Received 10/14/08
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Project Title Investigating the Needs of Childhood Cancer Survivors: Understanding Residual Treatment Effects (INSURE)
Planned research population (eligibility criteria) CCSS active participants who: 1)Are age 25 years and older on 07/01/ 2009 2)Were NOT treated at St. Jude Children's Research Hospital for their pediatric malignancy 3)Have a history of successful self-report completion of the CCSS Follow-Up Surveys AND St. Jude Lifetime Cohort participants who: 1)Are age 25 years and older on 07/01/2009 2)Successfully completed the self-report St. Jude Lifetime Baseline questionnaire
Proposed specific aims 1)Examine the construct validity, short-term stability, and internal consistency (including item-response theory) of the multifactorial Childhood Cancer Survivors' Unmet Needs and Life Quality Assessment; 2)Oversample minority and rural-residing survivors in order to: a) secure a more representative sample of childhood cancer survivors; and, b) inform strata selection in a longitudinal study of unmet needs and life quality in childhood cancer survivors; 3)Describe the unmet needs and important covariates in two separate stratified random samples of childhood cancer survivors; 4)Evaluate the sample selection methods, length of time to complete recruitment, and response rates in each of the study samples.
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? An R21 (feasibility) application will be submitted to the NCI Office of Cancer Survivorship in February, 2009.

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

Additional self-reported information Yes
Biological Samples No
Medical record data No
If yes to any of the above, please briefly describe. CCSS participants will be asked to complete a comprehensive needs assessment survey (approximately 160 short Likert format items) and an accompanying process evaluation (approximately 6 short answer responses). The survey will take approximately 45 minutes to complete; participants will be compensated $25 for their time.

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

Second Malignancy
Primary - No Secondary - No

Chronic Disease
Primary - No Secondary - Yes

Reproductive
Primary - No Secondary - No

Neurologic
Primary - No Secondary - No

Psychology / Neuropsychology
Primary - No Secondary - No

Genetics
Primary - No Secondary - No

Cancer Control
Primary - Yes Secondary - No

Epidemiology / Biostatistics
Primary - No Secondary - No

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

Late mortality
Primary - No Secondary - No Correlative Factors - No

Second Malignancy
Primary - No Secondary - No Correlative Factors - No

Health Behaviors

Tobacco
Primary - No Secondary - No Correlative Factors - No

Alcohol
Primary - No Secondary - No Correlative Factors - No

Physical activity
Primary - No Secondary - No Correlative Factors - No

Medical screening
Primary - No Secondary - No Correlative Factors - No

Other
Primary - No Secondary - No Correlative Factors - No

If other, please specify None for the feasibility study

Psychosocial

Insurance
Primary - No Secondary - No Correlative Factors - No

Marriage
Primary - No Secondary - No Correlative Factors - No

Education
Primary - No Secondary - No Correlative Factors - No

Employment
Primary - No Secondary - No Correlative Factors - No

Other
Primary - No Secondary - No Correlative Factors - No

If other, please specify None for the feasibility study

Medical conditions

Hearing/Vision/Speech
Primary - No Secondary - No Correlative Factors - No

Hormonal systems
Primary - No Secondary - No Correlative Factors - No

Heart and vascular
Primary - No Secondary - No Correlative Factors - No

Respiratory
Primary - No Secondary - No Correlative Factors - No

Digestive
Primary - No Secondary - No Correlative Factors - No

Surgical procedures
Primary - No Secondary - No Correlative Factors - No

Brain and nervous system
Primary - No Secondary - No Correlative Factors - No

Other
Primary - No Secondary - No Correlative Factors - No

If other, please specify None for the feasibility study

Medications

Describe medications

Pregnancy and offspring
Primary - No Secondary - No Correlative Factors - No

Family History
Primary - No Secondary - No Correlative Factors - No

Psychologic/Quality of Life

BSI-18
Primary - No Secondary - No Correlative Factors - No

SF-36

Primary - No | Secondary - No | Correlative Factors - No

CCSS-NCQ
Primary - No | Secondary - No | Correlative Factors - No

PTS
Primary - No | Secondary - No | Correlative Factors - No

PTG
Primary - No | Secondary - No | Correlative Factors - No

Other
Primary - No | Secondary - No | Correlative Factors - No

If other, please specify None for the feasibility study

Chronic conditions (CTCAE v3)
Primary - No | Secondary - No | Correlative Factors - No

Health status
Primary - No | Secondary - No | Correlative Factors - No

Demographic

Age
Primary - Yes | Secondary - No | Correlative Factors - No

Race
Primary - Yes | Secondary - No | Correlative Factors - No

Sex
Primary - Yes | Secondary - No | Correlative Factors - No

Others
Primary - Yes | Secondary - No | Correlative Factors - No

If others, please specify Age, race, gender, diagnosis, time since diagnosis, age at diagnosis, and residence category (urban, suburban, rural) will be used to inform study eligibility and subsequently stratification of the study sample.

Cancer treatment

Chemotherapy
Correlative Factors - No

Radiation therapy
Correlative Factors - No

Surgery
Correlative Factors - No

Anticipated sources of statistical support

CCSS Statistical Center Yes
Local institutional statistician Yes
If local, please provide the name(s) and contact information of the statistician(s) to be involved. Dr. Srivastava of St. Jude Children's Research Hospital (Department of Biostatistics and Cancer Control Program) will be involved in determining the eligible sample. Dr. Leisenring, of the CCSS Statistical Center,is a co-investigator and will assume responsibility for overseeing all analyses proposed except for IRT. An outside consultant will advise on the IRT analysis.
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 This study will use existing CCSS data (age,race, diagnosis,age at diagnosis, time since diagnosis, residence locale (urban, suburban, rural) to inform sample eligibility and stratification only. All other data, will be derived from the study questionnaire and will include a comprehensive needs assessment survey, a process evaluation of survey participation, additional demographic characteristics (marital status, household membership, and two indicators of economic status [highest household education and household income]. Household membership information (number of adults and children living in the household and their relationship to the participant) will be collected as well as the number of ill children and adults requiring care. Employment status of the participant, occupation and number of hours worked each week will be assessed. These variables will be used to construct profiles of socioeconomic status. Insurance status, health care access, and regular source of primary care will be assessed using index items from the National Health Interview Survey. While many of these variables are available in the baseline and follow-up surveys, it is important that these data be collected concurrently with the primary needs assessment survey data in order to support the covariate analysis proposed. Drs. Robison and Oeffinger are currently in the process of constructing a separate data file that will include residence locale classification. This file will become part of the CCSS and St. Jude Lifetime data bases.