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Requirements to submit AOI:

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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

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Project Title: Detecting Germ Cell Mutation by Family DNA Sequencing  
Planned research population (eligibility criteria): Select up to 15 families, where one parent is a CCSS survivor, who has at least two biologic children, whose other parent(s) is/are available to participate. Selection criteria might include type of cancer, presence of some late effect, such as an additional malignancy, or a child with an apparently de novo genetic disorder, and type of therapy.  
Proposed specific aims: 1) After proving paternity, perform total genomic sequencing on each family member; 2) analyze any new sequence in the offspring to determine parent of origin and correlate the type of mutation with parental exposures.  
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 5, 2010, earliest funding July 2011. Reapplication may be necessary. Or, an institution may wish to apply intramural resources to speed up the project.

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

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Additional self-reported information: Yes  
Biological Samples: Yes  
Medical record data: Yes  
If yes to any of the above, please briefly describe.: Ideally, families would be examined for dysmorphisms, family history collected, blood drawn, and sperm sample requested.

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

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Second Malignancy:

Chronic Disease:

Psychology / Neuropsychology:

Genetics: Primary

Cancer Control:

Epidemiology / Biostatistics:

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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)

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Late mortality: Correlative Factors

Second Malignancy: Correlative Factors

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Health Behaviors

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Tobacco: Correlative Factors

Alcohol: Correlative Factors

Physical activity:

Medical screening:

Other:

If other, please specify:

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Psychosocial

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Insurance:

Marriage:

Education:

Employment:

Other:

If other, please specify:

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Medical conditions

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Hearing/Vision/Speech:

Hormonal systems: Correlative Factors

Heart and vascular:

Respiratory:

Digestive:

Surgical procedures:

Brain and nervous system:

Other:

If other, please specify:

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Medications

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Describe medications:

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Pregnancy and offspring: Primary  
Family History: Correlative Factors

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Psychologic/Quality of Life

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

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Chronic conditions (CTCAE v3):  
Health status:

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Demographic

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

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Cancer treatment

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Chemotherapy: Correlative Factors  
Radiation therapy: Correlative Factors  
Surgery: Correlative Factors

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Anticipated sources of statistical support

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CCSS Statistical Center:  
Local institutional statistician: Yes  
If local, please provide the name(s) and contact information of the statistician(s) to be involved.: A genomic biostatistician and bioinformatician to be named and paid on grant  
Will this project utilize CCSS biologic samples?: Yes

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If yes, which of the following?

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Buccal cell DNA:

Peripheral blood: Yes

Lymphoblastoid cell lines:

Second malignancy pathology samples:

Other requiring collection of samples: Yes

If other, please explain: New blood for DNA on survivors, offspring, and other biologic parent

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Other general comments: Genetics WG endorsed at June meeting, realizing this work is new territory for CCSS to engage family members of subjects other than siblings.