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: Advancing Skin Cancer Screening Practices among Survivors of Childhood Cancer and Skin Cancer (ASK2)

Planned research population (eligibility criteria): Members of the LTFU cohort who have been diagnosed with any type of skin cancer since the inception of the study

Proposed specific aims: Specific Aims: Reducing Skin Cancer Risk in Childhood Cancer Survivors

There are currently more than 400,000 Americans who are long-term survivors of childhood and adolescent cancer. While these groups have greatly benefited from recent medical advances, primarily increasing overall survival rates, treatment advances have come at a cost. Childhood radiation therapy has caused survivors to be at extremely high risk for non-melanoma skin cancer (NMSC) and increased risk of melanoma. The rate of new skin cancers among childhood cancer survivors in the Childhood Cancer Survivor Study (CCSS) more than tripled between 2001 and 2010; these survivors are diagnosed at an average age of 33, some 30 years earlier than in the non-radiation exposed population. Recurrence rates are high- 712 CCSS participants were diagnosed with 1983 skin cancers between 1987-2008, nearly three skin cancers per individual.
Early detection is crucial to reduce the morbidity caused by NMSCs and the morbidity and mortality incurred due to melanoma. Both the National Cancer Institute and Children’s Oncology Group Guidelines recommend regular skin self-checks and annual clinical skin exams for survivors. The extraordinarily high rates of skin cancer, multiple recurrences, and new primary tumors in this young population point to the strong need to increase rates of skin self-examination and physician skin cancer examinations. Most recently, a study of 887 basal cell cancer (BCC) patients found larger BCCs among patients who did not report a physician skin check. Both patient and provider action are needed to detect and treat early skin cancers and to find new solutions to ensure expedited follow-up care and treatment, especially among those who live where they have little access to dermatologists.

Participants previously treated with radiation and no prior skin cancer history are currently being recruited into our NIH-funded R01 entitled Advancing Survivors’ Knowledge (ASK) about Skin Cancer. To date (11/18/15), 430 participants have been recruited to the study and we are on track to realizing our stated recruitment goals. From our outreach for the ASK study, we have discovered an additional 300 participants with a report of a new history of skin cancer, thus totaling at least 1,000 skin cancer survivors in the CCSS cohort. Of these 300 new cases, more than 60% report sub-optimal practices of both the recommended monthly skin self-exam and receipt of a routine physician skin cancer exam.

New interventions are required to optimize skin cancer screening for this young and dispersed population now faced with their first or subsequent skin cancer. In our proposed new study entitled Advancing Skin Cancer Screening Practices among Survivors of Childhood Cancer and Skin Cancer (ASK2), we will build on utilization of the web, text message, and print materials for all participants in the current ASK study. In ASK2, we will randomize half of the CCSS participants with a diagnosis of skin cancer to additional pro-active telephone calls designed to enhance rates of skin self-exam, request physician examinations, and provide assistance in participant use of dermoscopy, a technique that holds promise for earlier diagnosis and less costly follow-up.

Our specific aims are to:

Specific Aim 1: Among 400 LTFU patients with skin cancer, determine the impact of a Patient Activation and Education intervention (PAE) with and without pro-active telephone calls and dermoscopy (PAE + TC + TD) on skin cancer early detection practices measured at 12 and 18 months:
Hypothesis 1.1: Compared to PAE, participants randomized to the addition of pro-active telephone calls and teledermatology (PAE + TC + TD) will report higher rates of: (1) thorough skin self-exams and 2) full-body physician skin cancer exams;

Specific Aim 2: Determine the impact of the intervention on time to diagnosis
Hypothesis 1.1: Compared to PAE, participants in PAE + TC + TD will have a shorter time interval between discovery of a lesion and date of diagnosis;

Specific Aim 3: Estimate the cost and cost-effectiveness of the intervention as a secondary outcome

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? : We anticipate seeking NCI funding with a February or June 2016 application date

Group: Does this project require contact of CCSS study subjects for:
- Additional self-reported information : Yes
- Biological samples : No
- Medical record data : Yes

If yes to any of the above, please briefly describe. :
Should we receive funding, we will need to conduct multiple surveys of skin cancer patients.

We will also need to review pathology data to look for reports of second, third, and multiple skin cancers

Group: What CCSS Working Group(s) would likely be involved? (Check all that apply)
- Second Malignancy : Secondary
- Chronic Disease :
- Psychology / Neuropsychology :
- Genetics :
- Cancer Control : Primary
- Epidemiology / Biostatistics :

Section: Outcomes or Correlative Factors

Late mortality :
Second Malignancy : Secondary

Group: Health Behaviors

Tobacco :
Alcohol :
Physical activity :
Medical screening : Secondary
Other :
If other, please specify : We will want to examine rates of self-screening and physician screening off of the FU5 survey as well as review pathology data

Group: Psychosocial

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

**Group: Medical Conditions**
Hearing/Vision/Speech:
Hormonal systems:
Heart and vascular:
Respiratory:
Digestive:
Surgical procedures: Secondary
Brain and nervous system:
Other:
If other, please specify: *We will want to review the number of surgical procedures of the skin if such information is available.*

**Group: Medications**
Describe medications:

**Group: Psychologic/Quality of Life**
BSI-18:
SF-36: Primary
CCSS-NCQ:
PTS:
PTG:
Other:
If other, please specify:

**Group: Other**
Pregnancy and offspring:
Family history:
Chronic conditions (CTCAE v3):
Health status:

**Group: Demographic**
Age: Primary
Race: Primary
Sex: Primary
Other: Primary
If other, please specify: Education level

**Group: Cancer treatment**
Chemotherapy :
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 :