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Project Requirements and Description

Requirements to submit AOI

Requirements to submit AOI (all answers must be "yes" to proceed)

| | |
|---|-----|
| 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 Evaluating the Impact of Platinating Chemotherapy on Cardiovascular Toxicity among Childhood Cancer Survivors.

Planned research population (eligibility criteria)

This study will include five-year survivors of childhood cancer enrolled in the overall CCSS cohort (diagnosed between 1970 and 1999).

Proposed specific aims

Examine the association between platinum exposure and incident coronary artery disease/myocardial infarction (grade ≥ 3) in childhood cancer survivors.

Hypothesis: We hypothesize that exposure to platinum chemotherapy is independently associated with an increased risk of developing coronary artery disease/myocardial infarction among childhood cancer survivors.

Examine the association between platinum exposure and incident risk of cerebrovascular accidents (grade ≥ 2) in childhood cancer survivors.

Hypothesis: We hypothesize that exposure to platinum chemotherapy is independently associated with an increased risk of stroke among childhood cancer survivors.

Examine the association between platinum exposure and the incident hypertension (grade ≥ 2) in childhood cancer survivors.

Hypothesis: We hypothesize that exposure to platinum chemotherapy is independently associated with an increased risk of having high blood pressure among childhood cancer survivors.

Examine how each of the associations above (Aim 2.1, Aim 2.2 and 2.3) is affected by cardiovascular risk factors and sociodemographic characteristics.

Hypothesis: We hypothesize that the associations between platinum chemotherapy and cardiovascular outcomes persist after adjustment for pre-existing cardiovascular risk factors and sociodemographic characteristics.

Note: In the hypertension model (Aim 2.3), hypertension will not be included as a covariate. However, for the CAD/MI and stroke models (Aim 2.1 and Aim 2.2), hypertension will be included as a covariate.

Examine whether exercise intolerance, autonomic dysfunction as well as hypertension (if Aim 2.3 demonstrates an association) mediate the association between platinum exposure and cardiovascular disease incident in childhood cancer survivors.

Hypothesis: We hypothesize that hypertension, exercise intolerance, and autonomic dysfunction mediate the association between platinum exposure and the risk of major cardiovascular disease including CAD/MI grade ≥ 3 or cerebrovascular accident grade ≥ 2 among childhood cancer survivors.

Will the project require non-CCSS funding to complete?

No

If yes, what would be the anticipated source(s) and timeline(s) for securing funding?

Does this project require contact of CCSS study subjects for:

| | |
|---|----|
| Additional self-reported information | No |
| Biological samples | No |
| Medical record data | No |

If yes to any of the above, please briefly describe.

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

| | Primary | Secondary |
|----------------------------|---------|-----------|
| Second Malignancy | | |
| Chronic Disease | ✓ | |
| Psychology/Neuropsychology | | |
| Genetics | | |
| Cancer Control | | |
| Epidemiology/Biostatistics | | ✓ |

Outcomes or Correlative Factors

| | Primary | Secondary | Correlative Factors |
|-------------------|---------|-----------|---------------------|
| Late Mortality | ✓ | | |
| Second Malignancy | | | |

Health Behaviors

| | Primary | Secondary | Correlative Factors |
|-------------------|---------|-----------|---------------------|
| Tobacco | | | ✓ |
| Alcohol | | | ✓ |
| Physical Activity | | | ✓ |
| Medical Screening | | | ✓ |
| Other | | | ✓ |

If other, please specify

Psychosocial

| | Primary | Secondary | Correlative Factors |
|------------|---------|-----------|---------------------|
| Insurance | | | ✓ |
| Marriage | | | |
| Education | | | ✓ |
| Employment | | | |

| | Primary | Secondary | Correlative Factors |
|-------|---------|-----------|---------------------|
| Other | | | |

If other, please specify

Medical Conditions

| | Primary | Secondary | Correlative Factors |
|--------------------------|---------|-----------|---------------------|
| Hearing/Vision/Speech | | | |
| Hormonal Systems | | | |
| Heart and Vascular | | | |
| Respiratory | | | |
| Digestive | | | |
| Surgical Procedures | | | |
| Brain and Nervous System | | | |
| Other | | | |

If other, please specify

Medications

Describe medications

Psychologic/Quality of Life

| | Primary | Secondary | Correlative Factors |
|----------|---------|-----------|---------------------|
| BSI-18 | | | |
| SF-36 | | | |
| CCSS-NCQ | | | |
| PTS | | | |
| PTG | | | |
| Other | | | |

If other, please specify

Other

| | Primary | Secondary | Correlative Factors |
|-------------------------------|---------|-----------|---------------------|
| Pregnancy and Offspring | | | |
| Family History | | | |
| Chronic Conditions (CTCAE v3) | | | |
| Health Status | | | |

Demographic

| | Primary | Secondary | Correlative Factors |
|-------|---------|-----------|---------------------|
| Age | | | ✓ |
| Race | | | ✓ |
| Sex | | | ✓ |
| Other | | | |

If other, please specify

Cancer Treatment

| | Correlative Factors |
|-------------------|---------------------|
| Chemotherapy | ✓ |
| Radiation Therapy | ✓ |
| Surgery | |

Anticipated Sources of Statistical Support

| | |
|----------------------------------|-----|
| CCSS Statistical Center | Yes |
| Local Institutional Statistician | No |

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?

If other, please explain

Other General Comments

Agree

I agree to share this information with St. Jude

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