First Name: Lyn Last Name: Balsamo Institution: Yale University Address 1: 333 Cedar St. Address 2: LMP 2073 City: New Haven State/Province: CT Country: USA Zip: 06520 Phone: 203 785 4640 Alternate Phone: Email: <u>lyn.balsamo@yale.edu</u>

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: A Pilot Study to Investigate Stimulants to Improve Neurocogntive Impairment in Adult Survivors of Childhood Cancer

Planned research population (eligibility criteria): CCSS participants with scores on the NCQ in a low functioning range (ie, with impairment) on the task efficiency and/or memory domains. Impairment was defined as Tscore of 63 or higher, approximately corresponding to the worst 10% range of siblings' scores.

Proposed specific aims: 1) To determine if a stimulant intervention is feasible in a pilot study of adult survivors of childhood cancer with neurocognitive impairment as measured by participation rates, perceived burden of the intervention, study completion rates, and safety (i.e. insomnia, tachycardia, hypertension, behavior changes) 2) To collect prelinary data regarding the efficacy of a stimulant intervention in childhood cancer survivors with neurocognitive impairment in terms of improving working memory, attention, and processing speed.

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?: Plan to apply for the Childhood Cancer Survivor Study Career Development Award

Does this project require contact of CCSS study subjects for . . .

Additional self-reported information: Yes Biological Samples: Yes Medical record data: Yes If yes to any of the above, please briefly describe.: Blood pressure, Heart rate, updated cardiac history as well as baseline and f/u computer-based neuropsychological evaluation

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

Second Malignancy: Chronic Disease: Psychology / Neuropsychology: Primary Genetics: Cancer Control: Epidemiology / Biostatistics:

To describe the anticipated scope of the study, please indicate the specific CCSS data to be included as <u>outcome</u> (primary or secondary) or <u>correlative factors</u>. (Check all that apply)

Late mortality: Second Malignancy:

Health Behaviors

Tobacco: Alcohol: Physical activity: Medical screening: Other: If other, please specify:

Psychosocial

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

Medical conditions

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

Medications

Describe medications:

Pregnancy and offspring: Family History:

Psychologic/Quality of Life

BSI-18: SF-36: CCSS-NCQ: PTS: PTG: Other: If other, please specify: Neuropsychological functioning as measured by computer-based COG state

Chronic conditions (CTCAE v3): Health status:

Demographic

Age: Race: Sex: Others: If others, please specify:

Cancer treatment

Chemotherapy: Radiation therapy: Surgery:

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?

Buccal cell DNA: Peripheral blood: Lymphoblastoid cell lines: Second malignancy pathology samples: Other requiring collection of samples: If other, please explain:

Other general comments: If not successful in application for Childhood Cancer Survivor Study Career Development Award, will plan to apply to other external funding sources.