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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: NF1 and Second Malignant Neoplasms
Planned research population (eligibility criteria): i) CCSS participants (from baseline and expanded cohort) with NF1 (with and without SMNs) ii) CCSS participants (from baseline and expanded cohorts) without NF1 (with and without SMNs (n=1000) -frequency-matched to NF1 cohort
Proposed specific aims: to describe risk of SMNs and demographic/therapeutic factors associated with SMNs in individuals with NF1 and primary cancer
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?: Submission of SPORE (May, 2014)

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

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Additional self-reported information: No
Biological Samples: Yes
Medical record data: No
If yes to any of the above, please briefly describe.: germline DNA for confirming presence of NF1

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

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Second Malignancy: Primary
Chronic Disease:
Psychology / Neuropsychology:
Genetics: Secondary
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: Secondary
Second Malignancy: Primary

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Health Behaviors

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Tobacco: Secondary
Alcohol:
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:
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:

Pregnancy and offspring:
Family History:

Psychologic/Quality of Life

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

Chronic conditions (CTCAE v3):
Health status:

Demographic

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

Cancer treatment

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

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.:
Lennie Wong, PhD (flwonf@coh.org) Canlan Sun (casun@coh.org)
Will this project utilize CCSS biologic samples?: Yes

If yes, which of the following?

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

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Other general comments: