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 : **Intervening on reproductive health in young adult leukemia and lymphoma survivors**
Planned research population (eligibility criteria) :
Most young leukemia and lymphoma patients undergo chemotherapy, surgery and/or radiation, treatments that can impair ovarian function and result in significant late effects related to reproductive health. Our prior work shows high reproductive concerns, including concerns about fertility and the health of their offspring, and low rates of using highly effective methods of contraception in this population. These reproductive health issues negatively impact quality of life in survivorship. Scientific research and professional societies have identified reproductive health risks and clinical strategies to manage them, but data are dispersed and not readily available to young adult survivors.

The project will test an online reproductive health survivorship care plan (SCPR) targeting reproductive-aged female leukemia and lymphoma survivors. This intervention will be app- and web-based to deliver education and self-management materials to improve fertility concerns, offspring health concerns, and contraception in this population. This proposal leverages CCSS's large cohort of engaged survivors, well-characterized treatment exposures, and development of a mobile health platform to test the effectiveness of using

mHealth technology to deliver health information to young adult cancer survivors

The SCPR intervention was developed in the following manner. We conducted systematic reviews and searched professional society guidelines for up-to-date evidence on fertility potential, offspring health and cancer risk, and contraception in female, reproductive-aged leukemia and lymphoma survivors. We then summarized current evidence and recommendations on these 3 needs in a paper prototype. For each reproductive health need, the prototype included: 1) a 1- or 2-page survivorship care plan framed in a question and answer format; 2) a more detailed summary of the results of the systematic review, including planned hyperlinks to primary research articles; 3) curated web-based resources for survivors and healthcare providers on the topic; 4) a description of relevant clinical guidelines and planned hyperlinks to them. The prototype is undergoing focus group feedback from reproductive-aged leukemia and lymphoma survivors (summer, 2017).
For the clinical trial to test the SCPR, we will recruit 425 female young adult cancer survivors of leukemia and lymphoma who have completed primary cancer treatment and have a reproductive health need.

Inclusion criteria are:
- **Female**
- **Current ages 18-40 at study enrollment**
- **Age < 21 at cancer diagnosis**
- **History of leukemia or lymphoma**
- **No secondary malignancy**
- **Able to read English**
- **Able to consent to the study**
- **Access to a smartphone and Internet connection**
- **Presence of at least one of the following reproductive health issues:**
  - **Desires future fertility**
  - **At risk of unintended pregnancy**

Proposed specific aims :
Aim 1: To determine the efficacy of a web-based, tailored reproductive health survivorship care plan (SCPR) in improving fertility concerns, offspring health concerns, and contraception in female young adult leukemia and lymphoma survivors.

Hypothesis 1: Survivors who receive the tailored SCPR will have improved fertility concerns, offspring health concerns and contraception compared to survivors who do not receive the intervention.

Aim 2: To test if receipt of a web-based, tailored reproductive health survivorship care plan improves female young adult leukemia and lymphoma survivors' self-efficacy for managing fertility concerns, offspring health concerns and contraception needs.

Hypothesis 2: Survivors who receive the tailored SCPR will report improved self-efficacy in managing these reproductive health issues, compared to survivors who do not receive the intervention. Those receiving the intervention will have more knowledge of types of healthcare providers to seek for fertility, pregnancy and complex contraception counseling.

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? : **NIH R01 application (October 2017 submission, goal start summer 2018)**

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. :

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

Second Malignancy :

Chronic Disease : **Secondary**

Psychology / Neuropsychology : **Secondary**

Genetics :

Cancer Control : **Primary**

Epidemiology / Biostatistics :

Section: Outcomes or Correlative Factors

Late mortality : **Correlative Factors**

Second Malignancy : **Correlative Factors**

Group: Health Behaviors

Tobacco : **Correlative Factors**

Alcohol : **Correlative Factors**

Physical activity :

Medical screening : **Correlative Factors**

Other :

If other, please specify :

Group: Psychosocial

Insurance : **Correlative Factors**

Marriage : **Correlative Factors**

Education : **Correlative Factors**

Employment : **Correlative Factors**

Other :

If other, please specify :

Group: Medical Conditions

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

Group: Medications

Describe medications :

Group: Psychologic/Quality of Life

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

Group: Other

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

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 :

Local institutional statistician : **Yes**

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

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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 :

In addition to Irene Su, MD MSCE (UC San Diego) and Loki Natarajan PhD (UC San Diego), Saro Armenian, DO MPH (City of Hope) and Ksenya Shliakhsitsava, MD (Postodoctoral fellow, peds heme onc, Rady Children's and UC San Diego) are co-investigators on this project.