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Project Title GH therapy and brain tumors as SMNs

Planned research population (eligibility criteria) to determine the association of GH treatment and development of meningiomas and non-meningioma BT in the CCSS cohort

Proposed specific aims 1. to determine the association of GH treatment (as verified by Dr Sklar) and the development of a meningiomas as a second neoplasm. 2. to determine the association of GH treatment (as verified by Dr Sklar) and the development of a non-meningioma brain tumor as a second neoplasm. 3. Determine the association of time of exposure to GH with the development of meningiomas and non-meningioma brain tumors. ie did brain tumors develop while on GH therapy, 1-2 years after GH Rx or 3 or more years after completion of GH Rx. 4. determine the cumulative incidence of meningiomas for no GH exposure, GH exposure for 1-2 years, 3-4 years, 5-7 years, 8-9 years and > 10 years 5. 4. determine the cumulative incidence of non-meningioma brain tumors for no GH exposure, GH exposure for 1-2 years, 3-4 years, 5-7 years, 8-9 years and > 10 years

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 - Yes

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 - No 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 - Yes 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

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 - 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

Medications

Describe medications Growth hormone Rx as verified by Sklar

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 - No

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 - No

Radiation therapy

Correlative Factors - Yes

SurgeryCorrelative Factors - No

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.****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 I talked with Joe Neglia at the ACS meeting this week about looking at GH exposure and the development of the Brain tumors as an SN. He asked me to consider leading the analysis and approved of the submission of this AOI.