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Project Title Creation of a risk score algorithm to predict individual risk of future serious cardiovascular disease
Planned research population (eligibility criteria) All CCSS participants potentially eligible for primary analysis. Individuals free of cardiovascular disease at baseline survey in secondary analyses.
Proposed specific aims 1. Create an easily applied algorithm based on available baseline cancer treatment and demographic factors to predict individual risk of future serious cardiovascular (CV) disease, both in terms of cardiac-related mortality, as well as selected self-reported cardiovascular disease outcomes. 2. Among individuals free of significant CV disease at the baseline survey, determine improvements in prediction after inclusion of available behavioral factors and underlying medical conditions known to increase subsequent CV disease risk. 3. Validate the prediction algorithm using updated data from the original CCSS cohort (follow-up 2007) and/or when data from the new expanded cohort are available. While components of risk scores will differ given the available CCSS data, this project proposes similar methodology as has been used to generate Framingham or other CV disease risk score models, e.g. using results of multivariate time-to-event analyses and receiver operating characteristic curves to determine the values of relevant coefficients and the most parsimonious model. Given the numbers of events and relative young age of the CCSS cohort, a model examining longer-term risk (e.g. 20-30 years) may be more appropriate and clinically relevant than the typical 10-year risk estimated by most current CV risk score algorithms. This proposal differs from existing CCSS CV outcome proposals in that it seeks to estimate individual-level as opposed to population-level risk, and to describe the cumulative effect of multiple potential cardiovascular risk factors as opposed to risk associated with single risk factors, adjusted for others.
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? (Check all that apply)

Second Malignancy
Primary - No Secondary - No

Chronic Disease
Primary - Yes Secondary - No

Reproductive

Primary - No Secondary - No

Neurologic
Primary - No Secondary - No

Psychology / Neuropsychology
Primary - No Secondary - No

Genetics
Primary - No Secondary - No

Cancer Control
Primary - No Secondary - Yes

Epidemiology / Biostatistics
Primary - Yes 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 - Yes Secondary - No Correlative Factors - No

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

Health Behaviors

Tobacco
Primary - No Secondary - No Correlative Factors - Yes

Alcohol
Primary - No Secondary - No Correlative Factors - No

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

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

Other
Primary - No Secondary - No Correlative Factors - No

If other, please specify Data on medical care and medical screening (ECHO/MUGA) may be examined as correlative factors

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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

Medical conditions

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

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

Heart and vascular
Primary - Yes | 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 - Yes | 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 Cardiac related surgical procedures may be examined, realizing their limitations

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Medications

Describe medications Any used for cardiovascular disease (as identified in recently submitted metabolic syndrome/CV risk factor cluster study)

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

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

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

Demographic

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

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

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

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

If others, please specify

Cancer treatment

Chemotherapy
Correlative Factors - Yes

Radiation therapy
Correlative Factors - Yes

Surgery
Correlative Factors - Yes

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. E. Chow has familiarity with proposed methods. Dr. Yasui also to provide oversight.
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 Other investigators w/ whom this proposal has been discussed and who would be interested include: Greg Armstrong, William Border (cardiologist at Emory), Lillian Meacham, and Dan Mulrooney.