cohorts will be utilized in this study: (1) patients with CML who have**

enrolled on the CCSS, (2) healthy siblings enrolled on the CCSS and (3) patients with CML enrolled on the COG ACCRN07 study. Survey responses from patients treated in the TKI era have not yet been collected and this patient cohort will be offered participation on the current study. All patients with CML enrolled on ACCRN who eligible for participation in the patient/parent proxy survey will be identified, contacted, and asked to complete the survey tool.